VETERINARY EXAMINING BOARD

2811 Agriculture Drive, Madison, Wisconsin
Board Room (CR 106)
Contact: Melissa Mace 608-224-4883
January 22, 2020

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.

AGENDA

I. 9:00 A.M. OPEN SESSION – CALL TO ORDER – ROLL CALL

II. Introductions
A. Arden Sherpe – Public Member

III. Approval of the Agenda

IV. Approval of Board Meeting Minutes
A. Full Board October 23, 2019
B. Credentialing Committee November 14, 2019

V. Comment from the Chair

VI. Public Comments
Each speaker is limited to five minutes or less, depending on the number of speakers. Each speaker must fill out and submit an appearance card to the Board clerk.

VII. American Association of Veterinary State Boards (AAVSB) Matters
A. Board Basics & Beyond Training
B. AAVSB Request for Input

VIII. Board Guidance
A. Cannabis Guidance Document – Final Draft for Approval
B. Process for Finalizing Guidance Documents
C. Wisconsin Veterinary Medical Association (WVMA) Request for Guidance Regarding Dispensing of Veterinary Prescription Drugs
D. Wisconsin Veterinary Medical Association (WVMA) Request for Guidance Regarding Telemedicine

IX. Elections and Appointments

A. Election of Officers
    1. Chair
    2. Vice Chair
    3. Secretary
B. Appointment of Liaisons
    1. Education and Exams
    2. Continuing Education
    3. Legislative
    4. Administrative Rules
    5. Monitoring
    6. Other Liaisons?
C. Appointment of Committees
    1. Screening Committee
    2. Credentialing Committee
    3. Other Committees?
D. Delegated Authority Motions
    1. Urgent Matters
    2. Screening Committee
    3. Credentialing Committee
    4. Document Signatures
    5. Monitoring Liaison and Department Monitor

X. Administrative Items

A. Follow-up on Items from October 23, 2019 Meeting:
    1. Wisconsin Technical College System (WTCS) – Certified Veterinary Technician (CVT) Outreach
    2. Strategic Planning
    3. Board Outreach to the Wisconsin School of Veterinary Medicine on Licensing/Board Education
B. Establishing a Veterinary-Client-Patient Relationship (VCPR)

XI. Licensing/Exam Inquiries

XII. Administrative Code Items

A. VE 7 – Complementary, Alternative and Integrative Therapies – Informational
B. VE 1-11 – Reorganization – Board Approval of Preliminary Public Hearing and Comment Period and Discuss the Possibility of a Teleconference Meeting after the Hearing and Comment Period

XIII. Legislative Update

A. AB-130/SB-140 – Initial License Fees
B. AB-731/SB-654 – Reciprocal Credentials

XIV. Future Meeting Dates and Times

A. Teleconference Meeting?

B. April 29, 2020
C. July 29, 2020
D. October 21, 2020

XV. CONVENE TO CLOSED SESSION

CONVENE TO CLOSED SESSION to discuss the Wis. Admin. Code ch. VE 11 update on the request for proposals where bargaining reasons require a closed session (§ 19.85 (1) (e), Stats.); to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.).

XVI. Wis. Admin. Code Ch. VE 11 Update on the Request for Proposals (RFP)

XVII. Deliberation on Licenses and Certificates

A. AS Limited Order of Licensure
B. 19 VET 090 RG

XVIII. Deliberation on Proposed Stipulations, Final Decisions and Orders

A. 19 VET 016 JB
B. 19 VET 018 OJ
C. 19 VET 054 RW
D. 19 VET 083 KC
E. 17 VET 017 DW PM
F. 17 VET 040 BR
G. 18 VET 010 MH

XIX. Review of Veterinary Examining Board Pending Cases Status Report

XX. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

XXI. Open Session Items Noticed Above not Completed in the Initial Open Session

XXII. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

XXIII. Ratification of Licenses and Certificates

To delegate ratification of examination results to DATCP staff and to ratify all licenses and certificates as issued.

XXIV. ADJOURNMENT

The Board may break for lunch sometime during the meeting and reconvene shortly thereafter.

VETERINARY EXAMINING BOARD

MEETING MINUTES

Wednesday, October 23, 2019

PRESENT: Diane Dommer Martin, D.V.M.; Robert Forbes, D.V.M.; Kevin Kreier, D.V.M.; Hunter Lang, D.V.M.; Lyn Schuh; Lisa Weisensel Nesson, D.V.M. (Nesson attended via teleconference call)

STAFF: Department of Agriculture, Trade, and Consumer Protection (DATCP): Melissa Mace, VEB Executive Director; Cheryl Daniels and Liz Kennebeck, DATCP Attorneys; Robert Van Lanen, Regulatory Specialist Senior; Angela Fisher, Program Policy Analyst; Carrie Saynisch, License/Permit Program Associate; Karen Torvell, Program Assistant Supervisor; Darlene Konkle, D.V.M., State Veterinarian and Division of Animal Health Administrator; Introductions and Discussion.

Robert Forbes, Chair, called the meeting to order at 9:00AM. A quorum of six (6) members was confirmed.

I. 9:00 A.M. OPEN SESSION – CALL TO ORDER – ROLL CALL

II. Introductions

Lyn Schuh: new CVT member

III. Approval of the Agenda

MOTION: Hunter Lang moved, seconded by Kevin Kreier, to approve the agenda. Motion carried unanimously.

IV. Approval of Board Meeting Minutes

A. September 10, 2019

MOTION: Diane Dommer Martin moved, seconded by Kevin Kreier, to approve the minutes from the September 10, 2019 meeting. Motion carried unanimously.

V. Public Comments

Each speaker is limited to five minutes or less, depending on the number of speakers. Each speaker must fill out and submit an appearance card to the Board clerk.

No appearance cards were submitted.

VI. American Association of Veterinary State Boards (AAVSB) Matters

A. Updates from Annual Meeting

Dommer and Mace attended. The delegate assembly approved the VCPR changes. There was an interesting presentation about telehealth, AI, and a veterinary application with a decision tree

whether to seek immediate care, over the counter, or no action. There are higher veterinary suicide rates in the UK compared to the US. The delegate assembly passed the bylaws as proposed. Resolution 2019-01 (VIVA VAULT) passed. AAVSB encourages electronic submission of education verification. AAVSB encourages attendance of board attorney's at annual meetings.

The Executive Director session focused on strategic planning. Per Cheryl Daniels, a strategic plan might be helpful to do while rule is open but strategic plan could not get into the detail of rulemaking / rule content / licensees. Melissa Mace will reach out to AAVSB for possibilities of discussion at Board Basics and Beyond or for an in person or remote presentation about strategic planning.

Discussion of outreach to schools about licensure: spring of third year would be appropriate, AAVSB may be able to provide grant money for meeting foods, AAVSB provides a template PowerPoint, board members could introduce themselves and answer questions, some other boards have a student non-voting member/representative.

VII. Administrative Items

A. Terms for Drs. Dommer and Nesson

Both served part of their second terms prior to being reappointed and were appointed out to 2023. This would mean five members' terms would expire in 2023. There is no way to adjust the terms unless the members choose to leave early. If a member determined to leave in 2021, it is unclear whether the governor would appoint another member from 2021 to 2025 or from 2021 to 2023.

B. Guidance Documents

1. Bull Semen Collection

Review of final draft for Board approval. The document will be submitted for state guidance document process for posting and public comment.

MOTION: Hunter Lang moved, seconded by Kevin Kreier, to approve the bull semen collection guidance document (VEB-GD-001). Motion carried unanimously.

2. Cannabis Products

Discussion of first draft: If clients are giving cannabis products to their animals of their own volition, a veterinarian cannot stop them but can tell them about concerns (such as not enough science and not FDA approved). It is fine to talk about cannabis products with clients and advise clients but a veterinarian cannot recommend cannabis products or prescribe cannabis products to treat an animal health condition. Veterinarians cannot sell cannabis products that claim to treat animal health conditions, in their clinics because that would be considered recommending it. The FDA currently classifies any product containing CBD as a drug.

For guidance document updates: Veterinarians should not be recommending any substance that contains cannabis. It remains the responsibility of anyone selling the product to ensure they understand what the product contains (such as whether it is hemp

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seed oil or whether it contains CBD oil or whether it contains other additives). Legally it would not be a problem for a veterinarian to explain why they cannot recommend cannabis products. Veterinarians can discuss cannabis with clients, provide available information, and explain concerns.
Final Guidance will be brought to Jan board meeting.

C. Delegated Medical Services
IV catheter: The Board would be comfortable considering a rule change to allow CVTs to administer IV catheters under the direct supervision of veterinarian and unlicensed assistants to administer IV catheters under the direct supervision of the vet while the vet is personally present on the premises. ART lines would not be appropriate for an unlicensed assistant to put in. Delegation of IV catheters can be considered for a rule change when the VE 1-11 revised statement of scope is approved. There is not a mechanism for the board to make this change outside of rulemaking.
There was also confusion from the VE 1 surgery changes communications regarding a CVT administering injections. It has been explained that VE1 simply clarified that all injections can be delegated to a CVT under appropriate supervision.
The rule (VE 1 surgery) did not change how an owner can administer injections for their own animals.

D. Staffing Update
Dr. Darlene Konkle is the new State Veterinarian and Administrator of the Division of Animal Health.
Melissa Mace will continue as the VEB Executive Director (no longer "Acting").
Carrie Saynisch is the new License/Permit Program Associate, replacing Sally Ballweg.
Bob Van Lanen's position is currently a project position. The Division has requested a permanent position, which is currently in a passive review period in the Joint Committee on Finance. Board members may contact their representatives individually as constituents but cannot contact the Committee as a Board. A Limited Term Employee (LTE) position will fill a gap in the position from the time the project position expires in November.
A different LTE will start in November to help catch up with records.
The Division is considering an LTE to assist with legal tasks.

E. Outreach to WTCS – CVT Program Professors
Lyn Schuh and Melissa Mace will be doing outreach and will give an update in January.

VIII. **Licensing/Exam Inquiries**

A. Renewing a veterinarian license after a greater than 5-year break in licensing
Division staff received a contact from a veterinarian who has not been licensed for ten years and is seeking licensure. The Board discussed requiring 60 hours of continuing education hours, require that half of continuing education hours be in person, and require an AAVSB competency exam in area of practice if such an exam is available. The applicant would also has the option to retake the NAVLE and apply by examination. Melissa will reach out and get information related to type of practice and any relevant experience he may have had in the intervening years.

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This information will be provided to the Credentialing committee for a final decision on requirements.

IX. Administrative Code Updates

A. VE 7 - Complementary, Alternative and Integrative Therapies
The final draft was approved by the Governor on October 3, 2019. The final draft will be referred to the legislature for review by committees in the Senate and Assembly and then for review by the Joint Committee for Review of Administrative Rules (JCRAR).

B. VE 1-11 – Reorganization
The statement of scope has been revised and will soon be submitted to the Governor's Office for approval. After the Governor's approval, the revised scope will need to be approved by both the VEB and the DATCP Board.

X. Legislative Update

A. Wis. Stat. Ch. 89 Legislation: Initial License Fees
Bill was referred to committee on March 28, 2019.

XI. Future Meeting Dates and Times

A. Schedule 2020 Quarterly Board Meetings and Discuss Possibility of Alternate Locations
January 22
April 29
July 29
October 21
The Board discussed the possibility of reaching out to the UW vet school. Parking would need to be considered. Melissa Mace will contact vet school to see if that might be a possibility.

XII. CONVENE TO CLOSED SESSION

MOTION: Kevin Kreier moved, seconded by Lisa Weisensel Nesson, to convene to closed session to discuss the Wis. Admin. Code Ch. VE 11 update on the request for proposals where bargaining reasons require a closed session (§ 19.85 (1) (e), Stats.); to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.). Robert Forbes read the language of the motion. The vote of each member by was ascertained by voice vote. Roll Call Vote: Robert Forbes – yes; Kevin Kreier – yes; Diane Dommer Martin – yes; Lisa Weisensel Nesson – yes; Lyn Schuh – yes; Hunter Lang – yes; Motion carried unanimously.

XIII. Wis. Admin. Code Ch. VE 11 Update on the Request for Proposals (RFP)

XIV. Deliberation on Licenses and Certificates

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XV. Deliberation on Proposed Stipulations, Final Decisions and Orders

A. 14 VET 020 PB
B. 17 VET 037 RD
C. 18 VET 055 JA
D. 19 VET 001 SL
E. 19 VET 019 BM
F. 19 VET 042 LR

XVI. Review of Veterinary Examining Board Pending Cases Status Report

XVII. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Diane Dommer Martin moved, seconded by Kevin Kreier, to reconvene to open session. Motion carried unanimously. The Board reconvened at 11:33AM.

XVIII. Open Session Items Noticed Above not Completed in the Initial Open Session

XIX. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

MOTION: Kevin Kreier moved, seconded by Hunter Lang, to accept final decision orders in the cases of 18 VET 055, 19 VET 001, 19 VET 019, and 19 VET 042. Motion carried unanimously.

MOTION: Diane Dommer Martin moved, seconded by Kevin Kreier, to accept licensure with permanent restriction in the case of 14 VET 020. Motion carried unanimously.

MOTION: Hunter Lang moved, seconded by Kevin Kreier, to accept the final decision order as amended in the case of 17 VET 037. Motion carried unanimously.

MOTION: Kevin Kreier moved, seconded by Diane Dommer Martin, to grant full licensure in the cases of 18 VET 055, 19 VET 019, and 19 VET 042. Motion carried unanimously.

XX. Ratification of Licenses and Certificates

MOTION: Hunter Lang moved, seconded by Kevin Kreier, to delegate ratification of examination results to DATCP staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

XXI. ADJOURNMENT

MOTION: Kevin Kreier moved, seconded by Hunter Lang, to adjourn. Motion carried unanimously.

The meeting adjourned at 11:39AM.

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VETERINARY EXAMINING BOARD
CREDENTIALING COMMITTEE

MEETING MINUTES

Thursday, November 14, 2019

PRESENT: Diane Dommer Martin, D.V.M.; Robert Forbes, D.V.M.; Hunter Lang, D.V.M.

STAFF: Department of Agriculture, Trade, and Consumer Protection (DATCP): Melissa Mace, VEB Executive Director; Cheryl Daniels, DATCP Attorney; Angela Fisher, Program Policy Analyst; Introductions and Discussion.

Robert Forbes, Chair, called the meeting to order at 12:04PM. A quorum of three (3) members was confirmed.

I. OPEN SESSION – CALL TO ORDER – ROLL CALL

II. Discussion about Requirements for the Re-instatement of a Veterinarian who has not been Licensed as a Veterinarian for over 5 Years

III. CONVENE TO CLOSED SESSION

MOTION: Hunter Lang moved, seconded by Diane Dommer Martin, to convene to closed session to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.). Robert Forbes read the language of the motion. The vote of each member by was ascertained by voice vote. Roll Call Vote: Hunter Lang – yes; Diane Dommer Martin – yes; Robert Forbes – yes; Motion carried unanimously.

IV. Discussion about an Applicant for a Wisconsin Veterinarian License that is Named in Pending Litigation

V. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Hunter Lang moved, seconded by Diane Dommer Martin, to reconvene to open session. Motion carried unanimously. The Board reconvened at 12:37PM.

VI. Open Session Items Noticed Above not Completed in the Initial Open Session

MOTION: Diane Dommer Martin moved, seconded by Hunter Lang, to require that prior to licensing, DC must present evidence to the Board of having taken 75 hours of continuing education, of which 40 hours shall be in person, and having passed the International Council for Veterinary Assessment (ICVA) species-specific companion animals examination. Motion carried unanimously.

VII. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

MOTION: Hunter Lang moved, seconded by Diane Dommer Martin, to grant a license to AS with the condition that she inform the board of the final resolution in the pending case and any subsequent action taken by the Texas Board of Veterinary Medicine, for board review and possible action. Motion carried unanimously.

VIII. ADJOURNMENT

MOTION: Diane Dommer Martin moved, seconded by Hunter Lang, to adjourn. Motion carried unanimously.

The meeting adjourned at 12:40PM.

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	January 22, 2020
2) Requestor Name	M. Mace
3) Item Title for the Agenda	Board Basics and Beyond
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	AAVSB annually hosts a training for new board members and staff; Board Basics and Beyond. This training is held in Kansas City MO and will be April 17-18, 2020. The cost to the board is only $250/participant. Decision on member going, if any needs to be made so we can get out of state travel requests completed and get participants registered. For more information on the training please visit AAVSBs website: **https://www.aavsb.org/board-services/member-board-resources/trainings/**

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	M. Mace
3) Item Title for the Agenda	AAVSB Requests for input.
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	AAVSB Call for Nominations AAVSB Model Reg Controlled Substances AAVSB Model Reg Scope of Practice CVT
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	The AAVSB Regulatory Policy Task Force has been hard at work the past few months drafting two new model regulation documents: • ***DRAFT*** *- Model Regulations – Appropriate Use Of Opioids and Other Controlled Substances.pdf* • ***DRAFT*** *- Model Regulations - Veterinary Technician Scope of Practice.pdf* (Draft models can be accessed via link or they are also attached) Just like the Practice Act Model (PAM), these new model regulation documents (once finalized) will be used by AAVSB Member Boards to reference when drafting or editing their own regulations regarding these timely topics. Use of these documents is a valuable resource for Member Boards, but is completely optional and non-binding. **REVIEW & FEEDBACK REQUESTED** by February 20, 2020. Also attached is the AAVSB's annual call for nominations for your information. If you wish to nominate someone these are due to AAVSB by May 28, 2020

AAVSB
AMERICAN ASSOCIATION OF VETERINARY STATE BOARDS

MEMORANDUM

To: AAVSB® Member Board Members, Executive Directors and Registrars

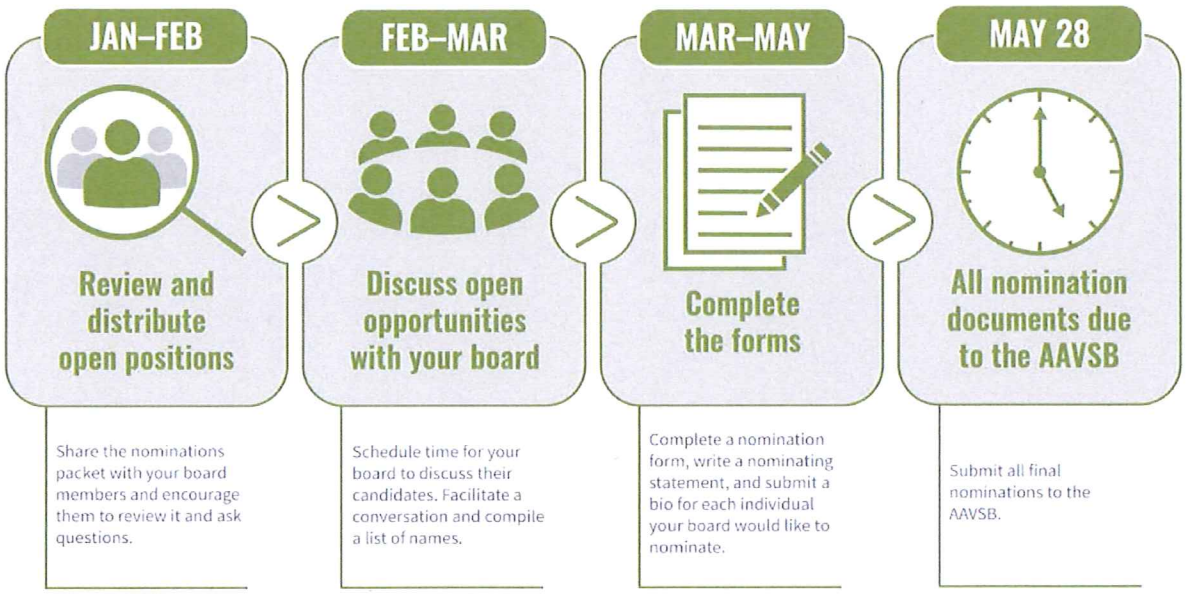
From: AAVSB Nominating Committee Dr. Mark Olson, Elected Member and Chair
Dr. Matthew Verbsky, Appointed Member
Dr. Steven Wills, Elected Member

Date: December 28, 2019

Subject: Call for Nominations – **Nominations Due May 28, 2020**

Each year, the Nominating Committee of the AAVSB sends out a *Call for Nominations* to provide Member Boards information regarding the open elected positions and to request nominations. The Nominating Committee is charged with preparing a ballot of candidates for all elected positions to be filled. This process is vital to the AAVSB's ability to carry out its mission.

There are 4 easy steps to complete the annual AAVSB nomination process.



Prior to submitting a nomination packet, the Committee asks you to confirm that the candidate is willing to accept a nomination. Upload the packet online at www.aavsb.org/nominations or by email, fax or mail to the AAVSB office.

Packets must be received in the AAVSB office by May 28, 2020.

The 2019 AAVSB Annual Meeting is being held September 24-26, 2020 in Portland, Oregon. The Delegates will vote on the candidates during the Annual Meeting.

Should you have any questions or need additional information, please contact Ms. Daphne Tabbytite, staff contact for the Nominating Committee, at dtabbytite@aavsb.org or 1-877-698-8482 ext. 223.

RECEIVED JAN 06 2020

American Association of Veterinary State Boards
Nomination Application for 2020-2021 Open Positions

3 REQUIREMENTS FOR A COMPLETED NOMINATION PACKET

1. Nomination Application (one for each nominee)
2. Biographical Information (2-page limit)
3. Statement from sponsor on rationale for the nomination

Please note: The bio and statement will be distributed to the AAVSB Member Boards.

SUBMIT BY MAY 28, 2020

ONLINE: http://bit.ly/2AEQSeR
EMAIL: dtabbytite@aavsb.org
FAX: (816) 931-1604
MAIL: AAVSB
Attn: Nominating Committee
380 West 22nd Street, Suite 101
Kansas City, MO 64108

2020-2021 OPEN POSITIONS

Indicate the desired position(s)

☐ President-Elect (1 position – 3-year term)
☐ Director (3 positions – 2-year terms)
☐ Nominating Committee Member (2-year term)
☐ ICVA Representative (1 Licensed Veterinarian position – 3-year term)

NOMINEE INFORMATION

Name: _____ State or Province: _____

Work Phone: _____ Cell Phone: _____

E-mail: _____

CHECK ALL THAT APPLY:

☐ Board Member (complete the following)

Term start date: _____ *Term end date:* _____ *Eligible for re-appointment:* Yes / No

☐ Board Administrator
☐ AAVSB Associate Member
☐ Current ICVA Representative
☐ Delegate or Alternate Delegate (at the time of nomination)
☐ Current AAVSB Board of Director
☐ AAVSB Committee Chairperson
☐ Licensed Veterinarian in Public/Private Practice

List year(s) nominee has attended the AAVSB Annual Meeting: _____

SPONSORED BY:

Name of Member Board: _____

Name of Contact at Member Board: _____

Phone # and Email of Contact: _____

Return or complete online by May 28, 2020

American Association of Veterinary State Boards

Nominee Biographical Information

3 REQUIREMENTS FOR A COMPLETED NOMINATION PACKET

1. Nominee Application (one for each nominee)
2. Biographical information (2 page limit)
3. Statement from sponsor on rationale for the nomination.

Please note: The bio and statement will be distributed to the AAVSB Member Boards.

The following biographical information should be provided for each nominee. The information should not exceed two pages.

- Name
- Elected Position of Interest
- Education
- Specialties, if any
- Jurisdictions Where Currently Licensed, if applicable
- Work History
- Type of Practice/Employment (public, private or other; concentration)
- Member Board Experience and Roles Served
- Experience with the AAVSB and Roles Served
- Leadership Positions Held
- Other Affiliations

American Association of Veterinary State Boards

Information on Board of Directors Elected Positions for 2020 - 2021

CURRENT 2019 - 2020 AAVSB® BOARD OF DIRECTORS

Immediate Past President:	Michael Gotchey, DVM from Colorado
President:	Roger Redman, DVM from Ohio
President-Elect:	Chris Runde, DVM from Maryland
Treasurer:	Kim Gemeinhardt, DVM from North Carolina
Director:	Vito DelVento, DVM from District of Columbia
Director:	Amy Haywood, LVT from District of Columbia
Director:	Timothy Kolb, DVM from Ohio
Director:	Mark Logan, VMD from New Jersey
Director:	Larry McTague, DVM from Oklahoma
Director:	Frank Richardson, DVM from Nova Scotia

Upcoming 2020 - 2021 AAVSB Board of Directors

Immediate Past President:	Roger Redman, DVM
President:	Chris Runde, DVM
President-Elect:	_____OPEN_____ (3-year commitment)
Treasurer:	Kim Gemeinhardt, DVM *(Dr. Gemeinhardt is currently serving the first year of a first 2-year term)*
Director:	_____OPEN_____ (2-year term) *(Dr. Vito DelVento is eligible to be nominated to an Officer position.)*
Director:	_____OPEN_____ (2-year term) *(Dr. Larry McTague is eligible to be nominated to an Officer position.)*
Director:	_____OPEN_____ (2-year term) *(Dr. Frank Richardson is currently serving the second year of a first 2-year term.)*
Director:	Amy Haywood, LVT *(Ms.Haywood is currently serving the first year of a first 2-year term)*
Director:	Timothy Kolb, DVM *(Dr. Kolb is currently serving the first year of a second 2-year term)*
Director:	Mark Logan, VMD *(Dr. Logan is currently serving the first year of a first 2-year term)*

James T. Penrod, CAE, FASLA, as Executive Director serves as Secretary and as an ex-officio non-voting member of the Board of Directors.

OVERVIEW

The AAVSB Board of Directors is a body of elected Directors which govern the Association and provide the strategic plan for the future of the Association.

RESPONSIBILITIES

- Governs and sets the course for the AAVSB's future.
- Ensures the overall strength and health of the AAVSB.
- Develops, supports and maintains focus on the strategic objectives and priorities.
- Commits to the mission and goals of the AAVSB.
- Attends the Association's Annual Meeting, Board of Director meetings, planning meetings, and assigned committee and/or task force meetings.
- Prepares for all meetings and seeks opportunities to expand knowledge about the organization.
- Shares wisdom and insights to help the Board of Directors make good decisions and policy.
- Ensures Board effectiveness.
- Hires, supports and develops the chief executive to lead and manage the AAVSB into the future.
- Ensures the availability of adequate resources and the long-term financial stability of the AAVSB.
- Approves annual budgets, audit, and Form 990 as well as updates to financial policies.
- Stays informed and supportive of the governing documents of the organization, e.g. Articles of Incorporation, Bylaws, policies, strategic plan, and budget.
- Accepts the legal duties of loyalty and care while serving as a director and complies with applicable laws, regulations, Bylaws, policies and code of conduct.
- Understands that all power rests with the full Board of Directors, not individual directors.

EXPECTED TIME COMMITMENT – Approximately 150 hours per

- Monthly conference calls (1 hour of preparation and 1.5 hours of participation per call)
- In-Person meeting in January each year (2-3 days of meetings with 2 hours of preparation time plus travel time).
- In-Person meeting in June each year (2-3 days of meetings with 2 hours of preparation time plus travel time).
- Annual Meeting in September (4 days of meetings with 3 hours of preparation time plus travel time).
- Frequent opportunities to attend AVMA meetings, ICVA Board meetings, or special assignments (approximately 2 days each).
- Additional time may be required if assigned as a liaison to a committee; the amount of additional time is dependent on the specific committee.
- Additional time is required of the Officers of the Board of Directors.

BYLAWS SPECIFICATIONS (Article VII)

The AAVSB Bylaws prescribe the authority, composition, and election of the Board of Directors which are described below.

Authority

The Board of Directors shall manage the affairs of the Association, including the establishment of an annual budget for the Association and the transaction of all business for and on behalf of the Association as authorized under these Bylaws. The Board of Directors shall carry out the resolutions, actions, or policies as authorized by the Delegates, subject to the provisions of the Association Articles of Incorporation and Bylaws.

Composition

There shall be ten (10) members of the Board of Directors including four (4) Officers and six (6) Directors at Large. The Officers shall be identified as President, President-Elect, Immediate Past President and Treasurer. The Officers and Directors at Large are collectively referred to as the Board of Directors. The Officers may, at times be collectively referred to as the Executive Committee. Notwithstanding any other provisions of these Bylaws, the Board of Directors shall be comprised of at least six Licensed Veterinarians and one Affiliate Member. The Executive Director shall serve as Secretary and as an ex-officio non-voting member of the Board of Directors.

Qualifications

a. Officers

To be eligible to serve as an Officer, a candidate shall when nominated and elected be currently serving on the Board of Directors, be a Delegate, Alternate Delegate, or be a member of a Member Board.

b. Directors at Large

To be eligible to serve as a Director at Large, a candidate shall when nominated be a Delegate, Alternate Delegate, member of a Member Board or have served as a member of a Member Board as of June 1st of the year preceding the election year.

If a Director ceases to meet eligibility criteria stated above, such Board of Director member shall, after completion of the current term, be eligible to serve one additional term on the Board of Directors.

Elections

The Board of Directors shall be elected at the Annual Delegate Assembly of the Association by the Delegates, either from nominations submitted by the Nominating Committee, or by nominations from the floor. Each Director shall assume office at the close of the Annual Delegate Assembly at which the member is elected and shall serve as specified in these Bylaws or until a successor is elected.

Terms of Office

For purposes of these Bylaws, the offices of Immediate Past President, President, and President-Elect shall be considered one (1) term. The terms of the Board of Directors shall be as follows:

a. *Immediate Past President. The Immediate Past President shall serve a one (1) year term automatically following the term as President. The Immediate Past President shall only vote on matters before the Board of Directors to break a tie.*
b. *President. The President shall serve a one (1) year term automatically following the term as President-Elect. In the event of a vacancy, the President-Elect shall succeed to the Presidency to fill the unexpired term and may, thereafter, complete the President's term.*
c. *President-Elect. A President-Elect shall be elected at the Annual Delegate Assembly to serve a one (1) year term and shall automatically succeed to the office of President and, thereafter, the office of Immediate Past President. Thus, the President-Elect office is a three (3) year commitment, one year as President-Elect, one year as President, and one year as Immediate Past President and is limited to one elected term. In the event of a vacancy, the President in consultation with the Board of Directors may appoint the office of President-Elect. In any event and under these circumstances, at the next Annual Delegate Assembly, there shall be an election for both President and President-Elect.*
d. *Treasurer. A Treasurer shall be elected at the Annual Delegate Assembly to serve a term of two (2) years. In the event of a vacancy, the Treasurer position shall be appointed by the President in consultation with the Board of Directors until the next Annual Delegate Assembly at which time an election shall be held. The Treasurer shall serve no more than two (2) consecutive terms.*
e. *Directors at Large. Directors at Large shall be elected at the Annual Delegate Assembly to serve two (2) year terms. In the event of a vacancy, the President in consultation with the Board of Directors shall appoint the Director at Large position until the next Annual Delegate Assembly at which time an election shall be held to fill the unexpired term. Directors at Large shall serve no more than two (2) consecutive terms.*
f. *No member of the Board of Directors shall hold more than one seat on the Board of Directors at any time. Any person appointed or elected to fill an unexpired term of less than one year for Treasurer or Director at Large may be eligible for election to the same position for two additional consecutive terms after completion of the unexpired term. If the unexpired term is more than one year, the person may be eligible for one additional consecutive term.*

American Association of Veterinary State Boards

Information on Nominating Committee
Elected Position for 2020-2021

CURRENT 2019-2020 NOMINATING COMMITTEE

Mark Olson, DVM, Chair, from Kansas (elected position)
Matthew Verbsky, DVM from Ohio (appointed position)
Steven Wills, DVM from Kentucky (elected position)

Upcoming 2020-2021 Nominating Committee

_____OPEN_____ (2-year elected position)

(Dr. Steven Wills is not eligible for nomination as he is currently serving in the second year of an unexpired two-year term.)

Elected position: Mark Olson, DVM
(Dr. Olson is currently serving the first year of a two-year term.)

Appointed position: Matthew Verbsky, DVM
(Dr. Verbsky is currently serving in the one-year appointed position.)

OVERVIEW

The overall role of the Nominating Committee is to review nominations and confirm eligibility of nominees from AAVSB Member Boards for the open elected positions.

RESPONSIBILITIES

- Prepares a Call for Nominations for the Member Boards which includes a nomination form and information on the open positions.
- Receives nominations from Member Boards for open positions 120 days prior to the upcoming Annual Delegate Assembly.
- Reviews nominations received and possibly distribute a questionnaire to nominees.
- Develops a ballot of candidates for mailing to Member Boards 30 days prior to Annual Delegate Assembly.

EXPECTED TIME COMMITMENT – Approximately 12 hours per year

- Participates in 4 conference calls (1 hour for preparation time and 1 hour for participation per call).
- Meets in September at Annual Meeting (1 hour meeting plus travel time).
- Additional time is required of the Committee Chair.

BYLAWS SPECIFICATIONS (Article X, Section 1 and Article IX, Section 3)

The AAVSB Bylaws prescribe the role, number of members, method of appointment, composition and terms of office of the Nominating Committee which are described below.

Role

The Nominating Committee shall review the qualifications of the applicants, verify sponsors and references on all applications submitted, and shall submit to the Member Boards at least thirty (30) days before the Annual Delegate Assembly, a ballot containing candidates for each position on the Board of Directors, the Nominating Committee and the International Council for Veterinary Assessment to be filled. The ballot shall contain the names of all candidates who have been found to be eligible and their applications verified as accurate by the Nominating Committee. In determining the slate of candidates for the Board of Directors, the Nominating Committee shall make every effort to ensure at least a majority of Members at Large are currently members of Member Boards. Persons serving on the Nominating Committee shall be ineligible to be on the ballot or elected to any position within the Association within their elected term.

Number of Members: *Three members.*

Elections and Qualifications

Two of the three Committee members are elected at the Annual Delegate Assembly by a plurality of votes, either from nominations submitted by the Nominating Committee or by nominations from the floor. Prior to nomination, the elected members to the Committee must have attended at least one Delegate Assembly meeting. At the time of nomination and election, candidates for the Committee must be a Delegate or Alternate Delegate, a member of a Member Board, a current Associate Member, or a chairperson of an Association committee. The President shall appoint the third member of the Committee and name the chair of the Committee.

Terms of Office

The terms of the elected members are two (2) years. The President shall appoint a third member of the Committee with the approval from the Board of Directors whose term will be one (1) year. Nominating Committee members may not serve consecutive terms, but are eligible for reelection consistent with this Article X, Section 1. The President shall name the chair of the Committee with approval from the Board of Directors. In the event of a vacancy, the President in consultation with the Board of Directors shall appoint the Nominating Committee member until the next Annual Delegate Assembly at which time an election shall be held to fulfill the unexpired term.

American Association of Veterinary State Boards

Information on Representatives to the ICVA Elected Positions for 2020-2021

CURRENT 2019-2020 AAVSB REPRESENTATIVES TO THE INTERNATIONAL COUNCIL FOR VETERINARY ASSESSMENT (ICVA)

Jon Betts, DVM from Oregon (Licensed Veterinarian)
Kathy Bowler from California (Public Member)
Bruce Louderback, DVM from Colorado (Licensed Veterinarian)
Helen Tuzio, DVM from New York (Licensed Veterinarian)

Upcoming 2020-2021 AAVSB Representatives to the ICVA

_____OPEN_____ (Licensed Veterinarian position; 3-year term)
(Dr. Helen Tuzio is currently serving the third year of a first 3-year term and is eligible for nomination to a second term.)

Jon Betts, DVM
(Dr. Betts is currently serving the second year of a third 3-year term)

Kathy Bowler
(Ms. Bowler is currently serving the second year of a second 3-year term)

Bruce Louderback, DVM
(Dr. Louderback is currently serving the first year of third 3-year term)

BYLAWS SPECIFICATIONS (Article IX)

The AAVSB Bylaws prescribe the composition, duties, election, qualifications and terms as described below.

Composition

There shall be a minimum of four AAVSB representatives to the International Council for Veterinary Assessment (ICVA).

Duties

The Representatives shall attend all meetings of the ICVA and shall report to the AAVSB Board of Directors following each ICVA or subcommittee meeting. The Representatives shall present the consensus opinions of the Association at such meetings and shall not vote in conflict with the AAVSB Bylaws.

Election

Delegates at the Annual Delegate Assembly shall elect the Representatives at the Annual Delegate Assembly of the Association either from nominations submitted by the Nominating Committee or by nomination from the floor. Each Representative shall assume his or her responsibilities at the close of the Annual Delegate Assembly at which elected and shall serve as specified in these Bylaws or until a successor is elected and qualified.

Qualifications

- *Three representatives must, when nominated and elected, be Licensed Veterinarians currently practicing in public or private practice and be either (i) a member of a Member Board, or (ii) have been a member of the AAVSB Board of Directors within the previous year, or (iii) have been a member of the ICVA within the previous year, or (iv) be a current Associate Member.*
- *One Representative must, when nominated and elected, be a Public Member and be either (i) a member of a Member Board, or (ii) have been a member of the AAVSB Board of Directors within the previous year, or (iii) have been a member of the ICVA within the previous year, or (iv) be a current Associate Member.*

Terms

Representatives can be eligible for three 3-year terms.

EXPECTATIONS

Please contact the AAVSB office for additional information on the AAVSB representatives to the ICVA.

AAVSB
AMERICAN ASSOCIATION OF VETERINARY STATE BOARDS

MODEL REGULATIONS – APPROPRIATE USE OF OPIOIDS AND OTHER CONTROLLED SUBSTANCES

As recommended by the AAVSB Regulatory Policy Task Force in August 2019

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Introduction

These Model Regulations are meant to support the statutory language that can be found in the AAVSB Practice Act Model (PAM). Each model regulation from the AAVSB is presented separately for ease of use for the AAVSB Member Boards to utilize as a model in developing regulations or rules specific to targeted topics. The AAVSB Regulatory Policy Task Force will continue to develop Model Regulations to address pressing issues in the regulation of Veterinary Medicine.

Revisions

Created 2019

Structure and Format

The AAVSB Model Regulations have been structured to allow Member Boards to develop new regulations or rules within their jurisdiction to address the specific language that can be found in the jurisdiction's existing statute or bylaws. It has been formatted to include the model language with corresponding commentary. To provide the rationale and thought processes behind the Model Regulations, readers are encouraged to read the commentary as well as the Regulation to receive a complete perspective. Commentary follows each section if appropriate.

Appropriate Use of Opioids and Other Controlled Substances

Model Regulation.

Veterinarians are allowed to prescribe, administer, and dispense controlled substances in keeping with the requirements of the laws of this Jurisdiction, and the statutes and regulations governing the practice of Veterinary Medicine. A Veterinarian-Client-Patient Relationship (VCPR) as set forth in the Act, must first exist before drugs may be prescribed by a Veterinarian.

Commentary
Article I, Section 105 (b). Practice of Veterinary Medicine in the AAVSB Practice Act Model (PAM) indicates that any individual practices Veterinary Medicine when performing any one or more of the following on an Animal: (b) Prescribes, dispenses or administers a drug, medicine, anesthetic, biologic, appliance, apparatus, application or treatment. Opioids and other controlled substances (i.e. benzodiazepines, tranquilizers, and barbiturates) can be very useful for pain management and the control of other conditions in Animals, but they have a high potential for misuse, addiction and overdose death in humans; therefore, these controlled substances are closely regulated by Jurisdictions and the federal government. The magnitude of the veterinary community's role in the opioid epidemic is unclear. However, Veterinarians prescribe, dispense, administer, and stock many of the same opioid drugs that have the potential to be diverted and abused by humans. Therefore, the veterinary community needs to be part of the effort to address this national crisis. Veterinarians are required to be compliant with all applicable Jurisdictional and federal veterinary and pharmacy laws and regulations related to controlled substances. One of the methods Jurisdictions have chosen to address the crisis is the implementation of prescription monitoring programs. Multiple Jurisdictions already require Veterinarians to participate in these programs. However, this document does not address whether Veterinarians should be required to participate in these programs. Regulatory boards should seek to provide commentary to ensure that special circumstances pertaining to veterinary medicine are taken into consideration. In light of the opioid crisis, many veterinarians are considering dispensing fewer controlled substance and writing prescriptions to be filled at a commercial pharmacy.

Section 1. Definitions.

Opioids means all pure opioids and partial agonist and antagonist opioids (including tramadol).

Controlled substances mean all Schedule II through V drugs as set forth in the U.S. Controlled Substances Act of the Drug Enforcement Act and the Canadian Controlled Drugs and Substances Act.

DEA is the United States Drug Enforcement Administration.

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Section 2. Prescribing of Controlled Substances for Acute Pain and Chronic Conditions

(a) Veterinarians must have a valid DEA license or meet requirements of the provincial licensing body, establish a Veterinarian-Client-Patient Relationship (VCPR) and comply with all DEA, federal, and Jurisdictional laws and statutes in order to provide opioids and other controlled substances for their Patients.

(b) The Veterinarian shall perform a history and physical examination appropriate to the complaint and conduct an assessment of the Patient's history as part of the initial evaluation.

(c) Before initiating treatment, nonpharmacologic and non-opioid treatment shall be given consideration prior to treatment with an opioid or other controlled substance.

(d) If an opioid or other controlled substance is necessary for treatment of acute pain, the Veterinarian shall prescribe it in the lowest effective dose appropriate to the size and species of the animal for the least amount of time. The initial dose shall not exceed a XX-day supply.

(e) For prescribing an opioid or other controlled substance for management of pain after the initial XX-day prescription, the Patient shall be seen and re-evaluated for the continued need for an opioid or a controlled substance.

(f) A Veterinarian may prescribe an opioid or other controlled substance containing an opioid for management of chronic pain, terminal illnesses, or certain chronic conditions, such as chronic heart failure, chronic bronchitis, osteoarthritis, collapsing trachea, or related conditions.

(g) For the prescribing of an opioid or other controlled substance for terminal illnesses or certain chronic conditions, it is not required to see and reevaluate the patient for prescribing beyond XX days. For any prescribing of an opioid or other controlled substance beyond XX days, the Veterinarian shall develop a treatment plan for the patient, which shall include measures to be used to determine progress in treatment, further diagnostic evaluations or modalities that might be necessary, and the extent to which the pain or condition is associated with physical impairment.

(h) The medical record for prescribing controlled substances shall include signs or presentation of the pain or condition, a presumptive diagnosis for the origin of the pain or condition, an examination appropriate to the complaint, a treatment plan, and the medication prescribed to include the date, type, dosage, and quantity prescribed.

(i) For continued prescribing of a controlled substance, the patient shall be seen and reevaluated at least every XX months, and the justification for such prescribing documented in the Patient record.

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(j) Prior to prescribing or dispensing an opioid or other controlled substance, the Veterinarian shall document a discussion with the Client about the known risks and benefits of drugs, the responsibility for the security of the drug and proper disposal of any unused drug.

Commentary

Section 2. Prescribing of Controlled Substances for Acute Pain and Chronic Conditions.

Regulations should cite the specific sections of the Jurisdiction's drug control act or section(s) of the Veterinary Medicine Act related to prescribing or dispensing controlled substances.

Section 2 (d) – The AAVSB recommends that the Jurisdiction limit the initial dose of an opioid or other controlled substance that is dispensed or prescribed to a maximum 14-day supply. Following the initial 14-day supply, the AAVSB recommends that Jurisdictions require that the Patient be seen and re-evaluated for the continued need of the opioid or other controlled substance.

Section 2 (g) – For terminal illnesses or chronic conditions, the AAVSB believes that the Veterinarian should not be required to see and re-evaluate the Patient after the specified time for the initial dose. However, the regulations should specify that the Veterinarian develop a specified treatment plan with measures to determine progress and further evaluations to assess the need for continued prescribing of the opioid or other controlled substance.

Section 2 (i) – The AAVSB recommends that for the continued prescribing of opioids or other controlled substances that the Patient should be seen and re-evaluated at least every six months and justification for continued use of the opioid or other controlled substance be documented in the medical record.

Section 3. Labels of Dispensed Opioids and Other Controlled Substances

(a) For labeling of dispensed opioid and other controlled substance prescriptions, labels must be compliant with federal and provincial laws and should contain at a minimum:

(1) the name and address of the Facility
(2) first and last name of the Client
(3) the name or identification of the Patient
(4) species of the Patient
(5) date dispensed
(6) directions for use
(7) the name, strength and quantity of the drug
(8) the expiration date
(9) number of refills, if applicable
(10) the name of the prescribing Veterinarian

(b) The label must be affixed to container.

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Commentary

Section 3. Labels of Dispensed Opioids and Other Controlled Substances.

In addition to the prescription label requirements outlined in this section, the Jurisdiction may require that the individual filling the prescription initial the label. The Jurisdiction may also want to require that the client initial the label once it has been filled.

Boards are encouraged to check the pharmacy requirements in their Jurisdiction to avoid conflicting regulations.

Section 4. Prescription Orders for Commercial Pharmacies.

Prescription orders for commercial pharmacies must be compliant with the requirements of the Jurisdiction.

Commentary

Section 4. Prescription Orders for Commercial Pharmacies.

The AAVSB encourages The Veterinary Medical Board to work with the pharmacy board on rules for accepting and recording prescriptions from a Veterinarian. As Veterinarians are not granted an NPI number, the AAVSB suggests that rules be established to identify the Veterinarian on a prescription record by their Jurisdiction of license and license number.

Section 5. Recordkeeping

Inventories and records, including original invoices, of Schedule II drugs shall be maintained separately from all other records, and the establishment shall maintain a continuous inventory of all Schedule II drugs received, administered, or dispensed, with reconciliation at least monthly. Reconciliation requires an explanation noted on the inventory for any difference between the actual physical count and the theoretical count indicated by the distribution record. A continuous inventory shall accurately indicate the physical count of each Schedule II drug in the general and working stocks at the time of performing the inventory.

Commentary

Section 5. Recordkeeping.

Maintaining inventories and records is federally required for all Schedule II drugs. The AAVSB also recommends that Jurisdictions consider drafting rules that require regular inventories and record keeping for Schedule III-V drugs.

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Section 6. Reporting Requirements.

[Placeholder for future regulations on reporting to a Prescription Drug Monitoring Program]

Commentary
Section 6. Reporting Requirements. If there are no requirements in the Jurisdiction to report to a Prescriction Drug Monitoring Program, Jurisdictions are encouraged to draft regulations that require the Veterinarian to retain records described in Section 5 to be available for inspection by Jurisdiction and federal authorities. The AAVSB Regulatory Policy Task Force is seeking information from the AAVSB Member Boards on effective measures for Veterinarian use of the Jurisdiction's PMP program. As requirements for Veterinary Medicine differ from human medicine, reporting requirements may conflict with existing regulations, such as: • Veterinarians are not addressed under HIPAA regulations and may be in conflict with privacy requirements for the Client if asked to query the PMP. • Veterinarians are not required to keep electronic medical records and may have difficulty reporting to the PMP given the nature of rural and mobile practices. • Drugs reported for Patient use listing the Client may be confused with physician reports for drugs that have been prescribed directly to the Client.

Section 7. Reporting Discrepancies

Whenever a theft or any unusual loss of Schedules II through V drugs is discovered, such theft or loss shall be immediately reported to the Board of Veterinary Medicine and the DEA and any other required entities. The report to the Board of Veterinary Medicine shall be in writing and sent electronically or by regular mail. The report to the DEA shall be in accordance with 21 CFR 1301.76(b). If the exact kind and quantity of the drug loss cannot be determined, a complete inventory must be immediately taken of all Schedules II through V drugs.

Commentary
Section 7. Reporting Discrepancies. DEA reporting requirements can be found here: https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm

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Section 8. Security

The DEA registrant under which the drugs were purchased is responsible for the effective security of the drug stock. Opioids and other controlled substances must be stored in a securely locked cabinet of substantial construction as per DEA requirements.

In order to minimize the opportunities for theft or diversion of controlled substances, Licensees have an obligation not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons as well as to provide alarm system where necessary

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AMERICAN ASSOCIATION OF VETERINARY STATE BOARDS

MODEL REGULATIONS – SCOPE OF PRACTICE FOR VETERINARY TECHNICIANS AND VETERINARY TECHNOLOGISTS

As recommended by the AAVSB Regulatory Policy Task Force in August 2019

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Introduction

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Scope of Practice for Veterinary Technicians and Veterinary Technologists

Commentary

Section 106. Practice of Veterinary Technology in the AAVSB Practice Act Model (PAM) encourages The Board to promulgate regulations establishing Animal health care tasks and an appropriate degree of Supervision required for those tasks that may be performed only by a Veterinary Technician or a Veterinarian.

Definitions.

Veterinary Technician means an individual who is duly licensed to practice Veterinary Technology under the provisions of this Act and has received an associate degree or its equivalent from a college level program accredited by the American Veterinary Medical Association – Committee on Veterinary Technology Education & Activities.

Veterinary Technologist means an individual who is duly licensed to practice Veterinary Technology under the provisions of this Act and is a graduate of a four-year baccalaureate program accredited by the American Veterinary Medical Association – Committee on Veterinary Technology Education & Activities.

Commentary

Definitions.

As there has been statute changes in at least one jurisdiction to recognize the education difference between a Veterinary Technician and a Veterinary Technologist, the AAVSB believes it will be helpful for Boards to define the distinction.

Model Regulation.

A Veterinary Technician or Veterinary Technologist may be allowed to perform the following acts under the direction, supervision, and responsibility of a licensed Veterinarian, who has established the Veterinarian-Client-Patient Relationship (VCPR). All Licensees will comply with the record keeping rule established by the Board. The Veterinarian shall be responsible for determining the competency of the Licensee to perform allowable Animal healthcare tasks.

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Allowable Animal Healthcare Tasks.

(a) Immediate Supervision

(1) Surgical assistance to a Veterinarian

(b) Direct Supervision

(1) General anesthesia and sedation, maintenance and recovery

(2) Endotracheal intubation

(3) Regional anesthesia, including paravertebral blocks, epidurals, local blocks

(4) Dental procedures including, but not limited to:

a. The removal of calculus, soft deposits, plaque, and stains;

b. The smoothing, filing, and polishing of teeth

(5) Euthanasia

(6) Collection, preparation, and administration of blood or blood components for transfusion purposes

(7) Placement of, including but not limited to, gastric, nasogastric, nasoesophageal, chest, and abdominal tubes

(8) Ear flushing with pressure or suction

(9) Application of casts or splints for the temporary immobilization of fractures

(10) Fluid aspiration from a body cavity or organ (i.e., cystocentesis)

(11) Suturing an existing surgical skin incision or

(12) Suturing a gingival incision

(13) Placement of epidural, osseous, and nasal catheters

(14) Administration of chemotherapy

(15) Administration of radiation therapy

(c) Indirect Supervision

(1) Administration, preparation, and application of treatments, including but not limited to, drugs, medications, controlled substances, enemas, biological and immunological agents, unless prohibited by government regulation

(2) Intravenous and intra-arterial catheterizations

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(3) Imaging including, but not limited to, radiography, ultrasonography, computed tomography, magnetic resonance imaging, and fluoroscopy and the administration of radio-opaque agents/materials

(4) Collection of blood except when in conflict with government regulations, (i.e., Coggins)

(5) Collection and preparation of cellular, or microbiological samples by skin scrapings, impressions, or other non- surgical methods except when in conflict with government regulations

(6) Collection of urine by free catch, expression, catheterization (unobstructed) and insertion of an indwelling urinary catheter

(7) Monitoring including, but not limited to, EKG, blood pressure, and blood oxygen saturation

(8) Clinical laboratory test procedures

(9) Handling and disposal of biohazardous waste materials

(10) Implantation of a subcutaneous identification chip

(11) Laser Therapy

(12) Animal Rehabilitation Therapies

(13) Ocular tonometry, Schirmer tear test, and fluorescein stain application

(14) Suture removal

Commentary

Indirect Supervision

Jurisdictions may want to have a special exception to allow a Veterinary Technician or Veterinary Technologist to conduct pregnancy examination of food animals, with or without diagnostic equipment, rectal palpation, and artificial insemination. Jurisdictions may also want to exclude Veterinary Technicians and Veterinary Technologists from performing these duties at livestock auctions due to the lack of a VCPR and abundance of governmental regulatory requirements (i.e., interstate health certificates).

The AAVSB Regulatory Policy Task Force also suggests that the definition for Indirect Supervision be revised in the AAVSB Practice Act Model to the following: **Indirect Supervision** means a Supervising Veterinarian need not be physically on the Premises but has given either written or oral instructions for the treatment of the Patient and is readily available for communication either in person or through use of electronic information and communication technology

DRAFT

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Cannabis Guidance Document – Final Draft for Approval
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	<u>Guidance Document:</u> "VEB-GD-002 Cannabis" "VEB-GB-002 Cannabis – Attachment A" "VEB-GB-002 Cannabis – Attachment B" "VEB-GB-002 Cannabis – Attachment C" <u>WVMA Article Regarding Cannabis:</u> "FW_December WVMA Vitals" <u>AVMA Article Regarding Cannabis:</u> "2019_12_AVMA Update on Cannabis Derived and Cannabis Related Products" <u>Initial Comment and Documents Provided:</u> "FW_ Choosing Legal Hemp Products_Information on Legal Unapproved FDA Products" "FDA Regulation of Cannabis and Cannabis-Derived Products" "FDA Nutritional Supplements for Companion Animals" "FDA Draft Supplements and Beverages" "GWCBDAnimalSafteyStudy" "FDA Is It Really FDA Approved" "Federal Register. Vol. 61, No. 78. Monday, April 22, 1996. Notices"
6) Is a Public Appearance Anticipated?	No

7) Description of the Agenda Item	Attached is the cannabis guidance document final draft for Board approval. Attached is also articles by the WVMA and AVMA regarding cannabis. Attached is also an initial comment received, and documents that were provided with the comment. If the final draft is approved by the Board and signed by the Chair, the guidance document will be submitted to the Legislative Reference Bureau and posted public comment, pursuant to Wis. Stat. s. 227.112.

State of Wisconsin

Veterinary Examining Board

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Guidance Document VEB-GD-002 DRAFT
Cannabis

Wis. Stat. § 89.03 (1)
Wis. Admin. Code § VE 7.06
11/26/19 DRAFT

Topic

This guidance document clarifies what a veterinarian may and may not do with regards to cannabis products.

Definitions

Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. Federal law divides cannabis into two categories: hemp and marijuana.

Hemp is defined by the 7 USC 1639o(1) as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." The 2018 Farm Bill removed hemp from Schedule I of the Controlled Substances Act.

Marijuana/Marihuana is defined by 21 USC 802(16) as "all parts of the plant Cannabis sativa L., whether grown or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivate, mixture, or preparation of such plant, its seeds or resin," except for "hemp, as defined in section 1639o of title 7; or the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." Marijuana/Marihuana is listed in Schedule I of the Controlled Substances Act.

THC is an abbreviation of delta-9-tetrahydrocannabinol, a compound of the cannabis plant. Hemp plants contain no more than 0.3 percent THC on a dry weight basis, and marijuana plants contain more than 0.3 percent THC on a dry weight basis.

CBD is an abbreviation of cannabidiol, a compound of the cannabis plant. Hemp plants and marijuana plants both contain CBD.

Hemp Seeds are the seeds of the Cannabis sativa plant. The seeds of the plant do not naturally contain THC or CBD. The seeds may pick up trace amounts of TCH and/or CBD during the harvesting and processing when they are in contact with other parts of the plant.

Relevant Statutes and Administrative Code

Wis. Stat. § 89.02 (6) defines the practice of veterinary medicine as to examine into the fact or cause of animal health, disease or physical condition, or to treat, operate, prescribe or advise for the same, or to under-take, offer, advertise, announce, or hold out in any manner to do any of said acts, for compensation, direct or indirect, or in the expectation thereof.

Wis. Stat. § 89.03 (1) authorizes the board to promulgate rules to establish the scope of the practice permitted for veterinarians and veterinary technicians, within the limits of the definition under Wis. Stat. § 89.02 (6).

Wis. Stat. § 89.068 (1) (a) prohibits making extra-label use of a drug on an animal without a prescription or in any manner not authorized by that prescription.

Wis. Stat. § 89.068 (1) (c) 3. prohibits a veterinarian from prescribing a drug to a client for extra-label use on a patient unless all of the following apply:

a. A veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian has made a careful medical diagnosis of the condition of the patient within the context of that veterinary-client-patient relationship.
b. The veterinarian determines that there is no drug that is marketed specifically to treat the patient's diagnosed condition, or determines that all of the drugs that are marketed for that purpose are clinically ineffective.
c. The veterinarian recommends procedures for the client to follow to ensure that the identity of the patient will be maintained.
d. If the patient is a food-producing animal, the veterinarian prescribes a sufficient time period for drug withdrawal before the food from the patient may be marketed.

Wis. Stat. § 89.07 (1) (b) classifies violating any federal or state statute or rule that substantially relates to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

Wis. Admin. Code § VE 7.06 (4) classifies violating or aiding and abetting the violation of any law or administrative rule or regulation substantially related to the practice of veterinary medicine as unprofessional conduct that may result in disciplinary action by the Board.

Federal Law and Regulation

The 2018 Farm Bill removed hemp from the Controlled Substance Act definition of marijuana. As a result, while marijuana remains a Schedule I drug, hemp is no longer a controlled substance under Federal law. The 2018 Farm Bill explicitly preserved the authority of the United States Food and Drug Administration (FDA) to regulate products containing cannabis or cannabis-derived compounds under the Food, Drug and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. It is illegal to market or sell cannabis products in interstate commerce for animal use unless the FDA approves the product for animal use. To date, the FDA has not approved any cannabis product for animal use.

Drugs: Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure of the body of humans or animals, is a drug. To date, the FDA has not approved any cannabis-containing, cannabis-derived, or cannabis-related drugs for animal use. The FDA has approved one cannabis-derived (Epidiolex) and three cannabis-related (Marinol, Syndros, and Cesamet) prescription drugs for human use. The Animal Medicinal Drug Use Clarification Act (AMDUCA)

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permits veterinarians to prescribe extra-label uses of FDA approved human and animal drugs for animals under certain conditions. Among other limitations, extra-label use of a drug is only allowed in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

Foods: All food ingredients must be approved by the FDA as either a food additive or as Generally Recognized as Safe (GRAS). The FDA also recognizes ingredients listed in the Official Publication of the Association of American Feed Control Officials (AAFCO). To date, neither the FDA nor AAFCO have approved any cannabis-containing or cannabis-derived foods for animal use. The FDA has approved three cannabis products as GRAS for human use only: hulled hemp seed, hemp seed protein powder, and hemp seed oil.

Supplements: The definition of dietary supplement only applies to human products. All products for animal use are classified as either foods or drugs and must be FDA approved. CBD and THC are the active ingredients in FDA approved human prescription drugs, so all products containing CBD or THC are classified as drugs.

See the attached FDA documents for additional information: "Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds," dated May 31, 2019; "FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers," dated November 13, 2019; and "FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns," dated November 25, 2019. See the FDA website at www.fda.gov for the latest information regarding FDA regulation of cannabis-containing and cannabis-derived products.

Board Position

Administering, prescribing, or dispensing drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Stat. § 89.07 (b) and Wis. Admin. Code § VE 7.06 (4)).

Referring or recommending drugs or food additives must conform to state and federal laws and regulations, including FDA regulations (Wis. Admin. Code § VE 7.06 (4)).

The Board acknowledges that cannabis products are currently being marketed to pet owners in a manner that does not conform to state and federal laws and regulations, including FDA regulations. To reduce the risk to animal health, veterinarians may discuss such products with their clients, provide available information, and express concerns. Veterinarians may also explain why they cannot administer, prescribe, dispense, refer, or recommend such products.

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IN THIS SECTION

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SPEECH

Remarks by Dr. Sharpless at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

MAY 31, 2019

Speech by

Norman E. "Ned" Sharpless, MD
Acting
Commissioner of Food and Drugs - Food and Drug Administration

White Oak, MD

(Remarks as prepared for delivery)

Thank you for joining FDA today for this public hearing titled “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds”.

I am pleased to see that there is such interest in this topic. We have over 500 people registered to attend in person, over 800 people registered to join us remotely, and over 100 speakers on today’s agenda presenting on this topic.

We encourage all stakeholders – presenters, attendees, and those unable to participate in today’s hearing – to submit comments to our docket on this topic, which is open until July 2, 2019.

Docket comments will help inform FDA as we consider the important policy options related to the regulation of products containing cannabis or cannabis-derived compounds.

It is important to note that the FDA's role in the regulation of products containing cannabis or cannabis-derived compounds is not new.

Cannabis contains more than 80 biologically active chemical compounds, including the two best known compounds, delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

If one of these compounds, or the plant itself, is added to a food or cosmetic, marketed as a drug, or otherwise added to an FDA-regulated product in interstate commerce, then it falls within FDA's jurisdiction. As I said, this is nothing new for FDA.

At the same time, some relevant laws have changed. First, some states have changed their laws to allow for "medical" use of marijuana or CBD, and others have begun allowing for recreational marijuana use, or decriminalized recreational marijuana possession.

Second, certain federal laws have changed as well. Parts of the Cannabis sativa plant have been controlled under the Federal Controlled Substances Act, or CSA, since 1970 under the drug class "Marihuana."

Marihuana is included in Schedule I of the CSA – the most restrictive schedule – due to its potential for abuse, largely attributable to the psychoactive effects of THC, and the absence of a currently accepted medical use in the United States.

Late last year, the federal scheduling of cannabis changed. The Agriculture Improvement Act of 2018, or the Farm Bill, removed hemp – meaning cannabis or derivatives of cannabis with a very low THC content (below 0.3% by dry weight) – from the CSA's definition of marijuana. As a result, while marijuana remains a Schedule I drug, hemp is no longer a controlled substance under Federal law.

As these laws have changed, FDA's authorities have become more relevant.

The 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds. In doing so, Congress recognized FDA's important public health role with respect to all the products it regulates – including when those products are or contain cannabis ingredients.

FDA treats substances derived from cannabis just like we do any other substances, and they are subject to the same authorities as any other substance.

Under FDA's authorities, the relevant legal requirements vary depending on which type of product we're talking about.

For example, if a product is being marketed as a drug – meaning, for example, that it's intended to have a therapeutic effect such as treating a disease or affecting the body's structure or function – then it's regulated as a drug, and it generally cannot be sold without FDA approval.

FDA has approved several drug products that contain compounds found in cannabis.

These include EPIDIOLEX, which contains CBD, for the treatment of specific types of seizures in certain pediatric patients, and MARINOL and SYNDROS, which contains dronabinol, a synthetic THC, for uses including the treatment of anorexia in patients with AIDS.

These drugs have important therapeutic value, and it is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis.

Food, including dietary supplements, is regulated differently, but with the same overarching goal of protecting consumers.

We know that American consumers depend on FDA to help make sure that the food they eat, and that they serve to their families, is safe. We do this through a number of requirements.

For example, while we don't generally require foods to be approved by FDA before coming to market, we do require that a new food additive be approved as safe by FDA before being put in the food supply, unless the substance is generally recognized as safe, or GRAS.

This requirement applies to cannabis-derived ingredients, just as it does to any other substance. Americans deserve to know that substances being added to their foods are safe, regardless of the source.

I will note that several cannabis-derived substances have already come to market through the GRAS pathway.

In December, FDA announced that we completed our evaluation of GRAS notices for three hemp seed ingredients and had no objection to their being marketed in human foods for certain uses without approval, provided they comply with all other requirements.

As I mentioned earlier, however, some compounds found in cannabis – specifically, CBD and THC – have been studied and even approved as drugs. It's important to note that the Federal Food, Drug & Cosmetic Act prohibits adding drugs to human or animal food in interstate commerce.

That includes both substances that have been approved as drugs, as well as compounds for which substantial clinical investigations have been instituted. Similarly, the law excludes these products from the statutory definition of a dietary supplement.

Based on the information available to FDA, we have concluded that these provisions apply to CBD and THC. And while there is an exception when the substance was marketed as a food or dietary supplement before it was studied as a drug, we have concluded that that is not the case for CBD or THC.

What that means is that, under current law, CBD and THC cannot lawfully be added to a food or marketed as a dietary supplement.

Although the law says that FDA can issue regulations to create new exceptions to these statutory provisions, FDA has never issued a regulation like that for any substance.

So, if we were thinking about doing that for a substance like CBD, it would be new terrain for the FDA.

There are important reasons to generally prohibit putting drugs in the food supply. When FDA approves a drug, we carefully evaluate the risks and benefits of a specific formulation, dosage form, and strength for a particular population.

Often, we conclude that to be safely used, it requires a prescription or other medical supervision to help protect against potentially dangerous misuse.

THC and CBD are no exception.

There are real risks associated with both those substances and critical questions remain about the safety of their widespread use in foods and dietary supplements, as well as other consumer products – including cosmetics, which are subject to a separate regulatory framework.

And given the new interest in marketing cannabis products across the range of areas FDA regulates, we will need to carefully evaluate how all these pieces fit together in terms of how consumers might access cannabis products.

Nowhere is this truer than with CBD. While we have seen an explosion of interest in products containing CBD, there is still much that we don't know.

Prior to the 2018 Farm Bill, population-based research mostly included cannabis-focused observations in aggregate, rather than specific to CBD.

When hemp was removed as a controlled substance, this lack of research, and therefore evidence, to support CBD's broader use in FDA-regulated products, including in foods and dietary supplements, has resulted in unique complexities for its regulation, including many unanswered questions related to its safety.

For example, how much CBD is safe to consume in a day? What if someone applies a topical CBD lotion, consumes a CBD beverage or candy, and also consumes some CBD oil? How much is too much? How will it interact with other drugs the person might be taking? What if she's pregnant? What if children access CBD products like gummy edibles? What happens when someone chronically uses CBD for prolonged periods?

These and many other questions represent important and significant gaps in our knowledge.

To help us evaluate these questions, as well as potential pathways for CBD products, FDA has formed an internal working group to address these data gaps specifically. You'll be hearing more from this group in the months to come.

FDA is aware that some companies appear to be marketing products containing cannabis and cannabis-derived compounds in ways that violate the law.

FDA has issued warning letters to companies selling unapproved CBD products.

Our biggest concern is the marketing of products that put the health and safety of consumers at risk, such as those claiming to prevent, diagnose, mitigate, treat, or cure serious diseases, such as cancer, in the absence of requisite approvals.

Selling unapproved drug products with unsubstantiated therapeutic claims is a violation of the law, and puts patients at risk.

Patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

That being said, the agency does not have a policy of enforcement discretion with respect to any CBD products.

There are lots of questions we will need to answer to ensure that FDA is taking an appropriate, well-informed, and science-based approach to the regulation of cannabis and cannabis derivatives, including CBD.

We hope that this meeting, and the comments submitted to our public docket, will help us as we try to approach this issue in an informed way. This hearing is an important step in our continued evaluation of cannabis and cannabis-derived compounds in FDA-regulated products.

I thank you all for taking the time to join us today and your contributions toward this important topic. We have a full agenda....

More Speeches by
FDA Officials (/news-events/speeches-fda-officials)

FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)

On this page:

- Consumer Information
- FDA Communications
- Regulatory Resources
- Questions and Answers

There is a significant interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products. FDA has a number of resources available that address cannabis and cannabis-derived products, such as CBD, and the agency wants to ensure that consumers and other stakeholders have access to these resources in a centralized location.

Consumer Information

- What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding (/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding)
- What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis)

FDA Communications

- Remarks at the Council for Responsible Nutrition Conference (/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019)
- Remarks at the National Industrial Hemp Council 2019 Hemp Business Summit (/news-events/speeches-fda-officials/remarks-national-industrial-hemp-council-2019-hemp-business-summit-08132019)
- Congressional Testimony: Hemp Production and the 2018 Farm Bill (/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019)
    - Archived Video (https://www.agriculture.senate.gov/hearings/hemp-production-and-the-2018-farm-bill)
- FDA is Committed to Sound, Science-based Policy on CBD (/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd)
- Statement on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products (/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation)

Regulatory Resources

- Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing
    - Federal Register Notice (https://www.federalregister.gov/documents/2019/04/03/2019-06436/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds)
    - Public Hearing Page (/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds)
    - Public Docket (https://www.regulations.gov/docket?D=FDA-2019-N-1482)

- Warning Letters and Test Results for Cannabidiol-Related Products (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products)
- State, Local, Tribal, Territorial (SLTT) Regulatory Officials: FDA is committed to working with our SLTT public health regulatory partners as developments occur in the regulatory landscape. Please contact the Intergovernmental Affairs team with any questions at IGA@fda.hhs.gov (mailto:IGA@fda.hhs.gov).

Questions and Answers

Below are a number of frequently asked questions and answers on this topic.

1. What are cannabis and marijuana?
2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?
3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?
4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?
5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?
6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?
7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?
8. Is it legal for me to sell CBD products?
9. Can THC or CBD products be sold as dietary supplements?
10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?
11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?
13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?
14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?
15. Can I import or export cannabis-containing or cannabis-derived products?
16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?
17. Does the FDA object to the clinical investigation of cannabis for medical use?
18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?
19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?
20. Does the FDA have concerns about administering a cannabis product to children?
21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?
22. What does the FDA think about making CBD available to children with epilepsy?
23. What should I do if my child eats something containing cannabis?
24. I've seen cannabis products being marketed for pets. Are they safe?
25. Can hemp be added to animal food?
26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

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1. What are cannabis and marijuana?

A. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21

U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

A. At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?

A. To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

FDA has approved Epidiolex (/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms), which contains a purified form of the drug substance CBD for the treatment of seizures

associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means FDA has concluded that this particular drug product is safe and effective for its intended use.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of cannabis. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

A. No. There are no other FDA-approved drug products that contain CBD. We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses , and we have issued several warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.

FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

The agency has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved. At the same time, FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA continues to believe that the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process (see Question #16).

5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?

A. FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products (see Question #2).

FDA relies on applicants and scientific investigators to conduct research. The agency's role, as laid out in the FD&C Act, is to review data submitted to the FDA in an application for approval to ensure that the drug product meets the statutory standards for approval.

The study of cannabis and cannabis-derived compounds in clinical trial settings is needed to assess the safety and effectiveness of these substances for the treatment of any disease or condition. FDA's December 2016 *Guidance for Industry: Botanical Drug Development* (/regulatory-information/search-fda-guidance-

documents/botanical-drug-development-guidance-industry) provides specific recommendations on submitting INDs for botanical drug products, such as those derived from cannabis, in support of future marketing applications for these products. The FDA will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of cannabis. Additional information concerning research on the medical use of cannabis is available from the National Institutes of Health, particularly the National Cancer Institute (https://www.cancer.gov/) (NCI) and National Institute on Drug Abuse (https://www.drugabuse.gov/drugs-abuse/marijuana/nih-research-marijuana-cannabinoids) (NIDA).

6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?

A. The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of cannabis and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of cannabis products through adequate and well-controlled clinical trials. We welcome the opportunity to talk with states who are considering support for medical research of cannabis and its derivatives, so that we can provide information on Federal and scientific standards.

7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?

A. The agency has received reports of adverse events in patients using cannabis or cannabis-derived products to treat medical conditions. The FDA reviews such reports and will continue to monitor adverse event reports for any safety signals, with a focus on serious adverse effects.

Information from adverse event reports regarding cannabis use is extremely limited; FDA primarily receives adverse event reports for approved products. General information on the potential adverse effects of using cannabis and its constituents can come from clinical trials that have been published, as well as from spontaneously reported adverse events sent to the FDA. Additional information about the safety and effectiveness of cannabis and its constituents is needed. Clinical trials of cannabis conducted under an IND application could collect this important information as a part of the drug development process.

8. Is it legal for me to sell CBD products?

A. It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

9. Can THC or CBD products be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the

agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (i.e., dietary ingredients that were not marketed in the United States in a dietary supplement before October 15, 1994) generally must notify FDA about these ingredients (see section 413 (d) of the FD&C Act [21 U.S.C. § 350b(d)]). Generally, the notification must include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury (see section 402(f)(1)(B) of the FD&C Act [21 U.S.C. 342(f)(1)(B)]).

Numerous other legal requirements apply to dietary supplement products, including requirements relating to Current Good Manufacturing Practices (CGMPs) (/food/current-good-manufacturing-practices-cgmps/current-good-manufacturing-practices-cgmps-dietary-supplements) and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website.

10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?

A. No. Under section 301(ll) of the FD&C Act [21 U.S.C. § 331(ll)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When this statutory prohibition applies to a substance, it prohibits the introduction into interstate commerce of any food to which the substance has been added unless FDA, in the agency's discretion, has issued a regulation approving the use of the substance in the food (section 301(ll)(2) of the FD&C Act [21 U.S.C. § 331(ll)(2)]). To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of 301(ll), and therefore might be able to be added to food. For example, as discussed in Question #12, certain hemp seed ingredients can be legally marketed in human food. However, all food ingredients must comply with all applicable laws and regulations. For example, by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive (sections 201(s) and 409 of the FD&C Act [21 U.S.C. §§ 321(s) and 348]). Aside from the three hemp seed ingredients mentioned in Question #12, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Food

companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS processes.

11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

A. THC (dronabinol) is the active ingredient in the approved drug products, Marinol capsules (and generics) and Syndros oral solution. CBD is the active ingredient in the approved drug product, Epidiolex.

The existence of substantial clinical investigations regarding THC and CBD have been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain (https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer))

12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?

A. In December 2018, FDA completed its evaluation (/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food) of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. These GRAS notices related only to the use of these ingredients in human food. To date, FDA has not received any GRAS notices for the use of hemp-derived ingredients in animal food (see Question #25).

Hemp seeds are the seeds of the *Cannabis sativa* plant. The seeds of the plant do not naturally contain THC or CBD. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds

may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high."

The GRAS conclusions can apply to ingredients for human food marketed by other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food.

13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

A. A cosmetic is defined in 201(i) as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."

Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way. A cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)]).

If a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. (See Question #3 for more information about drugs.)

FDA can take action if it has information that an ingredient or cosmetic product is unsafe to consumers. Consumers can report adverse events associated with cosmetic products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088, or by contacting your nearest FDA district office consumer complaint coordinator. For more information, please see the FDA's webpage on how to report a cosmetic-related complaint (/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint).

14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?

A. The FDA has sent warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

15. Can I import or export cannabis-containing or cannabis-derived products?

A. General information about the import/export of drug products regulated by FDA (/drugs/guidance-compliance-regulatory-information/import-export-compliance-branch-iecb) can be found online here. The Drug Enforcement Administration (https://www.dea.gov/) (DEA) is the federal agency responsible for enforcing the controlled substance laws and regulations in the U.S. and, as such, should be consulted with respect to any regulations/requirements they may have regarding the

import or export of products containing cannabis. Please see here for information about importing or exporting food ingredients (/food/guidance-regulation-food-and-dietary-supplements/food-imports-exports).

Regarding imports, if it appears that an article is adulterated, misbranded, in violation of section 505 of the FD&C Act, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll) of the FD&C Act, such article will be refused admission (see section 801(a)(3) of the FD&C Act [21 U.S.C. § 381(a)(3)]).

Research and Expanded Access

16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?

A. To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with the FDA and submit an IND application to the Center for Drug Evaluation and Research (CDER). The IND application process gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. For research for use as an animal drug product, researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

As discussed above (see Question #2), the 2018 Farm Bill removed hemp from the CSA. This change may streamline the process for researchers to study cannabis and its derivatives, including CBD, that fall under the definition of hemp, which could speed the development of new drugs.

Conducting clinical research using cannabis-related substances that are scheduled by the DEA often involves interactions with several federal agencies. This includes: a registration administered by the DEA; obtaining the cannabis for research from NIDA, within the National Institutes of Health, or another DEA-registered source; and review by the FDA of the IND or INAD application and research protocol. Additionally:

- For a Schedule I controlled substance under the CSA, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site cannabis will be studied.

- NIDA provides research-grade cannabis for scientific study. The agency is responsible for overseeing the cultivation of cannabis for medical research and has contracted with the University of Mississippi to grow cannabis for research at a secure facility. Cannabis of varying potencies and compositions is available. DEA also may allow additional growers (https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to) to register with the DEA to produce and distribute cannabis for research purposes.
- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs in CDER depending on the therapeutic indication. Based on the results obtained in studies conducted at the IND stage, sponsors may submit a marketing application for formal approval of the drug.

17. Does the FDA object to the clinical investigation of cannabis for medical use?

A. No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from cannabis. The FDA supports the conduct of that research by:

1. Providing information on the process needed to conduct clinical research using cannabis.
2. Providing information on the specific requirements needed to develop a drug that is derived from a plant such as cannabis. In December 2016, the FDA updated its Guidance for Industry: Botanical Drug Development (/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry), which provides sponsors with guidance on submitting IND applications for botanical drug products.
3. Providing specific support for investigators interested in conducting clinical research using cannabis and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.
4. Providing general support to investigators to help them understand and follow the procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research's Small Business and Industry Assistance group

(/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia).

18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?

A. Expanded access (/news-events/public-health-focus/expanded-access) is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies available. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?

A. Information for patients on Right to Try (/patients/learn-about-expanded-access-and-other-treatment-options/right-try) (RTT) is available on our website. RTT is designed to facilitate access to certain investigational drugs through direct interactions between patients, their physicians and drug sponsors – FDA is not involved in these decisions. Sponsors developing drugs for life-threatening conditions are responsible for determining whether to make their products available to patients who qualify for access under RTT. If you are interested in RTT, you should discuss this pathway with your licensed physician. Companies who develop drugs and biologics, also known as sponsors, can provide information about whether their drug/biologic is considered an eligible investigational drug under RTT and if they are able to provide the drug/biologic under the RTT Act.

Children and Pregnant/Lactating Women

20. Does the FDA have concerns about administering a cannabis product to children?

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products

containing cannabis or cannabis-derived compounds, and will continue to work with companies interested in bringing safe, effective, and quality products to market. With the exception of Epidiolex, Marinol, and Syndros, no product containing cannabis or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population, whether pediatric or adult.

21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?

A. The FDA is aware that there are potential adverse health effects with use of cannabis products containing THC in pregnant or lactating women. Published scientific literature reports potential adverse effects of cannabis use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and stillbirth. [1, 2, 3] Based on published animal research, there are also concerns that use of cannabis during pregnancy may negatively impact fetal brain development. [4, 5, 6] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue cannabis use. In addition, ACOG notes that there are insufficient data to evaluate the effects of cannabis use on breastfed infants; therefore, cannabis use is discouraged when breastfeeding. [7] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of cannabis use.

22. What does the FDA think about making CBD available to children with epilepsy?

A. The FDA has approved Epidiolex, which contains a purified form of the drug substance CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended use. Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring cannabis-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, and the assurance of manufacturing quality standards, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

23. What should I do if my child eats something containing cannabis?

A. With the exception of products such as the hemp seed ingredients discussed in Question #12, which have been evaluated for safety, it is important to protect children from accidental ingestion of cannabis and cannabis-containing products. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion. If the parent or caregiver has a reasonable suspicion that the child accidentally ingested products containing cannabis, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

Pets and other Animals

24. I've seen cannabis products being marketed for pets. Are they safe?

A. FDA is aware of some cannabis products being marketed as animal health products. We want to stress that FDA has not approved cannabis for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

While the agency is aware of reports of pets consuming various forms of cannabis, to date, FDA has not directly received any reports of adverse events associated with animals given cannabis products. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting cannabis, we encourage you to report the adverse event to the FDA. Please visit Reporting Information about Animal Drugs and Devices (/animal-veterinary/report-problem/how-report-animal-drug-side-effects-and-product-problems) to learn more about how to report an adverse event related to an animal drug or for how to report an adverse event or problem with a pet food.

25. Can hemp be added to animal food?

A. All ingredients in animal food must be the subject of an approved food additive petition or generally recognized as safe (GRAS) for their intended use in the intended species. If an animal food contains an ingredient that is not the subject of an approved food additive petition or GRAS for its intended use in the intended species, that animal food would be adulterated under section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)]. In coordination with state feed control officials, CVM also recognizes ingredients listed in the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) as being acceptable for use in animal food. At this time, there are no approved food additive petitions or ingredient definitions listed in the AAFCO OP for any substances derived from hemp, and we are unaware of any GRAS conclusions regarding the use of any substances derived from hemp in animal food. Learn more about animal food ingredient submissions (/animal-veterinary/safety-health/safe-feed) here.

With respect to products labeled to contain "hemp" that may also contain THC or CBD, as mentioned above it is a prohibited act under section 301(ll) of the FD&C Act to introduce or deliver for introduction into interstate commerce any animal food to which THC or CBD has been added.

26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

A. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), permits veterinarians to prescribe extralabel uses of approved human and animal drugs for animals under certain conditions. Extralabel use must comply with all the provisions of AMDUCA and its implementing regulation at 21 CFR § 530. Among other limitations, these provisions allow extralabel use of a drug only on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship and only in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

In addition, under 21 CFR 530.20, extralabel use of an approved human drug in a food-producing animal is not permitted if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the use. In addition, under 21 CFR 530.20(b)(2), if scientific information on the human food safety aspect of the use of the approved human drug in food-producing animals is not available, the veterinarian must take appropriate measures to ensure that the animal and its food products will not enter the human food supply.

For more information on extralabel use of FDA approved drugs in animals, see Extralabel Use of FDA Approved Drugs In Animals (/animal-veterinary/acts-rules-regulations/animal-medicinal-drug-use-clarification-act-1994-amduca).

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[1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. Clinical Chemistry. 2010; 56(9): 1442-1450.

[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ Open. 2016; 6:e009986.

[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. Pediatric Research. 2012; 71 (2): 215-219.

[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. Neurotoxicol and Teratol 2012; 34(1): 63-71.

[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. Psychopharmacology (Berl) 2008; 198(4): 529-537.

[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. Addict Biol 2007; 12(3-4): 485–495.

[7] ACOG Committee Opinion: Marijuana Use During Pregnancy and Lactation (https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

FDA NEWS RELEASE

FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns

Violations include marketing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to human, animal foods

For Immediate Release:

November 25, 2019

Today, the U.S. Food and Drug Administration issued warning letters to 15 companies for illegally selling products containing cannabidiol (CBD) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA also published a revised Consumer Update (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis) detailing safety concerns about CBD products more broadly. Based on the lack of scientific information supporting the safety of CBD in food, the FDA is also indicating today that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.

Today's actions come as the FDA continues to explore potential pathways for various types of CBD products to be lawfully marketed. This includes ongoing work to obtain and evaluate information to address outstanding questions related to the safety of CBD products, while maintaining the agency's rigorous public health standards. The FDA plans to provide an update on its progress regarding the agency's approach to these products in the coming weeks.

"As we work quickly to further clarify our regulatory approach for products containing cannabis and cannabis-derived compounds like CBD, we'll continue to monitor the marketplace and take action as needed against companies that violate the law in ways that raise a variety of public health concerns. In line with our mission to protect the public, foster innovation, and promote consumer confidence, this overarching approach regarding CBD is the same as the FDA would take for any other substance that we regulate," said FDA Principal Deputy Commissioner Amy Abernethy, M.D.,

Ph.D. “We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD ‘can’t hurt.’ Aside from one prescription drug approved to treat two pediatric epilepsy disorders, these products have not been approved by the FDA and we want to be clear that a number of questions remain regarding CBD’s safety – including reports of products containing contaminants, such as pesticides and heavy metals – and there are real risks that need to be considered. We recognize the significant public interest in CBD and we must work together with stakeholders and industry to fill in the knowledge gaps about the science, safety and quality of many of these products.”

Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD. The revised Consumer Update (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis) outlines specific safety concerns related to CBD products, including potential liver injury, interactions with other drugs, drowsiness, diarrhea, and changes in mood. In addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels and impair sexual behavior in males. Questions also remain about cumulative use of CBD and about CBD’s impacts on vulnerable populations such as children and pregnant or breastfeeding women.

CBD is marketed in a variety of product types, such as oil drops, capsules, syrups, food products such as chocolate bars and teas, and topical lotions and creams. As outlined in the warning letters issued today, these particular companies are using product webpages, online stores and social media to market CBD products in interstate commerce in ways that violate the FD&C Act, including marketing CBD products to treat diseases or for other therapeutic uses for humans and/or animals. Other violations include marketing CBD products as dietary supplements and adding CBD to human and animal foods.

The companies receiving warning letters are:

- Koi CBD LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/koi-cbd-llc-593391-11222019), of Norwalk, California

- Pink Collections Inc. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mr-pink-collections-llc-593395-11222019), of Beverly Hills, California
- Noli Oil (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/noli-oil-llc-593497-11222019), of Southlake, Texas
- Natural Native LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/natural-native-llc-593385-11222019), of Norman, Oklahoma
- Whole Leaf Organics LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/whole-leaf-organics-llc-593176-11222019), of Sherman Oaks, California
- Infinite Product Company LLLP (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/infinite-product-company-lllp-dba-infinite-cbd-593175-11222019), doing business as Infinite CBD, of Lakewood, Colorado
- Apex Hemp Oil LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apex-hemp-oil-llc-592691-11222019), of Redmond, Oregon
- Bella Rose Labs (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bella-rose-labs-594246-11222019), of Brooklyn, New York
- Sunflora Inc. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sunflora-incthe-cbd-store-llc-dba-your-cbd-store-585390-11222019), of Tampa, Florida/Your CBD Store, of Bradenton, Florida
- Healthy Hemp Strategies LLC, doing business as Curapure (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cdrl-nutritional-inc-593398-11222019), of Concord, California
- Private I Salon LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/private-i-salon-llc-593479-11222019), of Charlotte, North Carolina
- Organix Industries Inc., doing business as Plant Organix (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/organix-

industries-inc-dba-plant-organix-593512-11222019), of San Bernardino, California

- Red Pill Medical Inc. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/red-pill-medical-inc-593389-11222019), of Phoenix, Arizona
- Sabai Ventures Ltd. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sabai-ventures-ltd-593865-11222019), of Los Angeles, California
- Daddy Burt LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/daddy-burt-hemp-co-593866-11222019), doing business as Daddy Burt Hemp Co., of Lexington, Kentucky

The FDA has previously sent warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) to other companies illegally selling CBD products in interstate commerce that claimed to prevent, diagnose, mitigate, treat or cure serious diseases, such as cancer, or otherwise violated the FD&C Act. Some of these products were in further violation because CBD was added to food, and some of the products were also marketed as dietary supplements despite products which contain CBD not meeting the definition of a dietary supplement.

Under the FD&C Act, any product intended to treat a disease or otherwise have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. The FDA has not approved any CBD products other than one prescription human drug product (/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms) to treat rare, severe forms of epilepsy. There is very limited information for other marketed CBD products, which likely differ in composition from the FDA-approved product and have not been evaluated for potential adverse effects on the body.

Unlike drugs approved by the FDA, there has been no FDA evaluation of whether these unapproved products are effective for their intended use, what the proper dosage might be, how they could interact with FDA-approved drugs, or whether they have dangerous side effects or other safety concerns. In addition, the manufacturing process of unapproved CBD drug products has not been subject to FDA review as part of the human or animal drug approval processes. Consumers may also put off getting important medical care, such as proper diagnosis, treatment and supportive care due

to unsubstantiated claims associated with CBD products. For that reason, it's important that consumers talk to a health care professional about the best way to treat diseases or conditions with existing, approved treatment options.

Additionally, some of the products outlined in the warning letters issued today raise other legal and public health concerns:

- Some of the products are marketed for infants and children – a vulnerable population that may be at greater risk for adverse reactions due to differences in the ability to absorb, metabolize, distribute or excrete a substance such as CBD.
- Some of the products are foods to which CBD has been added. Under the FD&C Act, it is illegal to introduce into interstate commerce any human or animal food to which certain drug ingredients, such as CBD, have been added. In addition, the FDA is not aware of any basis to conclude that CBD is GRAS among qualified experts for its use in human or animal food. There also is no food additive regulation which authorizes the use of CBD as an ingredient in human food or animal food, and the agency is not aware of any other exemption from the food additive definition that would apply to CBD. CBD is therefore an unapproved food additive, and its use in human or animal food violates the FD&C Act for reasons that are independent of its status as a drug ingredient.
- Some of the products are marketed as dietary supplements. However, CBD products cannot be dietary supplements because they do not meet the definition of a dietary supplement under the FD&C Act.
- One product outlined in a warning letter to Apex Hemp Oil LLC is intended for food-producing animals. The agency remains concerned about the safety of human food products (e.g. meat, milk, and eggs) from animals that consume CBD, as there is a lack of data establishing safe CBD residue levels.

The FDA has requested responses from the companies within 15 working days stating how the companies will correct the violations. Failure to correct the violations promptly may result in legal action, including product seizure and/or injunction.

The FDA encourages human and animal health care professionals and consumers to report adverse reactions associated with these or similar products to the agency's MedWatch program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries

Media:

Peter Cassell (mailto:peter.cassell@fda.hhs.gov)

240-402-6537

Consumer:

888-INFO-FDA

Michael Felberbaum (mailto:michael.felberbaum@fda.hhs.gov)

240-402-9548

Related Information

- What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including Cannabidiol (CBD) (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis)
- FDA is Committed to Sound, Science-based Policy on CBD (/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd)
- FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd)

More Press Announcements (/news-events/newsroom/press-announcements)

From: Konkle, Darlene M - DATCP
To: Mace, Melissa A - DATCP; Daniels, Cheryl F - DATCP; Fisher, Angela H - DATCP
Subject: FW: December WVMA Vitals
Date: Friday, December 20, 2019 8:59:46 AM

Article on hemp and CBD by Jordan Lamb in this issue.

Darlene M. Konkle, DVM, MS, DACVIM
State Veterinarian
Wisconsin Department of Agriculture, Trade and Consumer Protection
Office Phone (608) 224-4884
darlene.konkle@wisconsin.gov

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From: Wisconsin Veterinary Medical Association <wvma@wvma.org>
Sent: Friday, December 20, 2019 8:57 AM
To: Konkle, Darlene M - DATCP <Darlene.Konkle@wisconsin.gov>
Subject: December WVMA Vitals

Volume 12 | December 2019

Your monthly news & updates

Connecting WVMA members to their profession with timely and important industry updates.

It's Renewal Time!

Membership Open to Non-Veterinarian Clinic Staff

When renewing your WVMA membership for 2020, why not get WVMA memberships for

your entire clinic team? As Veterinary Staff Affiliate members, your team would receive member benefits including discounted CE, advocacy representation, and electronic communications including the WVMA Voice and WVMA Vitals.

When you renew your membership, please check to make sure your contact information is up-to-date so you receive all email and printed communications sent by the WVMA. Email is the primary way the WVMA office communicates upcoming CE offerings and WVMA Alerts. If you previously unsubscribed from the WVMA emails and would like to get back on the email list, please call the WVMA office at (608) 257-3665.

Renew Now!

Register Now for WVMA Continuing Education!
All CE Events Open to Entire Clinic Teams

Pre-registration required. No refunds.

January 25, 2020 – Humane Equine Euthanasia by Various Firearms
Location: UW School of Veterinary Medicine, Madison, WI
Instructors: Howard Ketover, DVM, and Jane (JR) Lund, DVM, MS, DACVPM
Credits: 4.8 scientific CE credits

Register Now!

January 28, 2020 – Improving Pet Care Through Enhanced Communication
Location: Holiday Inn Stevens Point - Convention Center, Stevens Point, WI
Instructor: Amanda Donnelly, DVM, MBA
Credits: 7.2 non-scientific CE credits
Sponsored in Part By: Boehringer Ingelheim

Register Now!

February 20, 2020 – Bovine Breeding Soundness Exams
Location: Crowne Plaza Hotel, Madison, WI
Instructor: Chance Armstrong, DVM, MS, DACT
Credits: 7.2 scientific CE credits

Register Now!

Reminder to Keep CE Records

Please remember that for auditing purposes, you are required to maintain all records of your continuing education hours for at least five years.

For specifics on the requirements, click here.

Save the Date Reminders for 2020

October 22 – WVMA Annual Meeting

November 1 – WVMA Excellence in Veterinary Medicine Awards Ceremony

To read about the 2019 award winners, click here.

Overview of Marijuana, Hemp and CBD for Wisconsin Veterinarians

By Jordan Lamb, JD, DeWitt LLP

The WVMA has received numerous questions related to the use and sales of products derived from marijuana, CBD and hemp products, as it relates to the practice of veterinary medicine.

The first thing to consider is what is meant by the terms “marijuana,” “hemp” and “CBD,” as these terms are often used interchangeably.

Marijuana and hemp are both derived from the cannabis stavia L. plant. Cannabis contains several chemical compounds. Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) are two key compounds. THC is the compound that makes marijuana psychoactive. Hemp contains very little THC. CBD can be extracted from hemp or marijuana plants. Marijuana – cannabis that contains THC – is illegal under federal law. After the 2018 Farm Bill, hemp that contains no more than 0.3 percent THC on a dry weight basis is no longer a controlled substance under federal law. Hemp-derived CBD was also legalized under the 2018 Farm Bill. However, the Food and Drug Administration

(FDA) retains the authority to regulate products containing cannabis or cannabis-derived compounds – including hemp and CBD.

The second consideration is the use of the product. The FDA has not approved cannabis for the treatment of any human or animal disease or condition. The FDA has, however, approved one cannabis-derived and three cannabis-related drug products for human use. According to the FDA, “There are no other FDA-approved drug products that contain CBD.”

In addition, THC and CBD products cannot be sold as “dietary supplements” under Federal Law.

Further, according to both the Department of Agriculture, Trade and Consumer Protection and the FDA, industrial hemp, its byproducts and extracts (e.g., CBD concentrates, isolates, or synthetics) cannot be used in or on any animal feed product or animal feed ingredient for livestock, pets or any animals.

Based on all of the above information, it is critical that Wisconsin veterinarians understand that even if a hemp or CBD product meets the definition of “hemp” under the 2018 Farm Bill, it cannot be recommended as affecting animal health or treating animal health issues. Hemp and CBD cannot be sold as medicine, dietary supplements or added to animal feed. No cannabis, hemp or CBD products have been approved for use in veterinary medicine, as animal dietary supplements or as animal food products or treats. As such, veterinarians must not use, distribute or sell any of these products in conjunction with any animal health claims.

Check Compliance with Tax Requirements

With a new year just around the corner, it's a good time to check to make sure your business is in compliance with tax requirements.

To view the Wisconsin Department of Revenue sales and use tax document, click here.

RACE-Approved Antimicrobial Stewardship Education Platform Available Online

Do you still need CE credits for your license renewal? Food Armor, an organization dedicated to improving antimicrobial stewardship practices in food animal agriculture, now has an online educational platform providing high quality stewardship education to veterinarians and farmers.

There are currently 12 modules available for you to work through at your own pace. All

courses are RACE approved.

Antimicrobial Stewardship Fundamentals
Module 1: An Introduction to Antimicrobial Stewardship
Module 2: Veterinarian-Client-Patient-Relationships (VCPR)
Module 3: Relationships and Team Building
Module 4: Taking a Risk Management Approach

Treatment Decisions and Antimicrobial Stewardship
Module 5: Responsible Use
Module 6: Regulations
Module 7: Drug Lists
Module 8: Animal Medicinal Drug Use Clarification Act (AMDUCA)

Tools for Antimicrobial Stewardship
Module 9: Standard Operating Procedures (SOPs)
Module 10: Protocols
Module 11: Treatment Logs
Module 12: Permanent Records

To learn more about the program and to register, visit foodarmor.org.

Obituary

Our deepest sympathy to the family of Dr. Charles Mayer, who passed away on November 26, 2019. Dr. Mayer was a longtime WVMA member.

To read his obituary, click here.

Monthly Survey Question:

Have you ever been asked to be an expert witness in an animal neglect or animal cruelty case?

Yes Select

No Select

Special thanks to WVMA Vision Sponsor:

The WVMA strives to meet the needs of all members. Visit our website for resources to help you, your business and your clients. Not finding what you are looking for? Send us an email or call the WVMA office at (608) 257-3665.

Wisconsin Veterinary Medical Association | (608) 257-3665 | wvma@wvma.org | www.wvma.org

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December 11, 2019

Update on Cannabis-derived and Cannabis-related Products

As the discussion of the use of cannabis-derived and -related products in veterinary medicine continues to evolve, the AVMA is providing an update for practitioners regarding the legal and regulatory framework surrounding such use. The information below is not specific to the legal or regulatory status of products of any particular company. Rather, it reflects our understanding of the current status of this class of products based on information provided by federal agencies.

CBD (and Other Cannabinoids) as Controlled Substances

The Agriculture Improvement Act (2018 Farm Bill) removed hemp, defined as *"the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis"*, from the definition of 'marihuana' under the federal Controlled Substances Act (CSA). The Farm Bill also removed tetrahydrocannabinols included in 'hemp' from Schedule I under the CSA.

It did not, however, change the FDA's authority to regulate drugs and food under the federal Food, Drug, and Cosmetic Act (FDCA). As such, the FDA has the ability to work with DEA to appropriately schedule drug products, including those containing CBD and other cannabinoids. As an example, Epidiolex, which contains CBD as its active ingredient, is currently schedule V under the CSA.

In addition, the status of CBD and other cannabinoids varies under state pharmacy laws, so we encourage veterinarians to be sure to check those prior to assuming that such products are uniformly descheduled at both the state and federal levels.

Compounded Preparations

Under the FDCA, the compounding of an animal drug from bulk drug substances results in a 'new animal drug' that must comply with FDCA animal drug approval, conditional approval, or indexing requirements (sections 512, 517, and 572 of the FDCA). In addition, all animal drugs must, among other things, be made in accordance with current good manufacturing practices (cGMP, section 501(a)(2)(B) of the FDCA) and have adequate directions for use (section 502(f)(1) of the FDCA). According to 21CFR207.3(a)(4) a 'bulk drug substance' means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. Incidentally, the FDA just released draft Guidance for Industry (GFI) #256 for public comment, which describes the circumstances under which the FDA, at this time, does not intend to take enforcement action for violations of the FDCA with respect to the compounding

The content of this document is provided as information and education and should not be construed to suggest any particular course of action regarding the treatment of individual veterinary patients. Veterinarians should not use this information as a substitute for professional advice from a qualified legal professional.

of animal drugs from bulk drug substances. None of the circumstances described in that document appear to apply to CBD.

CBD as 'Supplement'

The FDA has commented on CBD products marketed as dietary supplements stating that, *"Some of the products are marketed as dietary supplements. However, CBD products cannot be dietary supplements because they do not meet the definition of a dietary supplement under the FD&C Act."*

Dietary supplements intended for humans

In warning letters issued in 2019, the FDA concluded, based on available evidence, that CBD products are excluded from the definition of 'dietary supplement' under sections 201(ff)(3)(B)(i) and (ii) of the FDCA, 21 U.S.C. 321(ff)(3)(B)(i) and (ii).

FDA has stated that when a substance is excluded from the definition of dietary supplement under section 201(ff)(3)(B) of the FDCA, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FDCA. **To date, no such regulation has been issued for any substance.**

Articles marketed as dietary supplements for non-human animals

With respect to the FDA's approach to CBD as a 'supplement' for animals, FDA has concluded that animal dietary supplements are not covered by the Dietary Supplement for Health Education Act (DSHEA) and are regulated as either food or drug, also stating that, *"…FDA believes it is prudent for the burden to remain, as it is now, on the manufacturer to generate safety and effectiveness data and provide it to FDA for review in feed additive petitions and new animal drug applications."*

The FDA provides further clarification on their approach to such products in the Compliance Policy Guide (CPG) on Nutritional Supplements for Companion Animals (CPG Sec 690.100), which was initially issued on October 1, 1980 and most recently revised in March 1995. For context, CPGs explain the FDA's policy on regulatory issues related to FDA laws or regulations. They advise FDA's field inspection and compliance staffs, as well as the industry, as to the Agency's strategy and policies to be applied when determining industry compliance.

The scope of CPG 690.100 is **nutritional supplementation** for animals, as indicated in the CPG's background, *"The *Center for* Veterinary Medicine is often asked to comment on the status under the Act of products intended for the nutritional supplementation of foods for animals. Such products would include vitamins, minerals, protein supplements, and fatty acid sources."*

CPG 690.100 includes a number of pertinent statements; however, we note in particular the following:

1. *"These products should not be misbranded by any direct or implied therapeutic or other claims for special benefits from their use"*

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2. *"Further, nutritional supplements should contain no drugs or unsafe food additives, either as direct or indirect ingredients.", and*
3. *The *Center for* Veterinary Medicine will not generally object to the marketing of nutritional supplements for oral administration to companion animals provided they conform to the following restrictions:*
    a. *There is a known need for <u>each nutrient ingredient</u> [emphasis added] represented to be in the product for each animal for which the product is intended."*

Considering the first statement, according to the FDA, products that are intended to diagnose, cure, mitigate, treat, or prevent disease, or otherwise affect the structure or any function of the body are considered to be 'drugs' under the federal FDCA.

In determining whether something is a drug, 'intent to use' is very important and is defined by the FDA as follows, *"Intended use is the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article."* The FDA determines a product's 'objective intent' by what appears in labeling claims, advertising matter, and oral or written statements by manufacturers, sponsors, or their representatives.

A frame of reference for how the FDA evaluates 'intent to use' can be gleaned from a review of recent Warning Letters issued to manufacturers of cannabis products, including products intended for animals. To illustrate, in its letter to Curaleaf, FDA includes examples of what it considers to be therapeutic claims. Those examples include statements issued by the manufacturer regarding the results of research looking at the effects of administering CBD on medical conditions. In fact, it's likely that FDA will look at all of the material referenced by a manufacturer or their surrogates (including telling veterinarians they can use the products for therapeutic purposes) in determining whether they are making therapeutic claims for these products. The consistency in FDA's approach is evident in reviewing the 15 additional warning letters FDA recently issued regarding these products.

In addition to 'intent to use' and its application to determine whether a substance is a 'drug', CBD is an active ingredient in a drug product (Epidiolex) that has already been approved under the FDCA, 21 USC § 355. Substances for which substantial clinical investigations have been instituted and for which the existence of such investigations have been made public—and the products containing those substances—have been considered to be drugs. This has been provided as part of the FDA's rationale for why CBD does not qualify as a human dietary supplement under DSHEA. The FDA has also indicated that a drug cannot be included in a dietary supplement and that it cannot be added to food without the food becoming adulterated.

With respect to the requirement referenced in CPG Sec 690.100 that animal nutritional supplements should also contain no 'unsafe food additives', by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by the FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise exempted from the definition of a food additive (which CBD is not). Except for three hemp seed

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ingredients (hulled hemp seed, hempseed protein powder, and hemp seed oil) that have been determined to be GRAS for certain uses in human (and only human) food, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by the FDA. The AAFCO, in issuing its comments related to the inclusion of hemp in animal food, has indicated that it does not believe that CBD-infused foods are eligible for the AAFCO review process, because discussions with FDA indicate that CBD products would be categorized as 'drug', rather than 'food.'

CBD in Food

According to a statement from the FDA, it is unlawful to introduce food containing added CBD into interstate commerce or to market CBD as, or in, dietary supplements, regardless of whether the substances are hemp-derived (see statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act [2018 Farm Bill] and the agency's regulation of products containing cannabis and cannabis-derived compounds).

Recent FDA warning letters also address the adulteration of food by adding CBD, specifically: *"Some of the products are foods to which CBD has been added. Under the FD&C Act, it is illegal to introduce into interstate commerce any human or animal food to which certain drug ingredients, such as CBD, have been added. In addition, the FDA is not aware of any basis to conclude that CBD is GRAS among qualified experts for its use in human or animal food. There also is no food additive regulation which authorizes the use of CBD as an ingredient in human food or animal food, and the agency is not aware of any other exemption from the food additive definition that would apply to CBD. CBD is therefore an unapproved food additive, and its use in human or animal food violates the FD&C Act for reasons that are independent of its status as a drug ingredient."*

Safety of CBD

While focused on the use of CBD for people, FDA recently updated its consumer-directed material.

To our knowledge, there are no long-term safety data available for the use of CBD in companion animals. Results of a very small-scale study (8 dogs, 8 cats; no animals used as controls) focusing on pharmacokinetics and safety were recently (October 19, 2019) published in *Animals*. The study included a preliminary safety and adverse effect assessment for the dogs and cats given CBD at a dose of 2 mg/kg for 12 weeks. Serum chemistry and CBC results showed no clinically significant alterations, nor did physical examinations; however, one cat showed a persistent rise in alanine aminotransferase (ALT) above the reference range for the duration of the trial. Cats appeared to absorb and eliminate CBD differently than dogs, showing lower serum concentrations and adverse effects of excessive licking and head-shaking during oil administration (although it could not be determined if these behaviors were related to CBD or to the fish oil vehicle). Other studies of the use of CBD for epilepsy and osteoarthritis in dogs have reported increases in liver enzymes associated with the administration of CBD. Whether such elevations in liver enzymes are problematic or not is not currently known. In addition,

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previous studies have reported substantial inter-individual variability in serum CBD concentrations despite a consistently administered dose.

Safety data currently available are largely derived from animal models of human disease. Animal models used in those studies include rodents (rats, mice) and pigs; such studies involving dogs and cats are rare. In addition, when considering the clinical applicability of such safety studies to veterinary patients it is important to keep in mind that many are designed to explore potential toxic effects in people and, as such, use human-analogous doses, rather than doses intended for clinical use in animals.

Finally, a paper was published in 2018 (see: https://www.vetsmall.theclinics.com/article/S0195-5616(18)30087-1/abstract) regarding increases in toxic exposures to cannabinoids in dogs and cats. While a common source of exposure was chocolate edibles containing THC, cases reported to the Pet Poison Hotline involved both accidental and intentional exposures to THC, synthetic cannabinoids, and high doses of CBD in dogs and cats.

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From: Mace, Melissa A - DATCP
To: Fisher, Angela H - DATCP
Subject: FW: Choosing Legal Hemp Products/Information on Legal Unapproved FDA Products
Date: Monday, January 13, 2020 3:00:17 PM

Melissa Mace
Director, Bureau of Field Services, Division of Animal Health
Executive Director Veterinary Examining Board
Wisconsin Department of Agriculture, Trade and Consumer Protection
Phone: 608-224-4883
Cell: 608-279-3861
Fax: 608-224-4903
Melissa.Mace@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Stacey Evans <stacey.evans@ellevetsciences.com>
Sent: Monday, January 13, 2020 10:50 AM
To: Mace, Melissa A - DATCP <Melissa.Mace@wisconsin.gov>
Subject: RE: Choosing Legal Hemp Products/Information on Legal Unapproved FDA Products

Dear Ms. Mace,

Know you are drafting guidelines regarding hemp use in Wisconsin.

Below are tips on choosing a legal hemp product:

1) Ensuring that the product is derived from hemp via the packaging or website of the product
2) Certificate of Analysis to confirm cannabinoids levels;
3) The manufacturer has done:
a. A safety study;
b. Dosing study; and
c. A study to prove efficacy by a 3rd party (university or independent clinic)
4) Cost effectiveness measured by cost per mg cannabinoid

FDA

There are unapproved FDA products that are legal which include compounded drugs and animal supplements. Such products do not require FDA approval and are legal. See https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved and https://www.govinfo.gov/content/pkg/FR-1996-04-22/pdf/96-9780.pdf.

Also the FDA which is much more strict with human supplements than with animal supplements, allows manufacturers of human supplements to bear statements that describe the role of a nutrient or ingredient "intended to affect the structure or function"..ie to support joint function, etc. 21 C.F.R. §101.93(f).

Am available to answer any questions you have.

Best,

Stacey

Stacey Evans
VP General Counsel
ElleVet Sciences, LLC
Direct Dial 1-844-673-7287 ext. 307
"ElleVet Products Proven Safe and Effective"

From: Stacey Evans
Sent: Monday, November 25, 2019 5:18 PM
To: Mace, Melissa A - DATCP <Melissa.Mace@wisconsin.gov>
Subject: RE: Comments/Information on Legality of Hemp CBD from Hemp/Veterinary Law Attorney

Your welcome and thanks. Attached is a safety study on the use of hemp CBD on dogs and cats. Another study involving hemp CBD on dogs and cats can be accessed at

file:///C:/Users/Stacey%20Evans/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/animals-09-00832%20(1).pdf.

Best,

Stacey Evans
VP General Counsel
ElleVet Sciences, LLC
"ElleVet Products Proven Safe and Effective"

From: Mace, Melissa A - DATCP <Melissa.Mace@wisconsin.gov>
Sent: Monday, November 25, 2019 5:02 PM
To: Stacey Evans <stacey.evans@ellevetsciences.com>
Subject: Comments/Information on Legality of Hemp CBD from Hemp/Veterinary Law Attorney

Ms. Evans;

Thank you for your comments on the legality of CBD and Hemp in the practice of Veterinary Medicine. The WI Veterinary Examining Board (VEB) is currently drafting a guidance document on this subject, as such the WI VEB will take these comments into consideration when it publishes its final guidance document.

227.112 Guidance documents.

(1)

(b) The agency shall provide for a period for public comment on a proposed guidance document submitted under par. (a), during which any person may submit written comments to the agency with respect to the proposed guidance document. Except as provided in par. (c), the period for public comment shall end no sooner than the 21st day after the date on which the proposed guidance document is published in the register under s. 35.93 (2) (b) 3. im. The agency may not adopt the proposed guidance document until the comment period has concluded and the agency has complied with par. (d).

(d) An agency shall retain all written comments submitted during the public comment period under par. (b) and shall consider those comments in determining whether to adopt the guidance document as originally proposed, modify the proposed guidance document, or take any other action.

Regards,
Melissa Mace
Director, Bureau of Field Services, Division of Animal Health
Executive Director Veterinary Examining Board
Wisconsin Department of Agriculture, Trade and Consumer Protection
Phone: 608-224-4883
Cell: 608-279-3861
Fax: 608-224-4903
Melissa.Mace@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Stacey Evans <stacey.evans@ellevetsciences.com>
Sent: Friday, November 15, 2019 2:21 PM
To: DATCP VEB <datcpveb@wisconsin.gov>
Subject: Comments/Information on Legality of Hemp CBD from Hemp/Veterinary Law Attorney

To Whom it May Concern,

Am the general counsel for hemp CBD company ElleVet Sciences and would love to help clarify legal issues surrounding hemp CBD in veterinary medicine. Prior to joining ElleVet, I presented on use of hemp and marijuana at the American Veterinary Medical Law Association Conference in August 2019 and in an NAVC webinar.

Below is information to help provide guidance regarding a policy for veterinary use of hemp.

The FDA acknowledges that it is legal to sell products with hemp CBD in interstate commerce—including for animal used—depending on how the intended use, how a product is labeled, and how it is marketed. See Question No. 8 at https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#legaltosell.

Hemp animal supplements are an example of such legal hemp CBD products. The FDA does not approve or regulate animal supplements, so FDA approval is not needed for such products to be legal.

While hemp CBD animal supplements do not need FDA approval to be legal, the FDA has a voluntary policy on animal supplements. The policy states that the FDA will not object to animal supplements if the label does not claim to prevent a disease, is not false or misleading, and does not represent that the supplement is a substitute for the daily health needs of an animal. FDA CPG Sec. 690.100 Nutritional Supplements for Companion Animals at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-690100-nutritional-supplements-companion-animals.

The Food and Drug Administration (FDA) must, however, approve products that it does regulate such as animal drugs, animal food, and animal medical devices. Accordingly, the FDA's statement that there are no FDA approved cannabis animal products means that there are no FDA approved cannabis animal drugs, food, or medical devices.

Hemp CBD animal products can be considered a drug if they have more than .3% THC and the manufacturer claims that the product can prevent or cure a disease or reduce a disease symptom like pain or inflammation in its labeling and marketing. Using a hemp CBD animal product with less than .3% THC to treat a disease in an animal, does NOT automatically make such product a drug. Instead the FDA focuses on the manufacturer's claims to determine whether a product is a drug not on a doctor, client, or patient use of such product.

For example, people use apple cider vinegar and olive oil to treat diseases—yet the FDA does not consider such products drugs—though people use them as therapeutic agents. Also, a product does not become a drug if a doctor recommends that a patient eat oatmeal to reduce cholesterol. If however, a manufacturer claims that oatmeal reduces cholesterol, then that particular brand of oatmeal is now a drug. This does not mean that all oatmeal is a drug—just the brand of oatmeal with drug claims from the manufacturer.

Hemp CBD animal products may be a food if hemp is in a "food." The FDA looks at the feeding portions, material, and wording, to determine whether a product is a food or not. For example, putting hemp CBD in a dog biscuit or in an item where the serving size is one cup per 10lbs of weight of a cat, would likely be considered a food. For more guidance on distinguishing between food items like beverages and dietary supplements see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-factors-distinguish-liquid-dietary-supplements-beverages-considerations. Though states can allow hemp CBD in food, federal law prohibits hemp CBD is in food.

Also, if a manufacturer claims that hemp CBD food can cure cancer in an animal, the FDA would likely consider such product a food and a drug.

This means that hemp animal supplements are legal federally and in many states. I am available to set up a call to answer any questions you have.

Best,

Stacey Evans
VP General Counsel
ElleVet Sciences, LLC
"ElleVet Products Proven Safe and Effective"

FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)

On this page:

- Consumer Information
- FDA Communications
- Regulatory Resources
- Questions and Answers

There is a significant interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products. FDA has a number of resources available that address cannabis and cannabis-derived products, such as CBD, and the agency wants to ensure that consumers and other stakeholders have access to these resources in a centralized location.

Consumer Information

- What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding (/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding)
- What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD (/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis)

- Some Medicines and Driving Don't Mix (/consumers/consumer-updates/some-medicines-and-driving-dont-mix)

FDA Communications

- FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns (/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details)
- Remarks at the Council for Responsible Nutrition Conference (/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019)
- Remarks at the National Industrial Hemp Council 2019 Hemp Business Summit (/news-events/speeches-fda-officials/remarks-national-industrial-hemp-council-2019-hemp-business-summit-08132019)
- FDA, FTC warn company marketing unapproved cannabidiol products with unsubstantiated claims to treat teething and ear pain in infants, autism, ADHD, Parkinson's and Alzheimer's disease (/news-events/press-announcements/fda-ftc-warn-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-teething)
- Congressional Testimony: Hemp Production and the 2018 Farm Bill (/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019)
    - Archived Video (https://www.agriculture.senate.gov/hearings/hemp-production-and-the-2018-farm-bill)
- FDA is Committed to Sound, Science-based Policy on CBD (/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd)
- Remarks at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds (/news-events/speeches-fda-officials/remarks-dr-sharpless-fda-public-hearing-scientific-data-and-information-about-products-containing)
- Statement on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products

(/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation)

- Statement on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds (/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys)
- Statement on the importance of conducting proper research to prove safe and effective medical uses for the active chemicals in marijuana and its components (/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-importance-conducting-proper-research-prove-safe-and)
- FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy (/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms)

Regulatory Resources

- FDA and Cannabis: Research and Drug Approval Process (/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process)
- Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing
    - Federal Register Notice (https://www.federalregister.gov/documents/2019/04/03/2019-06436/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds)
    - Public Hearing Page (/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds)
    - Public Docket (https://www.regulations.gov/docket?D=FDA-2019-N-1482)
- Warning Letters and Test Results for Cannabidiol-Related Products (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products)
- State, Local, Tribal, Territorial (SLTT) Regulatory Officials: FDA is committed to working with our SLTT public health regulatory partners as developments occur

in the regulatory landscape. Please contact the Intergovernmental Affairs team with any questions at IGA@fda.hhs.gov (mailto:IGA@fda.hhs.gov).

Questions and Answers

Below are a number of frequently asked questions and answers on this topic.

1. What are cannabis and marijuana?
2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?
3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?
4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?
5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?
6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?
7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?
8. Is it legal for me to sell CBD products?
9. Can THC or CBD products be sold as dietary supplements?
10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?
11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?
12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?
13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?
15. Can I import or export cannabis-containing or cannabis-derived products?
16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?
17. Does the FDA object to the clinical investigation of cannabis for medical use?
18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?
19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?
20. Does the FDA have concerns about administering a cannabis product to children?
21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?
22. What does the FDA think about making CBD available to children with epilepsy?
23. What should I do if my child eats something containing cannabis?
24. I've seen cannabis products being marketed for pets. Are they safe?
25. Can hemp be added to animal food?
26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

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1. What are cannabis and marijuana?

A. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

A. At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?

A. To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

FDA has approved Epidiolex (/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms), which contains a purified form of the drug substance CBD for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means FDA has concluded that this particular drug product is safe and effective for its intended use.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of cannabis. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

A. No. There are no other FDA-approved drug products that contain CBD. We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses , and we have issued several warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.

FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

The agency has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved. At the same time, FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA continues to believe that the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process (see Question #16).

5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?

A. FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products (see Question #2).

FDA relies on applicants and scientific investigators to conduct research. The agency's role, as laid out in the FD&C Act, is to review data submitted to the FDA in an application for approval to ensure that the drug product meets the statutory standards for approval.

The study of cannabis and cannabis-derived compounds in clinical trial settings is needed to assess the safety and effectiveness of these substances for the treatment of any disease or condition. FDA's December 2016 *Guidance for Industry: Botanical Drug Development* (/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry) provides specific recommendations on submitting INDs for botanical drug products, such as those derived from cannabis, in support of future marketing applications for these products. The FDA will continue to facilitate the work of companies interested in appropriately

bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of cannabis. Additional information concerning research on the medical use of cannabis is available from the National Institutes of Health, particularly the National Cancer Institute (https://www.cancer.gov/) (NCI) and National Institute on Drug Abuse (https://www.drugabuse.gov/drugs-abuse/marijuana/nih-research-marijuana-cannabinoids) (NIDA).

6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?

A. The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of cannabis and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of cannabis products through adequate and well-controlled clinical trials. We welcome the opportunity to talk with states who are considering support for medical research of cannabis and its derivatives, so that we can provide information on Federal and scientific standards.

7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?

A. The agency has received reports of adverse events in patients using cannabis or cannabis-derived products to treat medical conditions. The FDA reviews such reports and will continue to monitor adverse event reports for any safety signals, with a focus on serious adverse effects.

Information from adverse event reports regarding cannabis use is extremely limited; FDA primarily receives adverse event reports for approved products. General information on the potential adverse effects of using cannabis and its constituents can come from clinical trials that have been published, as well as from spontaneously reported adverse events sent to the FDA. Additional information about the safety and effectiveness of cannabis and its constituents is needed. Clinical trials of cannabis conducted under an IND application could collect this important information as a part of the drug development process.

8. Is it legal for me to sell CBD products?

A. It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

9. Can THC or CBD products be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (i.e., dietary ingredients that were not marketed in the United States in a dietary supplement before October 15, 1994) generally must notify FDA about these ingredients (see section 413 (d) of the FD&C Act [21 U.S.C. § 350b(d)]). Generally, the notification must include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury (see section 402(f)(1)(B) of the FD&C Act [21 U.S.C. 342(f)(1)(B)]).

Numerous other legal requirements apply to dietary supplement products, including requirements relating to Current Good Manufacturing Practices (CGMPs) (/food/current-good-manufacturing-practices-cgmps/current-good-manufacturing-practices-cgmps-dietary-supplements) and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website.

10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?

A. No. Under section 301(ll) of the FD&C Act [21 U.S.C. § 331(ll)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.

There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When this statutory prohibition applies to a substance, it prohibits the introduction into interstate commerce of any food to which the substance has been added unless FDA, in the agency's discretion, has issued a regulation approving the use of the substance in the food (section 301(ll)(2) of the FD&C Act [21 U.S.C. § 331(ll)(2)]). To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of 301(ll), and therefore might be able to be added to food. For example, as discussed in Question #12, certain hemp seed ingredients can be legally marketed in human food. However, all food ingredients must comply with all applicable laws and regulations. For example, by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive (sections 201(s) and 409 of the FD&C Act [21 U.S.C. §§ 321(s) and 348]). Aside from the three hemp seed ingredients mentioned in Question #12, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Food companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS processes.

11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous

determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

A. THC (dronabinol) is the active ingredient in the approved drug products, Marinol capsules (and generics) and Syndros oral solution. CBD is the active ingredient in the approved drug product, Epidiolex.

The existence of substantial clinical investigations regarding THC and CBD have been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain (https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer))

12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?

A. In December 2018, FDA completed its evaluation (/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food) of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. These GRAS notices related only to the use of these ingredients in human food. To date, FDA has not received any GRAS notices for the use of hemp-derived ingredients in animal food (see Question #25).

Hemp seeds are the seeds of the *Cannabis sativa* plant. The seeds of the plant do not naturally contain THC or CBD. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high."

The GRAS conclusions can apply to ingredients for human food marketed by other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to

beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food.

13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

A. A cosmetic is defined in 201(i) as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."

Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way. A cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)]).

If a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. (See Question #3 for more information about drugs.)

FDA can take action if it has information that an ingredient or cosmetic product is unsafe to consumers. Consumers can report adverse events associated with cosmetic products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088, or by contacting your nearest FDA district office consumer

complaint coordinator. For more information, please see the FDA's webpage on how to report a cosmetic-related complaint (/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint).

14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?

A. The FDA has sent warning letters (/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products) in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

15. Can I import or export cannabis-containing or cannabis-derived products?

A. General information about the import/export of drug products regulated by FDA (/drugs/guidance-compliance-regulatory-information/human-drug-imports) can be found online here. The Drug Enforcement Administration (https://www.dea.gov/) (DEA) is the federal agency responsible for enforcing the controlled substance laws and regulations in the U.S. and, as such, should be consulted with respect to any regulations/requirements they may have regarding the import or export of products containing cannabis. Please see here for information about importing or exporting food ingredients (/food/guidance-regulation-food-and-dietary-supplements/food-imports-exports).

Regarding imports, if it appears that an article is adulterated, misbranded, in violation of section 505 of the FD&C Act, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll) of the FD&C Act, such article will be refused admission (see section 801(a)(3) of the FD&C Act [21 U.S.C. § 381(a)(3)]).

Research and Expanded Access

16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?

A. To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with the FDA and submit an IND application to the Center for Drug Evaluation and Research (CDER). The IND application process gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. For research for use as an animal drug product, researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

As discussed above (see Question #2), the 2018 Farm Bill removed hemp from the CSA. This change may streamline the process for researchers to study cannabis and its derivatives, including CBD, that fall under the definition of hemp, which could speed the development of new drugs.

Conducting clinical research using cannabis-related substances that are scheduled by the DEA often involves interactions with several federal agencies. This includes: a registration administered by the DEA; obtaining the cannabis for research from NIDA, within the National Institutes of Health, or another DEA-registered source; and review by the FDA of the IND or INAD application and research protocol. Additionally:

- For a Schedule I controlled substance under the CSA, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site cannabis will be studied.
- NIDA provides research-grade cannabis for scientific study. The agency is responsible for overseeing the cultivation of cannabis for medical research and has contracted with the University of Mississippi to grow cannabis for research at a secure facility. Cannabis of varying potencies and compositions is available. DEA also may allow additional growers (https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to) to register with the DEA to produce and distribute cannabis for research purposes.

- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs in CDER depending on the therapeutic indication. Based on the results obtained in studies conducted at the IND stage, sponsors may submit a marketing application for formal approval of the drug.

17. Does the FDA object to the clinical investigation of cannabis for medical use?

A. No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from cannabis. The FDA supports the conduct of that research by:

1. Providing information on the process needed to conduct clinical research using cannabis.
2. Providing information on the specific requirements needed to develop a drug that is derived from a plant such as cannabis. In December 2016, the FDA updated its Guidance for Industry: Botanical Drug Development (/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry), which provides sponsors with guidance on submitting IND applications for botanical drug products.
3. Providing specific support for investigators interested in conducting clinical research using cannabis and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.
4. Providing general support to investigators to help them understand and follow the procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research's Small Business and Industry Assistance group (/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia).

18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?

A. Expanded access (/news-events/public-health-focus/expanded-access) is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory

therapies available. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?

A. Information for patients on Right to Try (/patients/learn-about-expanded-access-and-other-treatment-options/right-try) (RTT) is available on our website. RTT is designed to facilitate access to certain investigational drugs through direct interactions between patients, their physicians and drug sponsors – FDA is not involved in these decisions. Sponsors developing drugs for life-threatening conditions are responsible for determining whether to make their products available to patients who qualify for access under RTT. If you are interested in RTT, you should discuss this pathway with your licensed physician. Companies who develop drugs and biologics, also known as sponsors, can provide information about whether their drug/biologic is considered an eligible investigational drug under RTT and if they are able to provide the drug/biologic under the RTT Act.

Children and Pregnant/Lactating Women

20. Does the FDA have concerns about administering a cannabis product to children?

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products containing cannabis or cannabis-derived compounds, and will continue to work with companies interested in bringing safe, effective, and quality products to market. With the exception of Epidiolex, Marinol, and Syndros, no product containing cannabis or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population, whether pediatric or adult.

21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?

A. The FDA is aware that there are potential adverse health effects with use of cannabis products containing THC in pregnant or lactating women. Published scientific literature reports potential adverse effects of cannabis use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and stillbirth. [1, 2, 3] Based on published animal research, there are also concerns that use of cannabis during pregnancy may negatively impact fetal brain development. [4, 5, 6] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue cannabis use. In addition, ACOG notes that there are insufficient data to evaluate the effects of cannabis use on breastfed infants; therefore, cannabis use is discouraged when breastfeeding. [7] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of cannabis use.

22. What does the FDA think about making CBD available to children with epilepsy?

A. The FDA has approved Epidiolex, which contains a purified form of the drug substance CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended use. Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring cannabis-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, and the assurance of manufacturing quality standards, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

23. What should I do if my child eats something containing cannabis?

A. With the exception of products such as the hemp seed ingredients discussed in Question #12, which have been evaluated for safety, it is important to protect children from accidental ingestion of cannabis and cannabis-containing products. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion. If the parent or caregiver has a reasonable suspicion that the child accidentally ingested products containing cannabis, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

Pets and other Animals

24. I've seen cannabis products being marketed for pets. Are they safe?

A. FDA is aware of some cannabis products being marketed as animal health products. We want to stress that FDA has not approved cannabis for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

While the agency is aware of reports of pets consuming various forms of cannabis, to date, FDA has not directly received any reports of adverse events associated with animals given cannabis products. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting cannabis, we encourage you to report the adverse event to the FDA. Please visit Reporting Information about Animal Drugs and Devices (/animal-veterinary/report-problem/how-report-animal-drug-side-effects-and-product-problems) to learn more about how to report an adverse event related to an animal drug or for how to report an adverse event or problem with a pet food.

25. Can hemp be added to animal food?

A. All ingredients in animal food must be the subject of an approved food additive petition or generally recognized as safe (GRAS) for their intended use in the intended species. If an animal food contains an ingredient that is not the subject of an approved food additive petition or GRAS for its intended use in the intended species, that animal food would be adulterated under section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)]. In coordination with state feed control officials, CVM also recognizes ingredients listed in the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) as being acceptable for use in animal food. At this time, there are no approved food additive petitions or ingredient definitions listed in the AAFCO OP for any substances derived from hemp, and we are unaware of any GRAS

conclusions regarding the use of any substances derived from hemp in animal food. Learn more about animal food ingredient submissions (/animal-veterinary/safety-health/safe-feed) here.

With respect to products labeled to contain "hemp" that may also contain THC or CBD, as mentioned above it is a prohibited act under section 301(ll) of the FD&C Act to introduce or deliver for introduction into interstate commerce any animal food to which THC or CBD has been added.

26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

A. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), permits veterinarians to prescribe extralabel uses of approved human and animal drugs for animals under certain conditions. Extralabel use must comply with all the provisions of AMDUCA and its implementing regulation at 21 CFR § 530. Among other limitations, these provisions allow extralabel use of a drug only on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship and only in circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

In addition, under 21 CFR 530.20, extralabel use of an approved human drug in a food-producing animal is not permitted if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the use. In addition, under 21 CFR 530.20(b)(2), if scientific information on the human food safety aspect of the use of the approved human drug in food-producing animals is not available, the veterinarian must take appropriate measures to ensure that the animal and its food products will not enter the human food supply.
For more information on extralabel use of FDA approved drugs in animals, see Extralabel Use of FDA Approved Drugs In Animals (/animal-veterinary/acts-rules-regulations/animal-medicinal-drug-use-clarification-act-1994-amduca).

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[1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. Clinical Chemistry. 2010; 56(9): 1442-1450.

[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ Open. 2016; 6:e009986.

[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. Pediatric Research. 2012; 71 (2): 215-219.

[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. Neurotoxicol and Teratol 2012; 34(1): 63-71.

[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. Psychopharmacology (Berl) 2008; 198(4): 529-537.

[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. Addict Biol 2007; 12(3-4): 485–495.

[7] ACOG Committee Opinion: Marijuana Use During Pregnancy and Lactation (https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

COMPLIANCE POLICY GUIDE (CPG)

CPG Sec. 690.100 Nutritional Supplements for Companion Animals

MARCH 1995

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/cpg-sec-690100-nutritional-supplements-companion-animals)
Center for Veterinary Medicine
Office of Regulatory Affairs

BACKGROUND:

The *Center for* Veterinary Medicine is often asked to comment on the status under the Act of products intended for the nutritional supplementation of foods for animals. Such products would include vitamins, minerals, protein supplements, and fatty acid sources. The diets of livestock, poultry and fur-bearing animals are usually planned by nutritionists or other experts, and the nutritional ingredients are sold through industrial channels. On the other hand, nutritional supplements for companion animals such as cats, dogs and horses not intended for food, as well as other pets, are mostly sold over-the-counter direct to lay customers and are generally intended merely for the dietary supplementation of the particular species for which they are intended.

Malnutrition, with the exception of obesity, is infrequent in companion animals. Most receive ample nutrition to sustain healthy life through their regular daily diet. Most dog and cat foods are likewise rich in nutrients either through the natural content of the ingredients or because of manufacturer supplementation.

Animals on balanced rations do not require extra nutritional supplementation; in fact, excessive amounts of certain nutrients may cause health problems. Nevertheless, *CVM* does not object to the OTC marketing of dietary supplements in tablet, capsule, powder, or liquid form for companion animals similar to the special dietary

preparations sold for humans. We have, however, advised that such products should provide meaningful amounts of each of the nutrients they are represented to contain and these nutrients should be of known value for the intended or target animal.

The nutritional needs of animals do not necessarily parallel those of humans. For instance, only a few species are known to require Vitamin C in their diet. As most animals either receive adequate amounts of vitamins, minerals, protein (essential amino acids), fat (fatty acids) and carbohydrate in their diet or are able to synthesize them from a ration balanced to observe National Research Council nutrient requirements, we are not aware that supplementation would serve a useful purpose. FDA has published no regulation concerning the vitamin, mineral, or other dietary properties as special dietary products for animals as contemplated by section 403(j). In arriving at a level of supplementation which represents the best information presently available, FDA uses The Nutritional Requirements of Domestic Animals, a standard test published by the National Academy of Sciences-National Research Council. We have usually accepted as adequate those products providing a meaningful level of nutrition when compared with the NAS/NRC recommendations.

These products should not be misbranded by any direct or implied therapeutic or other claims for special benefits from their use. This would include representations for the products as a tonic, conditioner or toner which is proscribed by 21 CFRa. Nor should they bear such vague therapeutic suggestions as promotion of "health," "stamina," "strength," or that they are of any special value for breeding purposes or for show or racing purposes or for working animals, or that by virtue of their formulation "i.e., "chelated," "timed release," "natural") they are superior to the ordinary vitamin-mineral preparations of commerce. We would consider animal nutritional supplements to be adulterated if they contain upon analysis significantly more or significantly less of label declaration of a nutrient which could effect the health of the target animal. Further, nutritional supplements should contain no drugs or unsafe food additives, either as direct or indirect ingredients. Guidance in individual cases may be obtained from HFV-236.

Nutritional supplements marketed in injectable form are considered to be drugs and are not purview to this guide. As drugs, their status as new animal drugs must be resolved on a case by case basis.

POLICY:

The *Center for* Veterinary Medicine will not generally object to the marketing of nutritional supplements for oral administration to companion animals provided they conform to the following restrictions:

1. There is a known need for each nutrient ingredient represented to be in the product for each animal for which the product is intended.
2. The label represents the product for use only in supplementation of and not as a substitute for good daily rations.
3. The product provides a meaningful but not excessive amount of each of the nutrients it is represented to contain.
4. The labeling should bear no disease prevention of therapeutic, including growth promotional, representations.
5. The labeling should not be otherwise false or misleading in any particular.
6. The product is neither over-potent nor under-potent nor otherwise formulated so as to pose a hazard to the health of the target animal.

Appropriate regulatory action may be recommended against violative products. Except in cases of adulteration involving health considerations, the *Warning* Letter is the initial action of choice to achieve compliance.

a 21 CFR 500.52

Material between asterisks is new or revised

Issued: 10/1/80
Revised: 3/95

Submit Comments

Submit comments on this guidance document electronically via docket ID: FDA-2013-S-0610 (https://www.regulations.gov/docket?D=FDA-2013-S-0610) - Specific Electronic Submissions Intended For FDA's Dockets Management Staff (i.e., Citizen Petitions, Draft Proposed Guidance Documents, Variances, and other administrative record submissions)

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All comments should be identified with the title of the guidance.

Questions?

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GUIDANCE DOCUMENT

Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods

DECEMBER 2009

Draft

Not for implementation. Contains non-binding recommendations.

Docket Number:

FDA-2009-D-0542 (https://www.regulations.gov/docket?D=FDA-2009-D-0542)

Issued by:

(/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-factors-distinguish-liquid-dietary-supplements-beverages-considerations)
Office of Dietary Supplement Programs

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2375.

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

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I. Introduction

FDA is issuing this guidance to assist dietary supplement and beverage manufacturers and distributors in reaching a determination as to whether a liquid product may be labeled and marketed as a dietary supplement. The guidance describes factors that can be used to identify liquid products that are excluded from being dietary supplements because they are represented as conventional foods. Further, this guidance

reminds manufacturers and distributors of beverages and other conventional foods, particularly those that contain novel ingredients, about the requirements of the Federal Food, Drug, and Cosmetic Act (the FFDCA) regarding ingredients and labeling.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Background

The Food and Drug Administration (FDA) has observed and become concerned about two trends in the marketing of beverages. First, we have seen an increase in the marketing of beverages as dietary supplements, in spite of the fact that the packaging and labeling of many liquid products represent the products as conventional foods. Products that are represented as conventional foods do not meet the statutory definition of a dietary supplement in section 201(ff) of the FFDCA (21 U.S.C. 321(ff)) and must meet the regulatory requirements that apply to conventional foods.

Second, FDA has seen a growth in the marketplace of beverages and other conventional foods that contain novel ingredients, such as added botanical ingredients or their extracts. Some of these ingredients have not previously been used in conventional foods and may be unapproved food additives. In addition, ingredients that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels or in new beverages or other conventional foods. This trend raises questions regarding whether these ingredients are unapproved food additives when used at higher levels or under other new conditions of use. Some foods with novel ingredients also bear claims that misbrand the product or otherwise violate the FFDCA.

III. Discussion

A. Beverages Are Conventional Foods That May Not Be Marketed as Dietary Supplements

Under section 201(ff)(2)(B) of the FFDCA (21 U.S.C. 321(ff)(2)(B)), the term “dietary supplement” means a product that, among other requirements, “is not represented for use as a conventional food or as a sole item of a meal or the diet.” Beverages are conventional foods under the FFDCA. Even when the label of a liquid product characterizes it as a dietary supplement, the product may not in fact be a dietary supplement. Liquid products can be represented as conventional foods as a result of factors such as their packaging, the volume in which they are intended to be consumed, their product or brand name, and statements about the product in labeling or advertising. For example, the packaging of liquid products in bottles or cans similar to those in which single or multiple servings of beverages like soda, bottled water, fruit juices, and iced tea are sold, suggests that the liquid product is intended for use as a conventional food.

Based on data from the 2005-2006 National Health and Nutrition Examination Survey on daily intake of drinking water and other beverages in the United States, FDA estimates the average total daily drinking fluid intake[1] per person to be about 1.2 liters (1200 ml) (Ref. 1). Liquid products that suggest through their serving size, packaging, or recommended daily intake that they are intended to be consumed in amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the U.S., are represented as beverages. In addition, the name of a product can represent the product as a conventional food. Product or brand names that use conventional food terms such as “beverage,” “drink,” “water,” ‘juice,” or similar terms represent the product as a conventional food.

In sum, FDA considers a liquid product's name, packaging, serving size, and recommended conditions of use, as well as other representations about the product, to be important determinants of whether the product is represented as a conventional food and may not be marketed as a dietary supplement.

B. Ingredients in Beverages and Other Conventional Foods are Subject to the FFDCA's Requirements for Substances Added to Food

Many ingredients intentionally added to beverages and other conventional foods are food additives. Food additives require pre-market approval based on data demonstrating safety submitted to FDA in a food additive petition. The agency issues food additive regulations specifying the conditions under which an additive has been demonstrated to be safe and, therefore, may be lawfully used.

A substance is exempt from the definition of a food additive and thus, from pre-market approval, if, among other reasons, it is generally recognized as safe (GRAS) by qualified experts under the conditions of intended use. 21 U.S.C. 321(s). Accordingly, for a particular use of a substance to be GRAS, there must be both evidence of safety (the "technical element" of the GRAS standard) and a basis to conclude that this evidence is generally known and accepted by qualified experts. The technical element of the GRAS standard requires that the information about the substance establish that the intended use of the substance is safe; i.e., that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. 21 CFR 170.3(i). In addition, the data and information to establish the technical element must be generally available, and there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. See 21 CFR 170.30(a)-(c). Any substance added to a beverage or other conventional food that is an unapproved food additive (e.g., because it is not GRAS for its intended use) causes the food to be adulterated under section 402(a)(2)(C) of the FFDCA (21 U.S.C. 342(a)(2)(C)). Adulterated foods cannot be legally imported or marketed in the United States.

FDA is concerned that some of the novel ingredients that are being added to beverages and other conventional foods may cause the food to be adulterated because these added ingredients are not being used in accordance with an approved food additive regulation and may not be GRAS for their intended use. In addition, some ingredients that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels or in new beverages or other conventional foods. This trend raises questions regarding whether these higher levels and other new conditions of use are safe.

C. Beverages and Other Conventional Foods May Not Carry Unauthorized Labeling Claims and Must Carry the Appropriate Mandatory Labeling

Labeling Claims

* General prohibition on false or misleading labeling. All claims and statements in the labeling of a food are subject to section 403(a)(1) of the FFDCA (21 U.S.C. 343(a)(1)), which provides that a food is misbranded if its labeling is false or misleading in any particular. The FFDCA further provides in section 201(n) (21 U.S.C. 321(n)) that affirmative representations are not the only factor relevant to whether labeling is misleading. Rather, in determining whether the labeling of an article is misleading, "there shall be taken into account (among other things) ... the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual." 21 U.S.C. 321(n).

* Health claims. Health claims characterize the relationship between a substance (food or food component) and a disease or health-related condition. 21 C.F.R. 101.14(a)(1). Health claims are limited to claims about reducing the risk of a disease or health-related condition and do not include claims about treating, mitigating, or curing disease, which are drug claims. See Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir.), cert. denied, 125 S. Ct. 310 (2004)). See FDA's website for more information on health claims http://www.fda.gov/Food/LabelingNutrition/LabelClaims/default.htm.

There are three ways in which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food:

(1) FDA reviews health claim petitions and issues regulations authorizing health claims that meet the significant scientific agreement standard set forth in the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535).

(2) FDA reviews health claim notifications under the Food and Drug Administration Modernization Act of 1997, which amended the FFDCA to establish a notification procedure that streamlines the authorization of health claims that are based on an authoritative statement from a scientific body of the United States government with official responsibility for public health protection or research directly related to human nutrition, or from the National Academy of Sciences (now the National Academies) or any of its subdivisions, about the relationship between a nutrient and a disease or health-related condition. Such claims may be used beginning 120 days after submission of a health claim notification to FDA, unless the agency prohibits or modifies the claim by regulation or obtains a court order determining that the statutory requirements for an authoritative statement notification health claim have not been met. See section 403(r)(3)(C)-(D) of the FFDCA (21 U.S.C. 343(r)(3)(C)-(D)).

(3) As a result of court decisions interpreting the First Amendment to the U.S. Constitution, FDA reviews qualified health claim petitions and issues a letter of enforcement discretion when there is credible scientific evidence supporting the claim, but the strength of the evidence falls below the standard for FDA to issue an authorizing regulation. These claims are referred to as "qualified health claims" because they include qualifying language to describe the limitations in the evidence supporting the claim and to convey any other information necessary to prevent the claim from misleading consumers. Although FDA's enforcement discretion letters are issued to the petitioner who requested the qualified health claim, the qualified health claims are available for use on other products that meet the enforcement discretion conditions specified in the letter. See FDA's website for information on the procedures that FDA uses to evaluate and respond to qualified health claim petitions.

A beverage or other conventional food bearing a health claim that is not authorized by regulation or by the FFDCA is misbranded under section 403(r)(1)(B) of the FFDCA (21 U.S.C. 343(r)(1)(B)). Currently, the health claims that FDA has authorized by regulation are listed in 21 C.F.R. 101.72 to 101.83. Health claims that have been authorized through the notification procedure are listed on FDA's website at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm. Qualified health claims for which the agency has issued a letter of enforcement discretion are listed on FDA's website at: http://www.fda.gov/Food/LabelingNutrition/LabelClaimsQualifiedHealthClaims/ucm073992.htm.

As a legal matter, an unauthorized health claim or a claim that suggests that a beverage or other conventional food is intended to treat, cure or mitigate disease subjects the food to regulation as a drug under section 201(g)(1) of the FFDCA (21 U.S.C. 321(g)(1)). An example of a health claim that meets the

significant scientific agreement standard and is authorized by regulation is: "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors" (see 21 C.F.R. 101.74). In comparison, the following are examples of drug claims: “Shrinks tumors, “Kills influenza viruses,” and "We've loaded our product with nature's best cold fighters."

* Nutrient content claims. A nutrient content claim is a claim characterizing the level of a nutrient in a beverage or other conventional food. 21 C.F.R. 101.13(b). Beverages and other foods may bear authorized nutrient content claims on their labels and in other labeling. Nutrient content claims describe the level of a nutrient in a food using terms such as free, high and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced and lite.

There are three ways in which FDA exercises its oversight in determining which nutrient content claims may be used on a label or in labeling for a beverage or other conventional food:

(1) FDA reviews petitions for new nutrient content claims and, when appropriate, issues a regulation defining the claim and establishing nutritional criteria that a food must meet to use the claim. See 21 C.F.R. 101.69(m).

(2) FDA reviews petitions to establish a synonym for a nutrient content claim defined by regulation or to authorize the use of an implied nutrient content claim in a brand name and, when appropriate, issues a letter granting the petition. See 21 C.F.R. 101.69(n)-(o).

(3) FDA reviews nutrient content claim notifications under the Food and Drug Administration Modernization Act of 1997, which amended the FFDCA to establish a notification procedure that streamlines the authorization of claims that are based on an authoritative statement from a scientific body of the United States government with official responsibility for public health protection or research directly related to human nutrition, or from the National Academy of Sciences (now the National Academies) or any of its subdivisions, identifying the nutrient level to which the claim refers. Such claims may be used beginning 120 days after submission of a nutrient content claim notification to FDA, unless the agency prohibits or modifies the claim by regulation or obtains a court order determining that the statutory requirements for authorization of the claim have not been met. See section 403(r)(2)(G) of the FFDCA (21 U.S.C. 343(r)(2)(G)).

The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as high or low, are used consistently for all types of food products and are meaningful to consumers. A beverage or other conventional food bearing an unauthorized nutrient content claim is misbranded under section 403(r)(1)(A) of the FFDCA (21 U.S.C. 343(r)(1)(A)). Currently, the nutrient content claims that FDA has authorized by regulation are listed in 21 C.F.R. 101.13 and 21 C.F.R. 101.54 to 101.67. See FDA’s website for information on nutrient claims that have been authorized through the notification procedure. http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm.

Some nutrient content claims, such as "high" and "more," are defined only for substances with an established Reference Daily Intake (RDI) or Daily Reference Value (DRV). A list of nutrients with RDIs can be found at 21 C.F.R. 101.9(c)(8)(iv); a list of nutrients with DRVs can be found at 21 C.F.R. 101.9(c)(9). A food may bear a statement about a nutrient for which there is no established RDI or DRV as long as the

claim specifies only the amount of the substance per serving, does not characterize the level of the substance (e.g., by implying that there is a lot or a little of the substance in the product), and is not otherwise false or misleading. 21 C.F.R. 101.13(i)(3).

* Structure/function claims. The FFDCA defines "drug" to include articles intended to affect the structure or function of the body. This provision contains an exception for foods, which affect the structure and function of the body by virtue of providing nutrition to sustain life and health. See section 201(g)(1)(C) of the FFDCA (21 U.S.C. 321(g)(1)(C)). "Food" is defined in section 201(f) of the FFDCA (21 U.S.C. 321(f)) as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Consistent with case law interpreting the "other than food" exception as applying to articles consumed primarily for taste, aroma, or nutritive value, FDA does not intend to regulate conventional foods that bear structure/function claims in their labeling as drugs as long as the claimed structure/function effect derives from the product's character as a food — its taste, aroma, or nutritive value. See Nutrilab v. Schweiker, 713 F.2d 335 (7th Cir. 1983). However, if a structure/function claim promotes a product for a use other than providing taste, aroma or nutritive value, such as blocking the absorption of carbohydrates in the gut, the claim may cause the product to be a drug by changing its primary use. In other words, because of the use promoted in the claim, the product may no longer be consumed as a food -- primarily for taste, aroma, or nutritive value -- but rather as a drug for some other physiological effect.

Further, if a labeling claim about the effect of a beverage or other conventional food on the structure or function of the body also states or implies that the product is useful in treating, mitigating, curing, or diagnosing a disease, the claim subjects the product to regulation as a drug under section 201(g)(1)(B) of the FFDCA (21 U.S.C. 321(g)(1)(B)). The same is true for a disease prevention claim in the labeling of a conventional food, unless the claim is an authorized health claim about reducing the risk of a disease or health-related condition.

As with all claims in food labeling, structure/function claims for conventional foods may not be false or misleading. See section 403(a)(1) of the FFDCA (21 U.S.C. 343(a)(1)).

Required Labeling for Conventional Foods

Labeling requirements for beverages and other conventional foods differ from those for dietary supplements. For example, beverages and other conventional foods are required to bear nutrition information in the form of Nutrition Facts rather than Supplement Facts, and all ingredients in a beverage and other conventional food must be declared in the ingredient statement by their common and usual names, in descending order of predominance. In addition, a beverage or other conventional food should not be labeled with the FDA disclaimer that is required on dietary supplement labels that bear structure/function claims or other claims described in section 403(r)(6)(A) of the FFDCA (21 U.S.C. 343(r)(6)(A)).

Questions regarding the regulatory status of ingredients that you intend to use in your beverage or other conventional food, and about how to file a GRAS Notice or Food Additive Petition, should be directed to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, HFS-200, 5001 Campus Drive, College Park, MD 20740. Questions regarding the labeling requirements for beverages and other conventional foods, and about voluntary labeling claims for these foods, should be directed to the Food Labeling and Standards Staff, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, HFS-810, 5001 Campus Drive, College Park, MD 20740.

FDA's general food labeling requirements are located in Title 21 of the Code of Federal Regulations, Part 101, and additional guidance can be obtained from the Food Labeling Guide http://www.fda.gov/FoodLabelingGuide (http://www.fda.gov/FoodLabelingGuide), which is available on the FDA website.

IV. References

We have placed the following reference on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see it at that location between 9 a.m. and 4 p.m., Monday through Friday.

1. Foods Analysis and Residue Evaluation Program (FARE), Version 8.50, Consumption Analysis: Distribution and Means Analysis based on NHANES 2005-2006.

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RESEARCH PAPER

Species-specific susceptibility to cannabis-induced convulsions

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BACKGROUND AND PURPOSE

Numerous claims are made for cannabis' therapeutic utility upon human seizures, but concerns persist about risks. A potential confounder is the presence of both Δ^9-tetrahydrocannabinol (THC), variously reported to be pro- and anticonvulsant, and cannabidiol (CBD), widely confirmed as anticonvulsant. Therefore, we investigated effects of prolonged exposure to different THC/CBD cannabis extracts on seizure activity and associated measures of endocannabinoid (eCB) system signalling.

EXPERIMENTAL APPROACH

Cannabis extract effects on *in vivo* neurological and behavioural responses, and on bioanalyte levels, were measured in rats and dogs. Extract effects on seizure activity were measured using electroencephalography telemetry in rats. eCB signalling was also investigated using radioligand binding in cannabis extract-treated rats and treatment-naïve rat, mouse, chicken, dog and human tissue.

KEY RESULTS

Prolonged exposure to cannabis extracts caused spontaneous, generalized seizures, subserved by epileptiform discharges in rats, but not dogs, and produced higher THC, but lower 11-hydroxy-THC (11-OH-THC) and CBD, plasma concentrations in rats versus dogs. In the same rats, prolonged exposure to cannabis also impaired cannabinoid type 1 receptor (CB_1 receptor)-mediated signalling. Profiling CB_1 receptor expression, basal activity, extent of activation and sensitivity to THC suggested interspecies differences in eCB signalling, being more pronounced in a species that exhibited cannabis extract-induced seizures (rat) than one that did not (dog).

CONCLUSIONS AND IMPLICATIONS

Sustained cannabis extract treatment caused differential seizure, behavioural and bioanalyte levels between rats and dogs. Supporting radioligand binding data suggest species differences in eCB signalling. Interspecies variations may have important implications for predicting cannabis-induced convulsions from animal models.

LINKED ARTICLES

This article is part of a themed section on 8th European Workshop on Cannabinoid Research. To view the other articles in this section visit http://onlinelibrary.wiley.com/doi/10.1111/bph.v176.10/issuetoc

Abbreviations

CBD, cannabidiol; EEG, electrocorticography; eCB, endocannabinoid; PCA, principal component analysis; PSD, power spectrum density; THC, Δ^9-tetrahydrocannabinol

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Introduction

Recent legal and regulatory change in the USA and elsewhere has increased awareness, and use of, cannabis (marijuana) for recreational and potential medicinal purposes, including treatment-resistant paediatric epilepsies (Devinsky *et al.*, 2014; 2015). Such cannabis preparations typically contain significant amounts of **Δ^9-tetrahydrocannabinol (THC)**, a high potency, low intrinsic efficacy, **CB_1 receptor** partial agonist; however, there is little evidence of THC efficacy or safety in epilepsy (Press *et al.*, 2015). Moreover, reports are tempered by psychiatric complications of cannabis in adolescents (Volkow *et al.*, 2014) and medical and psychiatric emergencies, including seizures and mortality, among recreational users of novel synthetic CB_1 receptor high intrinsic efficacy agonists (Castaneto *et al.*, 2014; Gurney *et al.*, 2014). Short-term exposure to CB_1 receptor partial or full agonists typically exerts anticonvulsant effects in animal models of seizure and epilepsy (Rosenberg *et al.*, 2015). By contrast, sustained THC administration is reported to cause convulsions in rats and mice (Chan *et al.*, 1996; NTP, 1996) and, anecdotally, chickens. The other most common cannabinoid, cannabidiol (**CBD**), is not psychoactive, is widely confirmed as anticonvulsant in animal models of seizure and epilepsy and lacks reported proconvulsant effects (Rosenberg *et al.*, 2015). CBD reduces convulsive seizures in children and young adults with Dravet syndrome and with Lennox–Gastaut syndrome (Devinsky *et al.*, 2016; 2017). A meta-analysis found that CBD behavioural pharmacology is unrelated to direct effects at CB_1 receptors (McPartland *et al.*, 2015), although indirect CBD effects on the endocannabinoid (eCB) system, as well as negative allosteric modulation of CB_1 receptors *in vitro* (Laprairie *et al.*, 2015) have been reported; rather, CBD has several potential non-CB_1 receptor-mediated actions (Hill *et al.*, 2012).

Despite this knowledge, it remains unknown whether sustained cannabis-induced convulsions are spontaneous and/or epileptiform in nature, with reports of both depressed and enhanced epileptogenesis in animal models (Rosenberg *et al.*, 2017). Moreover, no relationship between convulsion incidence and other aberrant behaviours has been established. The extent to which changes in eCB signalling that may be involved in cannabis-induced convulsions in rodents are recapitulated in other species also remains to be elucidated. With these points in mind, we examined the effects of standardized extracts containing different doses of THC and CBD on *in vivo* behaviour and seizure activity in rats and dogs, species reportedly prone and resistant to cannabis-induced seizure respectively. We demonstrate for the first time that prolonged exposure to cannabis extracts produces dose-related motor convulsions subserved by epileptiform activity and associated seizure-related behaviours in rats. By contrast, cannabis extracts never caused seizures in dogs, which exhibited reduced THC but higher 11-OH-THC and CBD plasma concentrations than rats. Across several species, the eCB system signalling profile was highest in the rat but lowest in the dog. These data clarify several apparent inconsistencies in the field and suggest that choice of model species has important implications in the study of cannabis-induced convulsions.

Methods

Animals

Animal studies are reported in compliance with the ARRIVE guidelines (Kilkenny *et al.*, 2010; McGrath and Lilley, 2015). Rodent behavioural studies were conducted under contract by Covance Laboratories Ltd (Leeds, UK) according to the authors' experimental design and in accordance with the UK Animals (Scientific Procedures) Act 1986. Sixty-nine adult (240–280 g at study start) female Wistar–Han rats were used. Female rats were used here since they are reported to have an increased frequency of THC-induced convulsions compared to male rats (NTP, 1996). Rats, habituated for 16 days prior to the start of any experimental procedures, were singly housed in standard laboratory cages with environmental enrichment and provided access to food (RM1.(E).SQC.; SDS Ltd., Witham, UK) and water *ad libitum* throughout in an environment of 20–24°C, 45–65% humidity and a 12:12 h light : dark period.

Canine behavioural studies were conducted in accordance with good laboratory practice standards (US FDA Good Laboratory Practice Regulations 21 CFR Part 58) under contract by CIT Safety and Health Laboratories (Évreux, France) in accordance with EU Directive 86/609/EEC and to the authors' experimental design. A total of 40 [20 male (mean weight: 9.5 kg) and 20 female (mean weight: 7.8 kg)] adult (8 months) beagle dogs (Marshall Farms, NY, USA) were habituated for 2 weeks and maintained at 20°C, 30–70% humidity and a 12 h:12 h light : dark period in individual kennels containing wood shavings (SICSA, Leon, France) and provided free access to water plus ~300 $g \cdot day^{-1}$ pelleted diet (125 C3; SAFE, Augy, France). At the end of each behavioural study, animals were humanely killed 24 h after the final treatment, using an appropriate method, as described below. Adult, male C57BL/6 mice (n = 12), chickens (n = 12) and Wistar–Han rats (n = 6) were obtained from Charles River Ltd (Harlow, UK) and humanely killed in accordance with the UK Animals (Scientific Procedures) Act 1986 and associated guidelines for the humane use of experimental animals and approved by the University of Reading Animal Welfare and Ethical Review Body, to provide brain tissue for use in radioligand binding assays. Male beagle and male human cerebellae were supplied by Charles River (UK) and Asterand Bioscience (Herts, UK), respectively, and stored at −80°C until use. No distinct ethical approval was required for the use of beagle or human tissue since each was obtained from a licensed supplier.

Drugs and formulation

Standardized cannabis extracts (1.08:1 ratio of THC and CBD) were supplied by GW Research Ltd (river, UK). The extract's composition complied with the US Food and Drug Administration guidelines for botanical drug products.

Experimental design

Rat behavioural experiment. Rats were randomly allocated into three groups. One group received low-dose (1.08 $mg \cdot kg^{-1}$ THC + 1 $mg \cdot kg^{-1}$ CBD in sesame oil; n = 25), while another received high-dose (40.5 $mg \cdot kg^{-1}$ THC + 37.5 $mg \cdot kg^{-1}$ CBD in sesame oil; n = 25) cannabis extract. The dose levels used in rats were designed to lead to reported effective plasma

concentrations (Deiana *et al.*, 2012). A third group received vehicle (sesame oil; n = 19). Drugs (or vehicle) were administered once daily *via* p.o. gavage for 13 weeks (constant dose volume = 10 mL·kg^{-1} based on weekly animal weights. Five animals per group were humanely killed by a schedule 1 method (e.g. overdose of anaesthetic followed by cervical dislocation) at the end of each of day 2 and weeks 4, 8 and 13 for bioanalyte assessment and assessment of CB_1R function.

Canine behavioural experiment. Dogs were randomized to five groups each containing eight animals (four males and four females) that received, *via* p.o. gavage daily, vehicle (ethanol (sufficient quantity), propylene glycol 50% vv^{-1} and peppermint oil 0.05% vv^{-1}), sham treatment (purified water), low-dose (2.7 mg·kg^{-1} THC + 2.5 mg·kg^{-1} CBD), intermediate-dose (13.5 mg·kg^{-1} THC + 12.5 mg·kg^{-1} CBD) or high-dose (27 mg·kg^{-1} THC + 25 mg·kg^{-1} CBD) cannabis extract treatment for 56 weeks (up to 4 weeks habituation + 52 weeks steady-state treatment). Habituation to treatment in the intermediate- and high-dose groups was as follows: high dose (doses expressed as mg·kg^{-1}·day^{-1} THC/CBD): 5.4/5.0 (days 1–44), 8.1/7.5 (days 5–9), 10.8/10.0 (days 10–14), 13.5/12.5 (days 15–19), 16.2/15.0 (days 20–24) and 21.6/20.0 (days 25–28); intermediate dose: 2.7/2.5 (days 10–14), 5.4/5.0 (days 15 to 19), 8.1/7.5 (days 20–24) and 10.8/10.0 (days 25–28). We believe that this is the first study to investigate the effects of prolonged cannabis extract exposure on seizures in dogs; dose levels were selected on the basis of the results of a previous internal study in dogs with a similar route of administration and similar dose levels, which resulted in good systemic exposure *via* p.o. gavage administration. While acute cannabis intoxication in dogs has not been reported to cause seizures, there is some suggestion that longer-term, higher-dose cannabis may do so (Fitzgerald *et al.*, 2013); therefore, we tested the effects over a 52 week period in dogs to ensure maximum possibility of detecting cannabis extract-induced seizure activity. On completion of the treatment or treatment-free period, all surviving dogs were anaesthetized by an i.v. injection of thiopental sodium and killed by exsanguination.

Collection of behavioural and telemetry measures

In rats, a subgroup (vehicle: n = 4; low dose: n = 10; high dose: n = 10) was assessed by researchers trained to identify, code and discriminate between convulsive behaviours according to conventionally used rodent welfare criteria (Wolfensohn & Lloyd, 2013). Behaviours associated with generalized seizures in rodents included tonic or clonic convulsions, myoclonic jerk, forelimb paddling, forelimb clonus, forelimb flickering, popping (involuntary movement characterized by repeated and typically rhythmic jumping and/or twitching that can range from stationary hiccough-like movements to vigorous jumping) (Mastropaolo *et al.*, 2004), wet dog shakes, tremor, twitching and chewing (Luttjohann *et al.*, 2009). Behaviours not typically associated with seizure: piloerection, ptosis, digit biting, increased grooming, increased scratching, mouth rubbing, behavioural arrest, fasciculations, writhing, licking, salivation, hind limb extension, head searching, hunched posture and exophthalmos. Since THC-induced convulsions in rodents have been suggested to be associated with the act of drug administration and/or handling (Chan *et al.*, 1996; NTP, 1996), rats were observed undisturbed in the home cage for at least 5 min and for a further 5 min after removal from the home cage before final observation for at least 10 min after treatment had been administered each day. Behaviours were grouped into two categories: 'acute' (during the 10 min observation period following daily dosing) and 'persistent' (during the 10 min in the home cage prior to daily treatment). The subgroup of rats was obtained with F40-EET (DSI, New Brighton, MN, USA) telemetry transmitters and electrocorticography (EEG) electrodes already surgically implanted by Charles River (Cambridge, UK). Electrodes comprised two subcranial (dural) wires (frontal cortex AP +4.7 mm and ML −0.5 mm; parietal cortex AP −3.8 mm and ML −3.0 mm, c.f. bregma), and EEG data were collected for 22 h periods on each of 10 pre-specified days during the study (day −1 plus 1 day from each of the following day pairs: 28/29, 35/36, 42/43, 56/57, 63/64, 70/71, 77/78, 84/85 and 90/91). No animals exhibited unusual EEG activity in recordings taken during the 22 h prior to first treatment. Full details of EEG recording and signal processing approaches are described in the Supporting Information.

Dogs were examined for mortality, signs of morbidity and conventional clinical signs, including seizure behaviour, twice daily throughout the study period.

Analysis of drug and metabolite levels

In rats, terminal venous blood (~0.5 mL) was obtained into a heparin-containing polypropylene tube. Samples were mixed for ~2 min, placed on ice, centrifuged (~2300 *g*, 4°C, 10 min) within 30 min of collection and plasma stored in polypropylene tubes (−20°C) until analysis. Each rat brain was rapidly removed after death, cerebrum and cerebellum separated, flash frozen in liquid nitrogen and stored at −80°C. Venous canine blood was sampled immediately prior to the animals being killed in heparin-containing polypropylene tubes, centrifuged (~2300 × *g*, 4°C, 10 min) and plasma stored in polypropylene tubes at −20°C until analysis. Prior to analysis, rodent (cerebellum only) and canine brain samples were homogenized (Lysing Matrix D, MP Biomedical, Santa Ana, California, USA) in methanol and water (20:80 vv^{-1}) on ice using a FastPrep (MP Biomedical) for ~60 s. Plasma (rat and dog) and brain (rat) concentrations of THC, 11-OH-THC (Lemberger *et al.*, 1973) and CBD were determined, while plasma and brain concentrations of 6-hydroxy-CBD (6-OH-CBD) and 7-hydroxy-CBD (7-OH-CBD) were also determined for rats, using UPLC-MS/MS in all cases. Details of sample preparation and analysis are included in the Supporting Information.

Radioligand binding

Detailed methodology for membrane preparation, [^{3}H]-SR1416717A saturation binding and **GTPγS** assays are included in the Supporting Information. Membranes were prepared from all cerebellae tissue used in the rat cannabis extract treatment study; cerebellae tissue was used due to bioanalyte levels being measured from cerebellae tissue in these experiments and also due to high CB_1 receptor expression in rat cerebellum (Tsou *et al.*, 1998). Standardized cerebellar membrane preparations were also produced from

male treatment-naïve C57BL/6J mice, chickens, Wistar–Han rats, beagles and humans, also due to uniformly high CB_1 recepor expression in cerebellar tissue across different mammalian species (Herkenham *et al.*, 1990).

Saturation binding. The high affinity antagonist [^{3}H]-SR1416717A (pK_D 8.9–10, Alexander *et al.*, 2017) was used, assays were conducted in triplicate and three separate assays were performed in each case. Radioactivity bound to cortex membranes was quantified in disintegrations per minute (dpm) before conversion to pmol·mg^{-1}. Analyses of saturation binding data were conducted by non-linear regression and fitted to a one-binding site model to determine the equilibrium K_D (nM) and the maximal number of binding sites B_{max} (pmol·mg^{-1}) using GraphPad Prism software (GraphPad Software Inc., San Diego, CA, USA).

[^{35}S]-GTPγS binding assay. Assays were carried out in triplicate, and three separate assays were performed in each case. [^{35}S]-GTPγS assay data were analysed using GraphPad Prism. Concentration–response data were analysed using a sigmoidal concentration–response model or linear regression and compared using an *F*-test to select the appropriate model. On this basis, best fits to sigmoidal curves were obtained with Hill slopes of unity, and no other constraints applied. For curves showing no concentration-related increases, linear regression was performed to determine if slopes differed significantly from zero. Values for EC_{50} were derived from fitted curves to mean data and E_{max} expressed as percentage over basal or as percentage of the mean maximal response following stimulation with the highest concentration of the CB_1 receptor full agonist, **WIN55,212-2** (10 μM). In experiments that examined the effects of agonist stimulation in membranes prepared from drug-treated animals and where mathematically possible, data were fitted to an operational model of ligand binding (Black & Leff, 1983). Here, dpm were plotted, and the tissue-agonist combination that yielded the largest maximal stimulation was identified (i.e. WIN55,212-2 responses in vehicle-treated animals). The magnitude of this highest maximal stimulation was used to scale (0–100%) other tissue–agonist combinations. Prior to scaling, basal stimulation was subtracted to constrain the bottom of all derived curves to zero. In experiments that examined differences between tissues from different species using [^{35}S]-GTPγS assays, prior to normalization, data expressed as dpm were plotted in order to assess any differences arising from expression and sensitivity levels.

We produce a descriptive representation of the overall profile of THC-mediated CB_1 receptor-mediated signalling for each species (which we term the 'eCB signalling footprint') by normalizing (i) CB_1 receptor expression (B_{max}; 'Expression'), (ii) basal G-protein turnover (dpm at the lowest concentration of THC; 'Basal'), (iii) sensitivity (EC_{50}; 'Sensitivity') and (iv) activation (E_{max}; 'Extent') in response to agonist stimulation, to the species with the highest value for each measure.

Drugs. The following drugs were used: WIN55,212-2 (Tocris, Bristol, UK), [^{3}H]-SR141716A and [^{35}S]-GTPγS (GE Healthcare, Chalfont St. Giles, Buckinghamshire, UK).

Randomization and blinding

Canine and rat behavioural studies and canine and rat bioanalyte studies were conducted in accordance with industry-standard good laboratory practice and additional regulatory compliances as detailed above. Such compliance ensures randomization of animals to each specified group and appropriate blinding. For canine studies (CIT Safety and Health Laboratories), a computerized randomization procedure (using validated CIT software) was used. For rat studies (Covance, Leeds, UK), animals were identified by numbered tail marks and electronic ID; prior to the start of the study, animals were randomly allocated to treatment groups and individually tattooed by Charles River. In all cases, operators were blinded to treatment. For *in vitro* binding studies, membrane preparations were randomly selected by the operator; here, all parameters stated are measured numerical values, which were not influenced by any observer-related bias, and therefore, blinding was not considered to be necessary.

Statistics

Data subjected to statistical comparisons did not violate assumptions of normality (D'Agostino–Pearson omnibus test) and are expressed as mean ± SEM. Group sizes for data subjected to statistical comparisons were designed on the basis of power calculations to identify differences between cannabis extract doses. Groups were compared by one- or two-way ANOVA tests followed by Tukey's *post hoc* tests as appropriate using GraphPad Prism; *post hoc* tests were run only if *F* achieved $P < 0.05$ and there was no significant variance in homogeneity. A variance–covariance principal component analysis (PCA) of animal behavioural data was undertaken using XLSTAT (New York, NY, USA); this analysis used daily data normalized to the proportion of animals per group exhibiting any given behaviour before calculation of a group mean value for each behaviour for the 13 week treatment period. Interpretation of the variance described by the first and second principal components was undertaken by examination of the squared cosines and percentage contributions of each variable to the total variance (see Supporting Information). In accordance with the journal policy, $P < 0.05$ was reported as level of significance. The data and statistical analysis comply with the recommendations on experimental design and analysis in pharmacology (Curtis *et al.*, 2015).

Nomenclature of targets and ligands

Key protein targets and ligands in this article are hyperlinked to corresponding entries in http://www.guidetopharmacology.org, the common portal for data from the IUPHAR/BPS Guide to PHARMACOLOGY (Harding *et al.*, 2018), and are permanently archived in the Concise Guide to PHARMACOLOGY 2017/18 (Alexander *et al.*, 2017).

Results

Effects of cannabis extract treatment on plasma and brain cannabinoid bioanalyte levels

Concentrations of THC and its active metabolite, 11-OH-THC, plus CBD and its metabolites, 6-OH-CBD and 7-OH-CBD, in plasma and cortical homogenate from rats that received 13 weeks' vehicle, low-dose (1.08 mg·kg^{-1} THC and 1 mg·kg^{-1} CBD) or high-dose (40.5 mg·kg^{-1} THC and 37.5 mg·kg^{-1} CBD) cannabis extract treatment *via* p.o. gavage were measured (Table 1). With the exception of 6-OH-CBD, which was not detected in any samples from any group, all other bioanalytes were identified in at least one group of rats that received low- or high-dose cannabis extract treatment. One-way ANOVA tests revealed a significant effect of group upon THC, 11-OH-THC, CBD and 7-OH-CBD concentrations in brain and plasma, which arose from a significant increase in level of each cannabinoid and metabolite present in the high-dose, in comparison with low-dose, cannabis extract-treated groups (Table 1). THC, 11-OH-THC and CBD (but not 6-OH-CBD and 7-OH-CBD) were present at detectable levels in the low-dose group.

Concentrations of THC, 11-OH-THC and CBD in canine plasma samples from sham, vehicle, low-dose (2.7 mg·kg^{-1} THC and 2.5 mg·kg^{-1} CBD), intermediate-dose (13.5 mg·kg^{-1} THC and 12.5 mg·kg^{-1} CBD) and high-dose (27 mg·kg^{-1} THC and 25 mg·kg^{-1} CBD) cannabis extract-treated groups were measured (Table 1). All bioanalytes were identified in at least one group that received low-, intermediate- or high-dose treatment; one-way ANOVA tests revealed a significant effect of group upon THC, 11-OH-THC and CBD concentrations in plasma, which arose from significant increases in cannabinoid levels in the intermediate- and high-dose, in comparison with low-dose, cannabis extract-treated groups. THC, 11-OH-THC and CBD were detectable in the low-dose group in canines. No evidence for any cannabinoids was found in sham- or vehicle-treated samples. Overall, relative to dose administered, the THC plasma concentration was higher in rats than dogs; although the active metabolite 11-OH-THC, and CBD, was higher in dogs. Together, these data demonstrate that p.o. administration of higher dose cannabis extracts is effective in producing increased physiologically relevant levels of major cannabinoids and metabolites and that bioanalyte profiles differed between rats and dogs. These data provided a validated basis to study dose-dependency of seizure induction by cannabis extracts and permit qualitative comparisons between species.

Effects of cannabis extract treatment upon behaviours in rats and dogs

Low-dose cannabis extract treatment produced acute (observed during the 10 min period following daily dosing) behavioural signs in rats from day 17, which continued throughout the 13 week treatment (Figure 1). The most frequently observed acute effects (descending order of magnitude of the median proportion exhibiting a behaviour during the treatment period) were mouth rubbing, forelimb paddling, increased scratching, wet dog shakes, forelimb flickering, increased grooming, ptosis and chewing; less frequent effects (median incidence of zero but with non-zero interquartile range) were writhing and salivation (Table 2 and Supporting Information Table S1). Persistent (observed during the 10 min prior to daily treatment) behavioural effects of low-dose cannabis extract in rats occurred on day 18 and continued throughout the 13 week treatment (Figure 2). Here, the most frequently observed effects were increased grooming, increased scratching and ptosis; less frequent effects were wet dog shakes, forelimb flickering, forelimb paddling and writhing (Table 2 and Supporting Information Table S1). In the high-dose group, acute behavioural signs in rats were observed from day 17 and continued throughout the 13 week treatment (Figure 1). The most frequently observed acute effects were forelimb paddling, mouth rubbing, ptosis, increased scratching, piloerection, wet dog shakes, forelimb flickering, chewing, salivation and increased grooming; less frequently, behavioural arrest and twitch were observed (Table 2 and Supporting Information Table S1). The first persistent behavioural effects of high-dose treatment in rats were seen from day 18 and also continued throughout the 13 week treatment (Figure 2). Here, the most frequently observed behaviours were increased scratching, increased grooming, piloerection and wet dog shakes; less frequently, ptosis and forelimb paddling were observed (Table 2 and Supporting Information Table S1). No vehicle-treated animals exhibited any of the behaviours coded (results from this group are omitted for clarity). The mean values for the normalized incidence of each of the behaviours exhibited by cannabis extract-treated rats, prior to and after treatment administration (Figures 1 and 2 and Supporting Information Table S2), were subjected to PCA. The first three components accounted for 100% of the variability of which 90.1 and 8.4% of variability was accounted for by the first and second principal components respectively. Mouth rubbing and forelimb paddling behaviours made a cumulative contribution of 68.3% to the first principal component with corresponding squared cosine values >0.9 (Supporting Information Table S2). A biplot of the first two principal components revealed a positive correlation between 'acute' behaviours and the first principal component, while the converse applied to 'persistent' behaviours (Figure 3A); the first principal component therefore represents behaviours associated with administration of the drug. The second principal component positively correlated with high-dose cannabis extract treatment, indicating that this measure is dose related. A circle plot of these data (Figure 3B) revealed that several behaviours were strongly associated with acute exposure to cannabis extract, irrespective of dose. The circle plot revealed that several behaviour characteristics of generalized seizures such as popping, convulsion, myoclonic jerk and twitch were positively correlated with the high-dose group, while the converse applied to increased grooming and writhing (Figure 3B). Notably, myoclonic jerk and convulsion were independent, while popping, increased grooming and writhing were negatively associated, with acute measurement of behaviour. The remaining behaviours showed no overt dose-dependency.

In dogs, no behaviours associated with seizures were seen. There were seven unscheduled deaths across all groups except the sham control and low-dose groups, which occurred as follows: vehicle group (1 female; day 361), intermediate group (3 male; days 31, 315 and 339) and high

Table 1

Cannabis extract treatment phytocannabinoid and metabolite concentrations in plasma from rats and dogs and cortex homogenate from rats

	THC		11-OH-THC		CBD		6-OH-CBD		7-OH-CBD	
	Plasma (ng·mL^{-1})	Brain (ng·g^{-1})	Plasma (ng·mL^{-1})	Brain (ng·g^{-1})	Plasma (ng·mL^{-1})	Brain (ng·g^{-1})	Plasma (ng·mL^{-1})	Brain (ng·g^{-1})	Plasma (ng·mL^{-1})	Brain (ng·g^{-1})
Rat										
Vehicle	0	0	0	0	0	0	0	0	0	0
Low cannabis dose	1.25 ± 0.30	2.55 ± 0.24	0.75 ± 0.19	3.12 ± 0.51	0.31 ± 0.06	0.09 ± 0.09	0	0	0	0
High cannabis dose	226.10 ± 17.24*	614.30 ± 50.86*	24.07 ± 5.04*	63.77 ± 7.46*	97.81 ± 9.85*	161.7 ± 38.97*	0	0	28.80 ± 2.81*	7.42 ± 0.94*
Dog										
Sham	0	–	0	–	0	–	–	–	–	–
Vehicle	0	–	0	–	0	–	–	–	–	–
Low cannabis dose	22.02 ± 6.16	–	6.66 ± 4.48	–	50.76 ± 30.10	–	–	–	–	–
Intermediate cannabis dose	60.48 ± 9.01*	–	31.85 ± 10.1*	–	201.3 ± 39.03*	–	–	–	–	–
High cannabis dose	70.40 ± 11.49*	–	45.87 ± 11.14*	–	318.3 ± 58.30*	–	–	–	–	–

Phytocannabinoid and selected metabolite concentrations in plasma from rats and dogs and cortex homogenate from rats, following daily p.o. administration of vehicle/sham or cannabis extract treatment. Rats received vehicle ($n = 4$), low- (1.08 mg·kg^{-1} THC + 1 mg·kg^{-1} CBD; $n = 10$) or high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD; $n = 10$) cannabis extract for 13 weeks. Dogs ($n = 8$ per group) received vehicle, sham treatment, low-dose (2.7 mg·kg^{-1} THC + 2.5 mg·kg^{-1} CBD), intermediate-dose (13.5 mg·kg^{-1} THC + 12.5 mg·kg^{-1} CBD) or high-dose (27 mg·kg^{-1} THC + 25 mg·kg^{-1} CBD) cannabis extract for 56 weeks. Values are mean ± SEM. Values shown as zero reflect results below the limit of quantification.

*$P < 0.05$ for planned pairwise comparisons between low-dose, intermediate-dose (where used) and/or high-dose groups using Tukey's *post hoc* tests following a one-way ANOVA test.

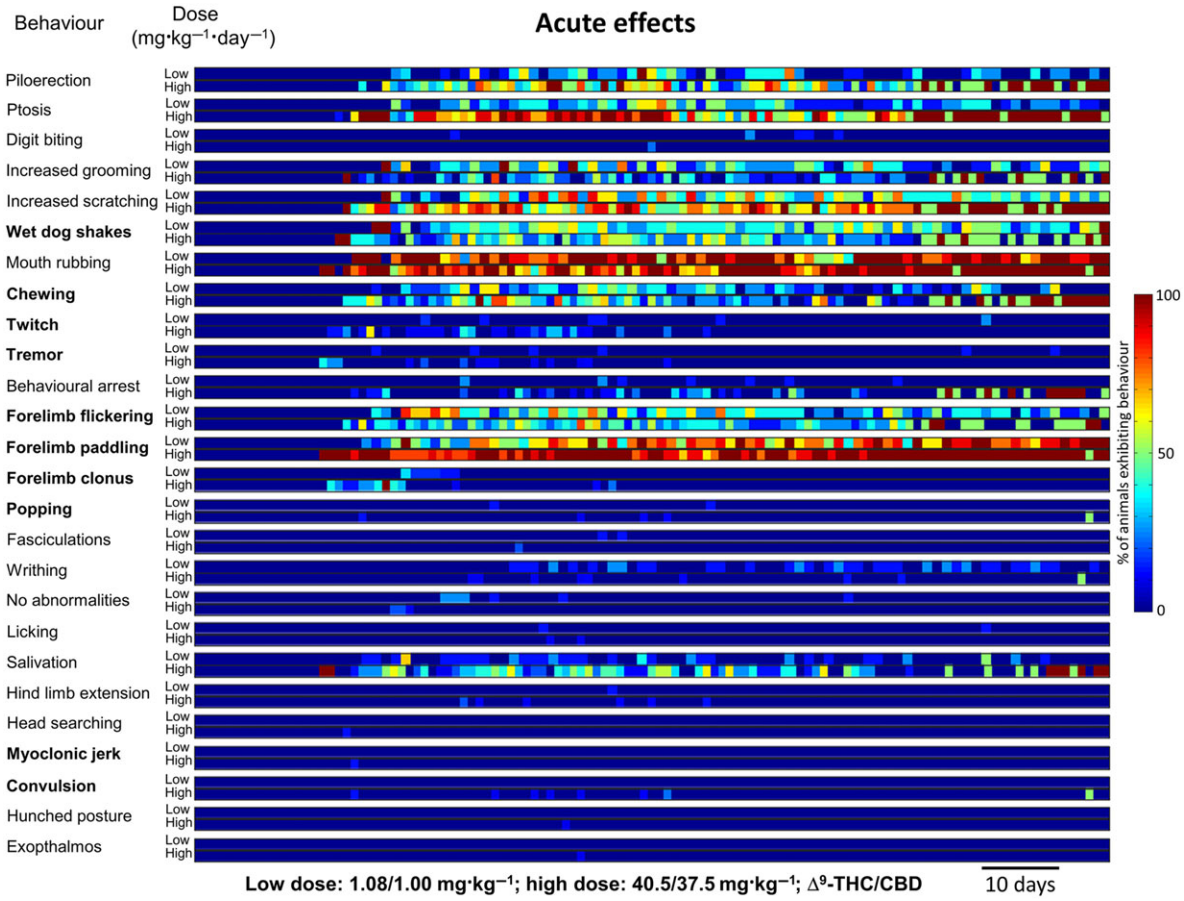

Figure 1

Temporal representation of acute behaviours in rats (n = 10 per group) 10 min after daily p.o. low-dose [1.08 mg·kg^{-1} THC (Δ^9-THC) + 1 mg·kg^{-1} CBD] or high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD) cannabis extract treatment for 13 weeks. Behavioural events associated with generalized seizures in rodents are highlighted in bold.

group (3 male; days 14, 30 and 221). The mortality pattern showed no measurable dose relationship, and *post-mortem* examination attributed mortality to clinical complications following reflux and aspiration of stomach contents and/or formulated treatment into the lungs rather than a drug-related effect. During the habituation period, ptyalism was observed in vehicle, intermediate- and high-dose groups, which continued in the steady-state period, during which time this sign was also noted in the low dose and, to the least extent, sham groups (Table 3). Incidence of ptyalism was not dose related and was attributed to vehicle excipients. Other clinical signs seen during habituation occurred predominantly in the high-dose group and could be assigned to two categories: (i) hypoactivity, ataxia and tremor (from day 2) and (ii) abdominal breathing, tachypnoea, lateral recumbency, reflux at dosing, vomiting, soft or liquid faeces and dehydration (from day 18). During the steady-state treatment period, dogs exhibited clinical signs (Table 3) divided into four categories: (i) dose-related neurological signs (ataxia, tremor and hypoactivity) occurred primarily in cannabis extract-treated groups but with decreased frequency compared with the habituation phase; (ii) thin appearance manifested without clear treatment, time, dose or sex relationship, and all dogs consumed ≥75% of food offered each day; (iii) gastrointestinal signs, occurred primarily in cannabis extract-treated groups with dose-related incidence; (iv) oro-respiratory signs (ptyalism, dyspnoea and abdominal breathing). Ptyalism occurred in all groups at steady state but was highest in cannabis extract-treated groups, suggesting attribution to the excipients. Overall, in dogs, cannabis extract, even at the highest dose tested, caused limited neurological, gastrointestinal and oro-respiratory behavioural signs. Most importantly, convulsive episodes were never observed in dogs from any group, and repeated drug treatment was well tolerated.

EEG and seizure analysis in rats

Visually identified motor convulsions (Racine stage: ≥3; Jones *et al.*, 2010, 2012) occurred in 80% (8/10) of rats in the high-dose cannabis extract group; by contrast, motor convulsions were never observed in the low-dose or vehicle treatment groups. A total of 24 motor convulsions were observed in the high-dose group where average time from start of treatment to first convulsion was 50.5 ± 7.5 days; convulsions continued until the end of the study (Supporting

Table 2

Incidence of acute and persistent cannabis extract-induced behaviours in rats

	Low dose (1.08/1.00 mg·kg^{-1} THC/CBD)				High dose (40.5/37.5 mg·kg^{-1} THC/CBD)			
Rank	**Acute**	**Median % (IQR)**	**Persistent**	**Median % (IQR)**	**Acute**	**Median % (IQR)**	**Persistent**	**Median % (IQR)**
1	Mouth rubbing	87.5 (62.5–100)	Increased grooming	50 (23–67)	**Forelimb paddling**	90 (80–100)	Increased scratching	40 (25–60)
2	**Forelimb paddling**	62.5 (31–88)	Increased scratching	37.5 (12.5–50)	Mouth rubbing	87.5 (62.5–100)	Increased grooming	25 (11–44)
3	Increased scratching	37.5 (12.5–50)	Ptosis	12.5 (0–12.5)	Ptosis	62.5 (32.5–90)	Piloerection	10 (0–22)
4	**Wet dog shakes**	37.5 (12.5–50)	**Wet dog shakes**	0 (0–12.5)	Increased scratching	62.5 (37.5–80)	**Wet dog shakes**	10 (0–12.5)
5	**Forelimb flickering**	37.5 (9.5–50)	**Forelimb flickering**	0 (0–12.5)	Piloerection	37.5 (8–60)	Ptosis	0 (0–20)
6	Increased grooming	25 (0–40.5)	**Forelimb paddling**	0 (0–12.5)	**Wet dog shakes**	25 (10–40)	**Forelimb paddling**	0 (0–11)
7	Ptosis	12.5 (0–37.5)	Writhing	0 (0–12.5)	**Forelimb flickering**	25 (12.5–37.5)	–	–
8	**Chewing**	12.5 (0–27)	–	–	**Chewing**	22.2 (0–40)	–	–
9	Writhing	0 (0–12.5)	–	–	Salivation	20 (0–40)	–	–
10	Salivation	0 (0–12.5)	–	–	Increased grooming	12.5 (0–25)	–	–
11	–	–	–	–	Behavioural arrest	0 (0–11)	–	–
12	–	–	–	–	**Twitch**	0 (0–10)	–	–

Incidence of behaviours in rats (n = 10 per group) observed immediately after 10 min (acute) or ~23 h after (persistent) daily p.o. administration of low-dose (1.08 mg·kg^{-1} THC + 1 mg·kg^{-1} CBD) or high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD) cannabis extract for 13 weeks. Behaviours are ranked by descending magnitude of median incidence over 13 weeks where the calculated median was non-zero. Thereafter, behaviours are ranked by descending order of magnitude of the 75th percentile where the IQR was non-zero. Behaviours exhibiting a median and IQR of zero are shown in Supporting Information Table S1. Behavioural events conventionally associated with generalized seizures in rodents are highlighted in bold. IQR, interquartile range.

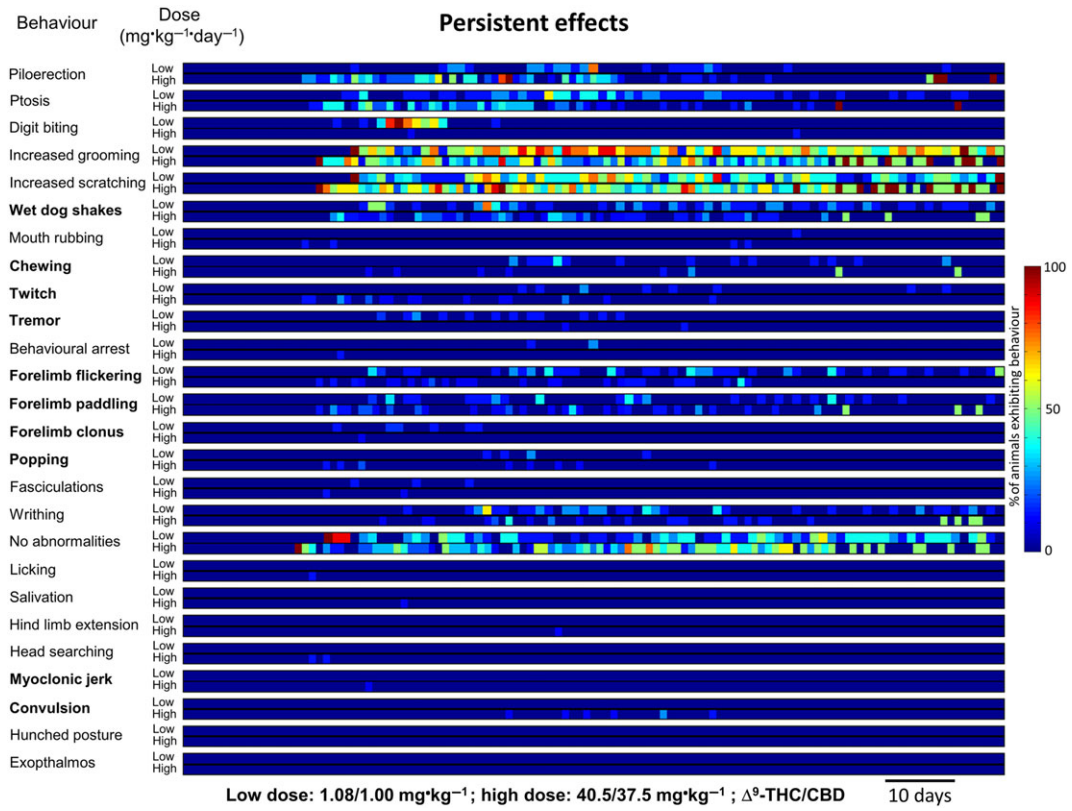

Figure 2

Temporal representation of persistent behaviours in rats (n = 10 per group) ~23 h after daily p.o. administration of low-dose [1.08 mg·kg^{-1} THC-(Δ^9-THC)+ 1 mg·kg^{-1} CBD] or high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD) cannabis extract treatment for 13 weeks. Behavioural events associated with generalized seizures in rodents are highlighted in bold.

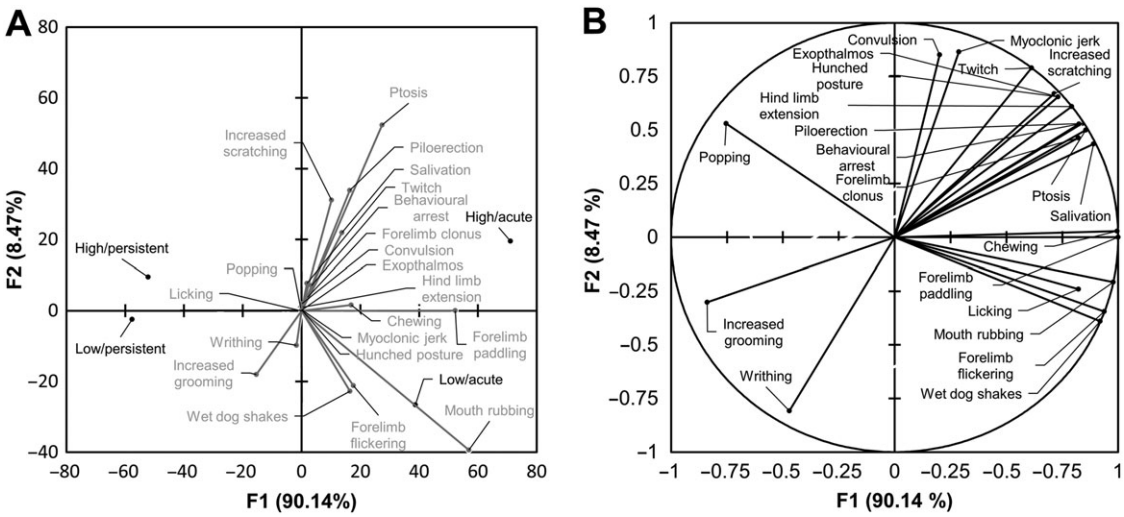

Figure 3

(A) Biplot of the first two principal components (F1 and F2) derived from daily behavioural data (see Methods). Positive values of the first principal component were positively correlated with observations made in the period shortly after dosing (acute), irrespective of dose, whereas the converse applied to observations made prior to daily treatment (persistent). Positive values of the second principal component were positively correlated with observations made in animals that received high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD; n = 10) cannabis extract, irrespective of dose timing, whereas the converse applied to observations made in animals that had received low-dose (1.08 mg·kg^{-1} THC + 1 mg·kg^{-1} CBD; n = 10) cannabis extract. (B) Correlation plot showing association of behaviours with the first and second principal components.

Table 3

Incidence of cannabis extract-induced behaviours in dogs

	THC/CBD dose (mg·kg^{-1}·day^{-1})																			
	Sham				Vehicle				2.7/2.5				13.5/12.5				27/25			
	Sex																			
	M		F		M		F		M		F		M		F		M		F	
	Phase																			
	H	SS	H	SS	H	SS	H	SS	H	SS	H	SS	H	SS	H	SS	H	SS	H	SS
	Number of survivors																			
	6		6		6		5		4		4		2		4		3		6	
Ptyalism	–	2	–	2	–	5	2	4	–	4	–	4	5	2	2	4	5	3	4	6
Reflux at dosing	–	–	–	–	–	–	–	–	–	–	–	–	1	–	–	–	1	–	–	–
Abdominal breathing	–	–	–	–	–	1	1	–	–	–	–	–	–	1	–	–	1	–	–	–
Dyspnoea	–	–	–	–	–	1	1	–	–	–	–	–	–	–	–	–	–	–	–	–
Tachypnoea	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	1	–	–	–
Hypoactivity	–	–	–	–	–	1	1	–	1	–	–	2	1	1	1	4	3	1	–	1
Lateral recumbency	–	–	–	–	–	–	1	–	–	–	–	–	1	–	–	–	2	–	–	–
Ataxia	–	–	–	–	–	–	–	–	–	2	–	1	–	–	–	–	5	–	2	–
Tremor	–	–	–	–	–	–	–	–	–	–	–	–	1	–	1	–	–	–	1	–
Vomiting	–	–	–	–	–	1	1	–	–	2	–	1	2	1	–	3	4	2	3	5
Soft/liquid faeces	–	–	–	–	–	–	1	–	–	–	–	1	2	–	–	–	2	3	1	3
Dehydration	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	1	–	–	1
Thin appearance	–	1	–	–	–	1	–	–	–	–	–	1	–	–	–	1	–	1	–	1

The incidence of clinical signs observed in dogs (n = 8 per group) treated (daily; p.o.) with sham (purified water), vehicle, low-dose (2.7 mg·kg^{-1} THC + 2.5 mg·kg^{-1} CBD), intermediate-dose (13.5 mg·kg^{-1} THC + 12.5 mg·kg^{-1} CBD) or high-dose (27 mg·kg^{-1} THC + 25 mg·kg^{-1} CBD) cannabis extract during H (weeks 1–4) and SS (weeks 5–56) periods. – indicates no clinical sign noted for a given group. H, habituation; SS, steady-state.

Information Table S3). Of the 24 convulsive events, 17 occurred during drug administration or the subsequent observation period, while the remaining 7 events occurred prior to animal handling or were detected after review of video data when EEG analysis revealed an epileptiform event. EEG recordings from the high-dose group revealed 18 events exhibiting epileptiform activity (handling-related artefacts rendered 2/18 recordings unsuitable for presentation and are omitted) (Figure 4 and Supporting Information Table S3). Video data or direct observation showed that 15/18 (~80%) of epileptiform events were accompanied by a motor convulsion (Racine stage: ≥3) from which each animal recovered without intervention. By contrast, only one animal (out of 10) from the low-dose group exhibited an epileptiform event (Figure 5A and Supporting Information Table S3); although the electrophysiological profile of this event was consistent with events seen the high-dose group (Figure 4 vs. Figure 5A, B), video data from this one animal did not reveal an accompanying motor convulsion. All epileptiform events exhibited rhythmic, large amplitude, sharp wave activity of increasing amplitude prior to spontaneous termination (c.f. pretreatment baseline activity; Figures 4 and 5A, B) that persisted for 55 ± 7.6 s (n = 17). Spectrograms showed that all epileptiform activities induced by high-dose and the single low-dose example dominated the 1–20 Hz range where accompanying measures of power spectrum density (PSD) revealed 2–7 Hz peaks [Figure 5B, panel b, C (inset)]. Mean PSD confirmed that epileptiform activity induced by high-dose cannabis extract exhibited a signal profile (Figure 5C) with peaks present at 2, 3 and 4.5 Hz, consistent with primary generalized seizures (Luttjohann *et al.*, 2009). Together, these data suggest that

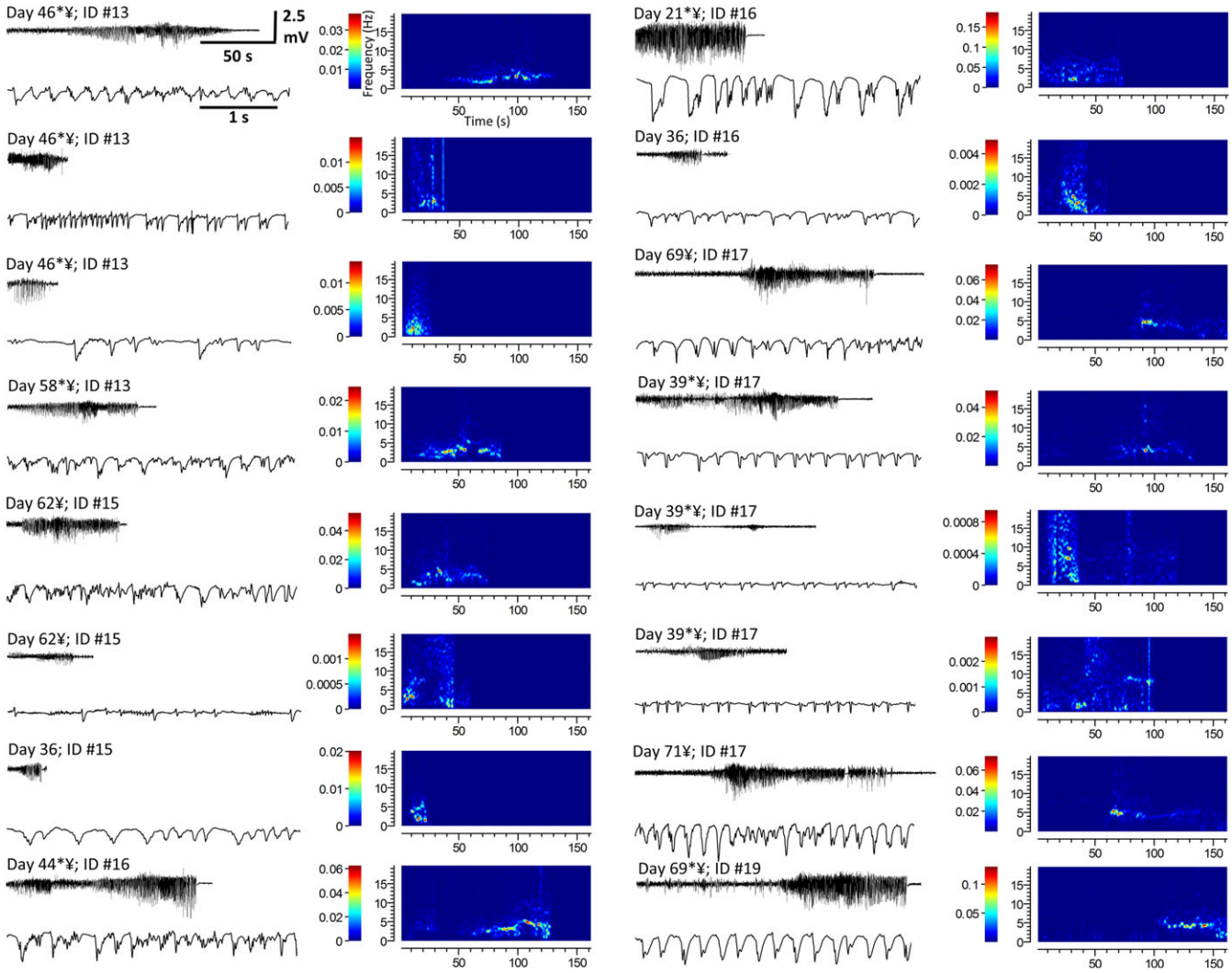

Figure 4

Epileptiform events recorded *via* EEG in rats treated with high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD) cannabis extract (Supporting Information Table S2). Each panel shows the EEG recording of the complete epileptiform event (top left), a shorter section of the event during the period of greatest amplitude activity represented on an extended timescale (bottom left) and a spectrographic representation of each event [right; *x*-axis: time (s); *y*-axis: frequency (Hz); and colour bar: power (dB·mV^{-2})]. * Indicates occurrence of a seizure during drug administration or within 10 min thereafter. ¥ Indicates an epileptiform event detected *via* EEG that was accompanied by a motor convulsion.

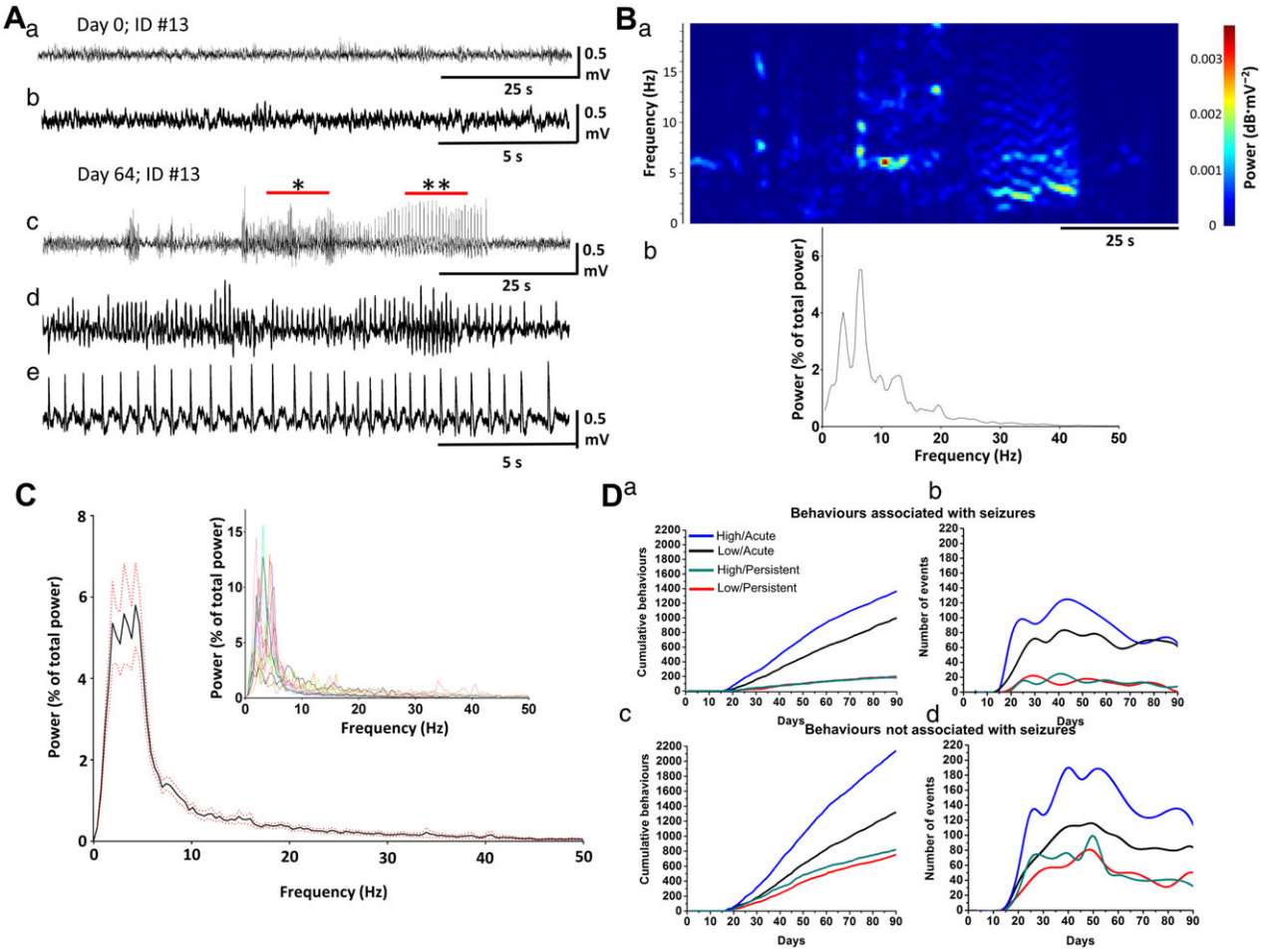

Figure 5

(A) EEG recordings from a rat treated with low-dose (1.08 mg·kg^{-1} THC + 1 mg·kg^{-1} CBD) cannabis extract during (panels a, b) pretreatment baseline and (panels c, d) an epileptiform event. In panel c, * and ** show areas reproduced in panels d, e respectively. (B, panel a) Spectrographic representation of [A, panel c, right; *x*-axis: time (s); *y*-axis: frequency (Hz); and colour bar: power (dB·mV^{-2})] and (panel b) resulting PSD. (C) Mean (black) ± SEM (red dotted) PSD of epileptiform events recorded *via* EEG from animals treated with high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD; $n = 10$) cannabis extract. Inset shows overlay of individual PSD plots per event per animal. (D) (panel a) Cumulative incidence and (panel b) temporal distribution of coded behaviours associated with seizures in animals (see Methods) treated with low- or high-dose cannabis extracts. (panel c) Cumulative incidence and (panel d) temporal distribution of coded behaviours not associated with seizures in animals (see Methods) treated with low- or high-dose cannabis extracts.

sustained high-dose treatment reliably caused motor convulsions, subserved by spontaneous epileptiform activity in rat.

Coded behaviours were re-examined, and those consistent with primary generalized seizure in rats were pooled before calculation of cumulative incidence (Figure 5D, panel a) to reveal more frequent occurrence of acute than persistent seizure-related behaviours in both low-dose and high-dose treatment groups. Irrespective of these acute effects, seizure-related behaviours occurred more frequently in the high-dose than the low-dose group (Figure 3B). Further, when behaviours consistent with seizure (bold in Figures 1 and 2) were examined (Figure 5D, panel b), event incidence reached maximum levels at 40–50 days treatment before declining, irrespective of dose or time of observation (i.e. 'acute' or 'persistent'). Some behaviours are not typically associated with seizure in rodents (not bold in Figures 1 and 2); nevertheless, their cumulative incidence (Figure 5D, panel c) and temporal distribution (Figure 5D, panel d) were similar to those of seizure-associated behaviours (Figure 5D, panels a, b), suggesting a common underlying aetiology. These data suggest that behaviour signs in rat are increased during or immediately after handling/drug administration and that such variations should be considered when testing for drug effects in rodents.

Effects of cannabis extract treatment on CB_1 receptor expression and G-protein turnover in rat cerebellar membranes

CB_1 receptor density was investigated in membranes from cerebellar brain tissue of all rats used in the above behavioural studies obtained at four time points (2 days and weeks 4, 8 and 13) during treatment with vehicle, low-dose or high-dose cannabis extract by saturation binding assay using the CB_1

receptor antagonist, [^{3}H]-SR141716A, and expressed as B_{max} (Figure 6A, panels a–d, B and Table 4). [^{35}S]-GTPγS binding was also examined in the same rat brain cerebellar membrane preparations from the 13 week treatment groups to assess CB_1 receptor sensitivity to the partial agonist, THC, and the full agonist, WIN55,212-2 (Figure 6C, panels a–d). Here, in membranes from vehicle-treated animals, THC had a profile consistent with partial agonism (EC_{50}: 69 nM; E_{max}: 27%),

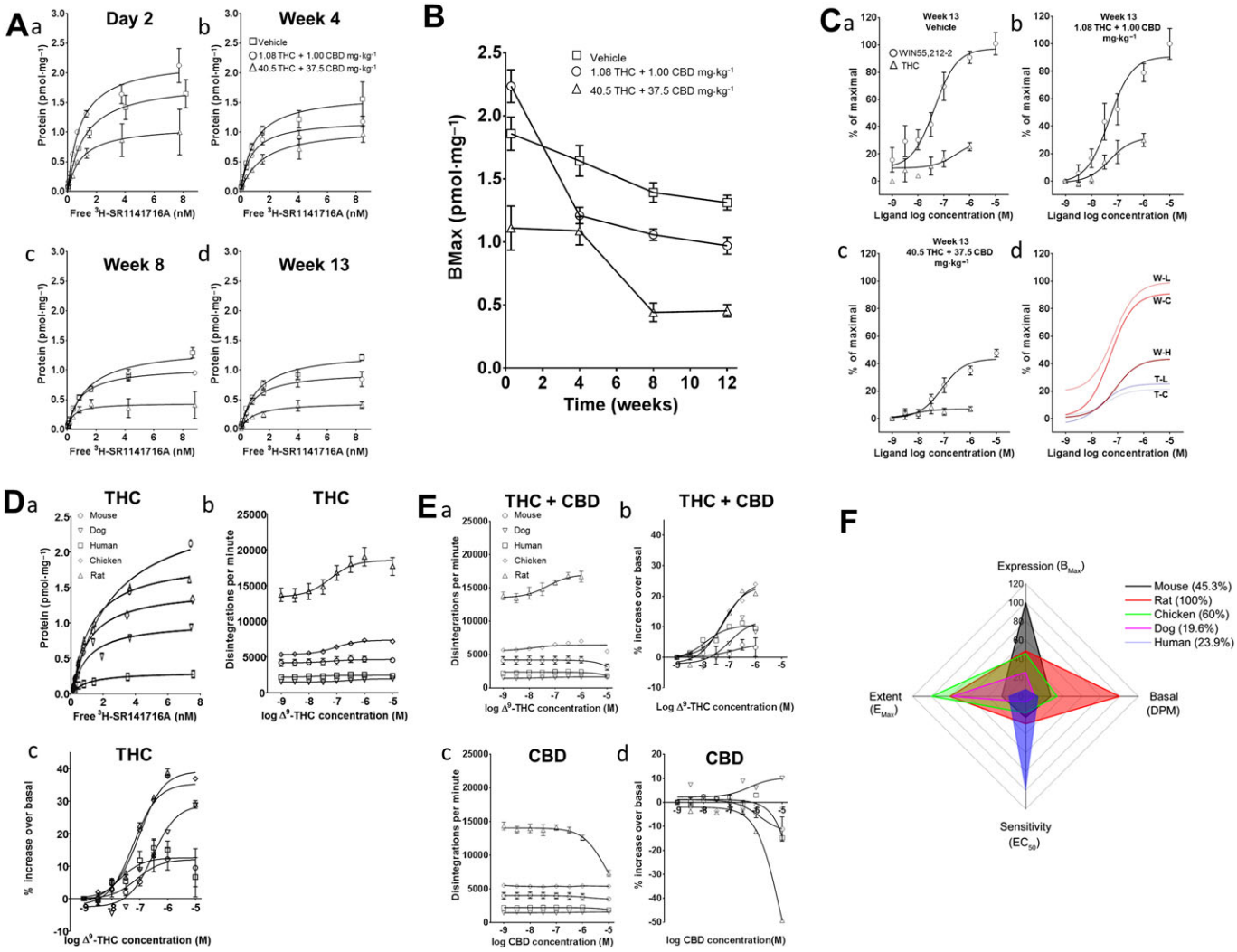

Figure 6

Saturation binding of [^{3}H]-SR141716A to cerebellar membranes from rats treated with vehicle, low-dose (1.08 mg·kg^{-1} THC + 1 mg·kg^{-1} CBD) or high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD) cannabis extracts for (i) 2 days, (ii) 4, (iii) 8 and (iv) 13 weeks. (B) Temporal profile of B_{max} (pmol·mg^{-1}) derived from (A, panels a–d). (C) Log concentration–response best-fit curves for stimulation of [^{35}S]-GTPγS binding by THC and WIN55 212-2 in cerebellar membranes for week 13 data shown in (A). Data expressed as % maximal stimulation by 10 μM WIN55,212-2 in vehicle group membranes fitted to an operational model of ligand binding (THC/high dose lack of response prevented valid curve derivation, and a subjectively assessed non-linear fit was employed). (panel d) Overlay of best fit curves derived from panels a–c. W, WIN55,212-2; T, THC; C, control (vehicle); L, low dose; H, high dose. No 'T–H" curve presented. (D) (panel a) Saturation binding of [^{3}H]-SR141716A to human, chicken, dog, mouse and rat cerebellar membranes. (panel b) Log concentration–response curves for stimulation of [^{35}S]-GTPγS binding (dpm) by THC in cerebellar membranes from species indicated. (panel c) Log concentration–response curves for stimulation of [^{35}S]-GTPγS binding (normalized) by THC in cerebellar membranes from the species indicated. (E) (panel a) Equivalent (to D, panel b) curves for THC (Δ^9-THC)+ CBD (1.08:1.00). (panel b) Equivalent (to D, panel c) curves for THC + CBD (1.08:1.00). Data obtained from chicken, dog and human membrane samples were not amenable to sigmoidal curve fitting; here, subjective best fits are shown, but EC_{50} not calculated. Concentration expressed as THC. (panel c) Equivalent (to D, panel b) curves for CBD. (panel d) Equivalent (to D, panel c) curves for CBD. Data obtained were not amenable to sigmoidal curve fitting; here, subjective best fits are shown but EC_{50} not calculated. (F) Radar plot showing CB_1 receptor ('Expression'; D, panel a), basal G-protein turnover ('Basal'; D, panel b) and sensitivity to and extent of agonist stimulation ('Sensitivity' and 'Extent'; D, panel c) by species based upon (A–E) scaled as percentage of the species exhibiting the highest value for a given measure. With the exception of (F), all values shown are mean ± SEM; n = 3 experiments of three technical replicates in all cases.

Table 4

[^{3}H]-SR141716A saturation binding in cannabis extract-treated rats

Treatment group	Treatment period							
	2 days		4 weeks		8 weeks		13 weeks	
	B_{max} (pmol·mg^{-1})	K_D	B_{max} (pmol·mg^{-1})	K_D	B_{max} (pmol·mg^{-1})	K_D	B_{max} (pmol·mg^{-1})	K_D
Vehicle	1.86 ± 0.13	1.19 ± 0.25	1.64 ± 0.12	0.93 ± 0.23	1.39 ± 0.08	1.43 ± 0.23	1.31 ± 0.06	1.18 ± 0.16
Low dose	2.23 ± 0.13	0.90 ± 0.17	1.21 ± 0.06	0.74 ± 0.13	1.06 ± 0.05	0.90 ± 0.13	0.97 ± 0.07	0.88 ± 0.20
High dose	1.11 ± 0.17	0.95 ± 0.47	1.10 ± 0.11	1.54 ± 0.45	0.44 ± 0.07	0.39 ± 0.25	0.45 ± 0.05	0.90 ± 0.31

B_{max} (pmol·mg^{-1}) and K_D values for CB_1 receptor expression using saturation binding of [^{3}H]-SR141716A to cerebellar membranes from animals that had been treated with vehicle, low-dose (1.08 mg·kg^{-1} THC + 1 mg·kg^{-1} CBD) or high-dose (40.5 mg·kg^{-1} THC + 37.5 mg·kg^{-1} CBD) cannabis extract for 2 days and 4, 8 and 13 weeks (Figure 6A, panels a–d, B). Values shown are mean ± SEM; experiments in triplicate in three separate preparations.

while WIN55,212-2 exhibited a comparable EC_{50} but with a numerically greater E_{max} (EC_{50}: 68 nM; E_{max}: 99%), consistent with its profile as a full agonist. In tissue from the low-dose-treated group, responses to THC (EC_{50}: 40 nM; E_{max}: 31%) and WIN55,212-2 (EC_{50}: 53 nM; E_{max}: 93%) were similar to those seen in the vehicle-treated group; this was in clear contrast to the high-dose group, where the response to WIN55,212-2 (EC_{50}: 84 nM; E_{max}: 44%) was attenuated, and the THC response so markedly attenuated as to be too small for an EC_{50} value to be accurately derived, and E_{max} was depressed to ~7%. These results indicate that prolonged cannabis extract treatment clearly attenuates CB_1 receptor-mediated G-protein signalling in rats with more profound effects in the high-dose cannabis group.

Inter-species differences in CB_1 receptor expression and effects of cannabinoids on G-protein turnover in cerebellar membranes

CB_1 receptor density was first investigated by saturation binding assay using [^{3}H]-SR141716A in membranes from treatment-naïve mouse, rat, chicken, dog and human cerebellar tissue (Figure 6D, panel a, and Table 5). [^{35}S]-GTPγS binding assays were also conducted using the same membrane preparations to examine the effects of THC, THC + CBD (in the same 1:08:1.00 ratio used in *in vivo* rat study above) and CBD alone. For THC-alone datasets, a range of basal activity (measured as actual dpm in the presence of the lowest concentration of agonist) between species was observed (Figure 6D, panel b). Following data normalization (Figure 6D, panel c), rats, mice and chickens were shown to have similar EC_{50} values, while humans showed the highest and dogs the lowest EC_{50}; however, it is possible to have greater sensitivity but less consequence of activation, and THC E_{max} was numerically higher for chickens, rats and dogs than mice and humans (Table 5). For THC plus CBD, while a range of basal activity was again evident (Figure 6E, panel a), normalized treatment-induced increases in stimulation were much more limited in comparison with THC alone (Figure 6 E, panel b, vs. D, panel c) and, for the human, dog and mouse, fits could not be derived (Table 5). For CBD alone, a range of basal activity was again seen, and approximately negligible [^{35}S]-GTPγS binding was observed (Figure 6E, panels c, d), consistent with a lack of CB_1 receptor agonist effect, as reported by us previously (Jones *et al.*, 2010).

Table 5

Species-specific responses in radioligand binding assays

Species	Saturation binding		[^{35}S]-GTPγS assays			
			THC		THC + CBD (1.08:1.00)	
	B_{max} (pmol·mg^{-1})	K_D (nM)	EC_{50} (nM)	E_{max} (% over basal)	EC_{50} (nM)	E_{max} (% over basal)
Mouse	3.94 ± 0.38	3.18 ± 0.59	76	9.4 ± 5.9	N/A	N/A
Rat	1.91 ± 0.04	1.14 ± 0.13	58	29.0 ± 1.2	52	20.8 ± 0.9
Chicken	1.80 ± 0.09	2.21 ± 0.98	97	37.0 ± 4.5	72	23.9 ± 2.1
Dog	1.01 ± 0.11	0.97 ± 0.36	281	28.8 ± 4.1	N/A	N/A
Human	0.30 ± 0.11	1.03 ± 0.18	17	6.6 ± 6.1	N/A	N/A

B_{max} (pmol·mg^{-1}) and K_D (nM) derived from saturation binding of [^{3}H]-SR141716A (Figure 6D, panel a) and EC_{50} (nM) (derived from a single fit to group data) and E_{max} (% over basal) for THC (Figure 6D, panel c) and THC + CBD (1.08:1.00 ratio) (Figure 6E, panel b) derived from [^{35}S]-GTPγS assays conducted using membranes prepared from treatment-naïve cerebellae. EC_{50} for THC + CBD (derived from a single fit to group data) is expressed against concentration of THC present in the assay. CBD alone was also examined in all species but revealed approximately negligible [^{35}S]-GTPγS binding (Figure 6E, panel d), as was also the case for THC + CBD in human, dog and mouse membranes. In these cases, EC_{50} and E_{max} could not be confidently estimated and are omitted and recorded as N/A. Values shown are mean ± SEM; experiments in triplicate in three separate preparations. N/A, not available.

To best assess our supporting *in vitro* data, we combined these observations to provide an overall profile of THC-mediated, CB_1 receptor-mediated signalling for each species (Figure 6F) by normalizing CB_1 receptor expression (B_{max}; 'Expression') (Figure 6D, panel a), basal G-protein turnover (dpm at the lowest concentration of THC; 'Basal'; Figure 6D, panel b) and sensitivity (EC_{50}; 'Sensitivity') and activation (E_{max}; 'Extent') in response to agonist stimulation (Figure 6D, panel c), to the species with the highest value for each measure. We term this measure the 'eCB signalling footprint'; as discussed more fully below, together these data suggest species-specific differences in this profile with the highest value in the rat, intermediate values in the mouse and chicken and comparably lower values for humans and dogs.

Discussion

We show that motor convulsions in rats, but not dog, can be induced by sustained treatment with cannabis extract in a dose-related manner; effects of higher dose cannabis extract in rats are subserved by primary, generalized epileptiform discharges *in vivo* and are associated with impaired CB_1 receptor-mediated signalling. Furthermore, *in vitro* profiling experiments suggest that eCB signalling plays a more dominant role in rat, a species susceptible to cannabis extract-induced seizures, than in dog, a species resistant to such seizures.

Prolonged cannabis extract treatment causes spontaneous convulsions due to primary, generalized epileptiform events and associated deficits in CB_1 receptor signalling in rats

In behavioural analysis of cannabis extract-treated rats, behaviours classically associated with primary generalized seizures, including myoclonic jerk and convulsions (Mastropaolo *et al.*, 2004; Luttjohann *et al.*, 2009), were positively correlated with high-dose treatment; by contrast, rats exhibited limited peripheral symptoms following such treatment. Sustained cannabis extract exposure induced spontaneous convulsions in rats. Here, the frequency of convulsive episodes induced at the higher dose was lower than that reported in a previous study for comparable doses of THC (administered alone) in rats (Chan *et al.*, 1996). Since the same route and administration frequency, plus similar formulation, were used, we suggest that CBD in our cannabis preparations may exert anticonvulsant effects (Rosenberg *et al.*, 2015) that limited, but did not prevent, proconvulsant effects of THC. We also propose that measurements of acute cannabis extract effects in rats reflect handling and/or drug-related stress effects; thus, when measured within 10 min of drug administration, several behaviours were exacerbated, and similar behavioural responses have been noted previously (Chan *et al.*, 1996; NTP, 1996). As such, for measures of acute cannabis extract effects, it may be difficult to determine the relative influences of (i) interactions between handling and pharmacological effects of cannabinoids already present, (ii) acute responses to formulation palatability and/or gavage and (iii) rising plasma concentrations of cannabinoids after dosing (phytocannabinoid T_{max} in rodents (p.o.): ~30–60 min (Deiana *et al.*, 2012), upon positively correlated seizure-associated behaviours in rats. Persistent behavioural symptoms only manifested after several days' sustained treatment in both rat and dog. Phytocannabinoid p.o. bioavailability is known to be poor, but lipophilicity is high, meaning that repeated administration for several days is needed to saturate the fat compartment and thereafter achieve higher plasma concentrations (Sharma *et al.*, 2012). Moreover, adaptive responses by signalling systems (e.g. protein trafficking) targeted by phytocannabinoids may require several days to manifest (Silva *et al.*, 2016).

We demonstrate for the first time that cannabis extract-induced convulsions in rats are subserved by spontaneous epileptiform discharges. Such seizures in rodents are characterized by EEG abnormalities such as 6–10 Hz spike–wave discharges (behavioural arrest), 5–9 Hz spiking (facial clonus) and rising and falling frequency 2–3 to 6–7 Hz high-amplitude events (clonic or tonic–clonic seizures) (Luttjohann *et al.*, 2009). We routinely observed these associated behaviours in rat; moreover, power spectra revealed peaks in the equivalent frequency bands. Of further interest was that high-dose cannabis extract reliably produced such seizures; however, only one rat with low-dose treatment demonstrated epileptiform activity, and this was not accompanied with a motor convulsion.

Our radioligand binding results in cannabis extract-treated rats demonstrate that THC effects on the endogenous cannabinoid system signalling were clearly impaired in a dose-related manner. Thus, among the 13 week treatment groups, high-dose cannabis extract treatment caused CB_1 receptor-mediated G-protein signalling to be severely attenuated such that we were unable to fit curves to derive any EC_{50} value and E_{max} was clearly depressed. Overall, we propose that prolonged high-dose cannabis extracts functionally impairs eCB system signalling and that this mechanism underlies the reported exacerbation of seizures in rat. It was of interest that the incidence of seizure-associated behaviours in rats diminished from day ~50; these data are consistent with a long-term suppression of seizures, as reported from day ~500 in rats treated with THC for 2 years (Chan *et al.*, 1996). Temporal profiles of this sort are distinct from that associated with kindling, a commonly used model of human epilepsy (Bertram, 2007), and, we suggest, are manifestations of an adaptive response to a down-regulated eCB system to restore physiological seizure threshold.

Inter-species differences in susceptibility to cannabis extract-induced convulsions

The predictive validity of non-human models for cannabinoid effects is generally regarded as inconsistent; moreover, therapeutic cannabis benefits are predicted from animal models of anxiety, depression, schizophrenia and pain; conversely, evidence supports exacerbation of mental illness and contraindication of CB_1 receptor ligands in people with a history of seizures (Hill *et al.*, 2012). We therefore investigated the effects of different cannabis extracts on behaviours (including seizure activity) in an alternative (canine) species to rat. Of interest is that dogs (including beagles) are highly susceptible to epilepsy (Heske *et al.*, 2014). Cannabinoid

plasma concentrations detected were consistent with ranges associated with human recreational and medicinal use in both the rat and dog (Lee *et al*., 2015). Here, we report that, despite this general sensitivity, sustained cannabis extract exposure for up to 52 weeks in dogs is not a precipitating factor for seizures; although we cannot fully rule out the effects at higher cannabis extract doses than tested here, we demonstrate clear species differences in terms of lack of cannabis extract-induced seizures and limited effects on CNS behavioural measures in dogs. Brain cannabinoid concentration levels were not measured in dogs; however, we reason that plasma cannabinoid concentration is proportional to brain concentration [as phytocannabinnoids readily penetrate the mammalian blood–brain barrier (Deiana *et al*., 2012) and there is no *a priori* reason to believe that the canine blood–brain barrier differentially affects this parameter] allowing us to extrapolate from plasma data. Dogs receiving intermediate- and high-dose cannabis extract treatment also received a habituation phase to avoid potentially toxic effects in this higher species; however, no seizures were seen in this period. Moreover, by directly comparing cannabinoid plasma concentrations, it is clear that despite low-dose cannabis extract-treated rats having THC plasma levels ~70-fold lower than high-dose-treated dogs, we saw more pronounced CNS behavioural effects in rats and were still able to report seizure-related behaviours and (albeit rare) epileptiform events, which were never seen dog, even at high dose. It is also of note that, relative to dose administered, the plasma concentration of the active metabolite 11-OH-THC, which has reportedly higher *in vivo* potency than THC (Lemberger *et al*., 1973), was higher in dog than rat. Overall, these data are consistent with THC pharmacokinetic differences not being able to explain fully these differences in seizure behaviour. A pertinent difference was that plasma CBD levels were also consistently higher in the dog than rat; thus, our data are also consistent with increased CBD levels in dogs acting to ameliorate the proconvulsant effects of long-term THC seen in rats, as reported recently for CBD prevention of chronic THC-induced long-term behavioural abnormalities in mice (Murphy *et al*., 2017).

Results from our supporting description of eCB signalling footprint between species suggest a profile whereby rat > chicken > mouse > human = dog. Of interest is that this profile was highest in rat, a species in which cannabis extracts induced reliable epileptiform convulsions and caused clear signalling down-regulation, but was lowest in dog, a species in which epileptiform convulsions did not occur. These data also support previous meta-analysis across different studies whereby THC was reported to show differential inhibitory constant (K_i) values between human versus rat CB_1 receptors (McPartland *et al*., 2007). Our data further confirms a lack of CB_1 receptor signalling by CBD alone and, consistent with previous reports (McPartland *et al*., 2015), that the presence of higher concentrations of CBD reduced THC-induced effects in our [^{35}S]-GTPγS assays. The latter may reflect an attenuation of THC's effects by CBD, and these data are further consistent with the lack of seizure-related behaviour seen in dogs, as discussed above; alternatively, this may reflect CBD negative allosteric modulation (Laprairie *et al*., 2015) and/or non-specific effects due to cannabinoid lipophilicity. Taken together, this description suggests that seizure activity in rats reflects THC proconvulsant effects and that the eCB system plays a greater role in the physiology of species susceptible to THC/cannabis-induced seizures than species where seizures are not seen.

In terms of potential mechanism of action, CB_1 receptor-mediated signalling acts primarily to inhibit neurotransmitter release from excitatory and inhibitory presynapses in the CNS (Diana & Marty, 2004). We propose that eCB signalling plays a greater role in regulating neurotransmitter release in species susceptible to cannabis-induced seizure; for example, a THC-induced down-regulation of eCB signalling may lead to a net loss of CB_1 receptor-mediated inhibition of excitatory neurotransmitter release in these species to allow seizures to manifest. It is possible that the lower eCB signalling footprint we identified in dogs is reflected by a resistance of CB_1 receptors to down-regulation or, for example, that CB_1 receptors are more weakly coupled to inhibition of presynaptic neurotransmitter release.

Conclusions and future perspectives

Our data suggest that choice of model species to study cannabis-induced convulsions may have important implications in extrapolation to the human condition. We reveal clear differences in seizure behaviour and in cannabinoid plasma concentrations in response to cannabis extract consumption in rats versus dogs and suggest differences in eCB signalling in rats compared with dogs and humans (and to a lesser extent to mice and chickens). In humans, the reported THC : CBD plasma concentration ratio following p.o. (Guy & Robson, 2003) or oromucosal (Karschner *et al*., 2011) administration of similar cannabis extracts better approximates values for rats, rather than dogs, reported here. When set beside our findings that prolonged cannabis extract treatment induced seizures in rats but not dogs, our study indicates a poor predictive validity for animal models when assessing cannabis-mediated effects in humans. Thus, we propose a number of important caveats that must be considered in this context; specifically, irrespective of species, responses to acute exposure to eCB system modulators are unlikely to reflect responses to sustained exposure, the latter potentially due to a propensity for CB_1 receptor down-regulation. Further, the eCB system may play a more dominant role in the physiology of lower-order species. As such, assertions of therapeutic benefits or risks from rodent data may be diminished in clinical conditions. It is therefore important that an investigation of comparative eCB system physiology between species is undertaken to determine model predictive validity. As such, greater use of acutely excised human tissue and characterization of the eCB system in human stem cell-derived cultures may address these problems and better predict potential risks associated with an emerging new wave of cannabinoid therapeutics.

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Author contributions

B.J.W., R.A.G., C.E.R., M.B. and G.J.S. wrote the manuscript, designed the experiments and analysed the data; H.L. conducted the radioligand binding; L.B. analysed the data; T.H. wrote the manuscript and designed the experiments; A.P. designed the experiments and analysed the data; and O.D. and C.M.W. wrote the manuscript and analysed the data.

Conflict of interest

T.H. is formerly an employee of GW Pharmaceuticals Ltd. B.J.W., A.P., R.A.G., C.E.R. and M.B. were employees of GW Pharmaceuticals Ltd at the time of article submission. O.D. has commercial interests in several companies involved in the production of medicinal cannabis products, including consultant work for GW Pharmaceuticals Ltd and equity interests in other companies involved in the production of cannabis-related products to treat epilepsy, including Privateer Holdings, Tilray, Receptor Life Sciences and Egg Rock.

Correction note

This article was corrected on the 20th of February 2019 following original publication online Early View on the 25th of March 2018. The Conflict of interest section was updated to include interests mistakenly omitted from the original submission.

Declaration of transparency and scientific rigour

This Declaration acknowledges that this paper adheres to the principles for transparent reporting and scientific rigour of preclinical research recommended by funding agencies, publishers and other organisations engaged with supporting research.

References

Alexander SPH, Christopoulos A, Davenport AP, Kelly E, Marrion NV, Peters JA *et al*. (2017). The Concise Guide to PHARMACOLOGY: G protein-coupled receptors. Br J Pharmacol 174: S17–S129.

Bertram E (2007). The relevance of kindling for human epilepsy. Epilepsia 48: 65–74.

Black JW, Leff P (1983). Operational models of pharmacological agonism. Proc R Soc Lond B Biol Sci 220: 141–162.

Castaneto MS, Gorelick DA, Desrosiers NA, Hartman RL, Pirard S, Huestis MA (2014). Synthetic cannabinoids: epidemiology, pharmacodynamics, and clinical implications. Drug Alcohol Depend 144: 12–41.

Chan PC, Sills RC, Braun AG, Haseman JK, Bucher JR (1996). Toxicity and carcinogenicity of Δ^9-tetrahydrocannabinol in Fischer rats and B6C3F1 mice. Fundam Appl Toxicol 30: 109–117.

Curtis MJ, Bond RA, Spina D, Ahluwalia A, Alexander SP, Giembycz MA *et al*. (2015). Experimental design and analysis and their reporting: new guidance for publication in BJP. Br J Pharmacol 172: 3461–3471.

Deiana S, Watanabe A, Yamasaki Y, Amada N, Arthur M, Fleming S *et al*. (2012). Plasma and brain pharmacokinetic profile of cannabidiol (CBD), cannabidivarine (CBDV), Δ^9-tetrahydrocannabivarin (THCV) and cannabigerol (CBG) in rats and mice following oral and intraperitoneal administration and CBD action on obsessive–compulsive behaviour. Psychopharmacology (Berl) 219: 859–873.

Devinsky O, Cilio MR, Cross H, Fernandez-Ruiz J, French J, Hill C *et al*. (2014). Cannabidiol: pharmacology and potential therapeutic role in epilepsy and other neuropsychiatric disorders. Epilepsia 55: 791–802.

Devinsky O, Cross JH, Laux L, Marsh E, Miller I, Nabbout R *et al*. (2017). Trial of cannabidiol for drug-resistant seizures in the Dravet syndrome. N Engll J Med 376: 2011–2020.

Devinsky O, Marsh E, Friedman D, Thiele E, Laux L, Sullivan J *et al*. (2016). Cannabidiol in patients with treatment-resistant epilepsy: an open-label interventional trial. Lancet Neurol 15: 270–278.

Devinsky O, Whalley BJ, Di Marzo V (2015). Cannabinoids in the treatment of neurological disorders. Neurotherapeutics 12: 689–691.

Diana MA, Marty A (2004). Endocannabinoid-mediated short-term synaptic plasticity: depolarization-induced suppression of inhibition (DSI) and depolarization-induced suppression of excitation (DSE). Br J Pharmacol 142: 9–19.

Fitzgerald KT, Bronstein AC, Newquist KL (2013). Marijuana poisoning. Top Companion Anim Med 28: 8–12.

Gurney SM, Scott KS, Kacinko SL, Presley BC, Logan BK (2014). Pharmacology, toxicology, and adverse effects of synthetic cannabinoid drugs. Forensic Sci Rev 26: 53–78.

Guy GW, Robson P (2003). A phase I, open label, four-way crossover study to compare the pharmacokinetic profiles of a single dose of 20 mg of a cannabis based medicine extract (CBME) administered on 3 difference areas of the buccal mucosa and to investigate the pharmacokinetics of CBME per oral in healthy male and female volunteers. J Cannabis Ther 3: 79–120.

Harding SD, Sharman JL, Faccenda E, Southan C, Pawson AJ, Ireland S *et al*. (2018). The IUPHAR/BPS Guide to PHARMACOLOGY in 2018: updates and expansion to encompass the new guide to IMMUNOPHARMACOLOGY. Nucl Acids Res 46: D1091–D1106.

Herkenham M, Lynn AB, Little MD, Johnson MR, Melvin LS, de Costa BR *et al*. (1990). Cannabinoid receptor localization in brain. Proc Natl Acad Sci U S A 87: 1932–1936.

Heske L, Nødtvedt A, Jäderlund KH, Berendt M, Egenvall A (2014). A cohort study of epilepsy among 665,000 insured dogs: incidence, mortality and survival after diagnosis. Vet J 202: 471–476.

Hill AJ, Williams CM, Whalley BJ, Stephens GJ (2012). Phytocannabinoids as novel therapeutic agents in CNS disorders. Pharmacol Ther 133: 79–97.

Jones NA, Glyn SE, Akiyama S, Hill TDM, Hill AJ, Weston SE *et al*. (2012). Cannabidiol exerts anti-convulsant effects in animal models of temporal lobe and partial seizures. Seizure-Eur J Epilepsy 21: 344–352.

Jones NA, Hill AJ, Smith I, Bevan SA, Williams CM, Whalley BJ *et al*. (2010). Cannabidiol displays antiepileptiform and antiseizure properties *in vitro* and *in vivo*. J Pharmacol Exp Ther 332: 569–577.

Karschner EL, Darwin WD, Goodwin RS, Wright S, Huestis MA (2011). Plasma cannabinoid pharmacokinetics following controlled oral Δ^9-tetrahydrocannabinol and oromucosal cannabis extract administration. Clin Chem 57: 66–75.

Kilkenny C, Browne W, Cuthill IC, Emerson M, Altman DG (2010). Animal research: reporting *in vivo* experiments: the ARRIVE guidelines. Br J Pharmacol 160: 1577–1579.

Laprairie RB, Bagher AM, Kelly ME, Denovan-Wright EM (2015). Cannabidiol is a negative allosteric modulator of the cannabinoid CB_1 receptor. Br J Pharmacol 172: 4790–4805.

Lee D, Bergamaschi MM, Milman G, Barnes AJ, Queiroz RH, Vandrey R *et al*. (2015). Plasma cannabinoid pharmacokinetics after controlled smoking and ad libitum cannabis smoking in chronic frequent users. J Anal Toxicol 39: 580–587.

Lemberger L, Martz R, Rodda B, Forney R, Rowe H (1973). Comparative pharmacology of Δ^9-tetrahydrocannabinol and its metabolite, 11-OH-Δ^9-tetrahydrocannabinol. J Clin Invest 52: 2411–2417.

Luttjohann A, Fabene PF, van Luijtelaar G (2009). A revised Racine's scale for PTZ-induced seizures in rats. Physiol Behav 98: 579–586.

Mastropaolo J, Rosse RB, Deutsch SI (2004). Anabasine, a selective nicotinic acetylcholine receptor agonist, antagonizes MK-801-elicited mouse popping behavior, an animal model of schizophrenia. Behav Brain Res 153: 419–422.

McGrath JC, Lilley E (2015). Implementing guidelines on reporting research using animals (ARRIVE etc.): new requirements for publication in BJP. Br J Pharmacol 172: 3189–3193.

McPartland JM, Duncan M, Di Marzo V, Pertwee RG (2015). Are cannabidiol and Δ^9-tetrahydrocannabivarin negative modulators of the endocannabinoid system? A systematic review. Br J Pharmacol 172: 737–753.

McPartland JM, Glass M, Pertwee RG (2007). Meta-analysis of cannabinoid ligand binding affinity and receptor distribution: interspecies differences. Br J Pharmacol 152: 583–593.

Murphy M, Mills S, Winstone J Leishman E, Wager-Miller J, Bradshaw H *et al*. (2017). Chronic adolescent Δ^9-tetrahydrocannabinol treatment of male mice leads to long-term cognitive and behavioral dysfunction, which are prevented by concurrent cannabidiol treatment. Cannabis Cannabinoid Res 2: 235–246.

NTP (1996). National Toxicology Program – toxicology and carcinogenesis studies of 1-trans-Δ^9-tetrahydrocannabinol (CAS no. 1972-08-3) in F344 rats and B6C3F1 mice (gavage studies). Natl Toxicol Program Tech Rep Ser 446: 1–317.

Press CA, Knupp KG, Chapman KE (2015). Parental reporting of response to oral cannabis extracts for treatment of refractory epilepsy. Epilepsy Behav 45: 49–52.

Rosenberg EC, Tsien RW, Whalley BJ, Devinsky O (2015). Cannabinoids and epilepsy. Neurotherapeutics 12: 747–768.

Rosenberg EC, Patra PH, Whalley BJ (2017). Therapeutic effects of cannabinoids in animal models of seizures, epilepsy, epileptogenesis, and epilepsy-related neuroprotection. Epilepsy Behav 70: 319–327.

Sharma P, Murthy P, Bharath MM (2012). Chemistry, metabolism, and toxicology of cannabis: clinical implications. Iran J Psychiatry 7: 149–156.

Silva L, Black R, Michaelides M, Hurd YL, Dow-Edwards D (2016). Sex and age specific effects of Δ^9-tetrahydrocannabinol during the periadolescent period in the rat: the unique susceptibility of the prepubescent animal. Neurotoxicol Teratol 58: 88–100.

Tsou K, Brown S, Sanudo-Pena MC, Mackie K, Walker JM (1998). Immunohistochemical distribution of cannabinoid CB_1 receptors in the rat central nervous system. Neuroscience 83: 393–411.

Volkow ND, Baler RD, Compton WM, Weiss SR (2014). Adverse health effects of marijuana use. N Engl J Med 370: 2219–2227.

Wolfensohn S, Lloyd M (2013). Handbook of Laboratory Animal Management and Welfare. Wiley & Sons: Oxford.

Supporting Information

Additional Supporting Information may be found online in the supporting information tab for this article.

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Table S1 Incidence of behaviours in rats (n=10 per group) observed immediately after (10 min; 'acute') or ~23 hours after ('persistent') daily oral administration of low dose (1.08 mg kg^{-1} Δ^9-THC + 1 mg kg^{-1} CBD) or high dose (40.5 mg kg^{-1} Δ^9-THC + 37.5 mg kg^{-1} CBD) cannabis extract for 13 weeks that exhibited a median and IQR of zero. Behavioural events conventionally associated with generalised seizures in rodents are highlighted in bold.

Table S2 Table showing squared cosine and percentage contribution of each measured behaviour following variance-covariance principal component analysis applied to all behaviours recorded in low dose (1.08 mg kg^{-1} Δ^9-THC + 1 mg kg^{-1} CBD) and high dose (40.5 mg kg^{-1} Δ^9-THC + 37.5 mg kg^{-1} CBD) cannabis extract treated animals. Behaviours highlighted in bold show those conventionally associated with primary generalised seizures in rodents (see also: Figures 1 & 2). Squared cosine values shown in bold highlight the principal component in which the value exhibited its highest value. Table also shows factor values for each observation for the first two principal components (F1 and F2).

Table S3 Incidence of all convulsive motor events and/or epileptiform events exhibited in rats treated with low dose (1.08 mg kg^{-1} Δ^9-THC plus 1 mg kg^{-1} CBD) or high dose (40.5 mg kg^{-1} Δ^9-THC plus 37.5 mg kg^{-1} CBD) cannabis extract for 13 weeks. Note that in some case, accompanying EEG recordings (see Figure) showed (*) multiple, discrete, epileptiform events during a single motor convulsion and (**) animal handling or severity of motor convulsion that prevented acquisition of valid EEG data.

Is It Really 'FDA Approved?'

"FDA approved!"

Maybe you saw those words on a company's website, or in a commercial promoting a new product or treatment. Some marketers may say their products are "FDA approved," but how can you know for sure what the U.S. Food and Drug Administration approves?

FDA is responsible for protecting public health by regulating human drugs and biologics, animal drugs, medical devices, tobacco products, food (including animal food), cosmetics, and electronic products that emit radiation.

But not all those products undergo premarket approval — that is, a review of safety and effectiveness by FDA experts and agency approval before a product can be marketed. In some cases, FDA's enforcement efforts focus on products after they are already for sale. That is determined by Congress in establishing FDA's authorities (/about-fda/fda-basics/what-does-fda-regulate). Even when FDA approval is not required before a product is sold, the agency has regulatory authority (http://www.fda.gov/NewsEvents/ProductsApprovals/default.htm) to act when safety issues arise.

Here is a guide to how FDA regulates products — and what the agency does (and doesn't) approve.

FDA doesn't approve companies.

FDA does not “approve” health care facilities, laboratories, or manufacturers. FDA does have authority to inspect regulated facilities to verify that they comply with applicable good manufacturing practice regulations.

Owners and operators of domestic or foreign food, drug, and most device facilities must register their facilities with FDA, unless an exemption applies. Blood and tissue facilities also must register with the agency.

Mammography facilities must be FDA certified and must display their FDA certificates where patients can see them. The certificate indicates that the facilities have met stringent standards for providing quality mammography (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm).

FDA approves new drugs and biologics.

New drugs and certain biologics must be proven safe and effective to FDA’s satisfaction before companies can market them in interstate commerce. Some examples of biologics that require approval are therapeutic proteins, vaccines, cellular therapies, and blood and blood products. Manufacturers must also prove they are able to make the drug product according to federal quality standards.

FDA does not develop or test products before approving them. Instead, FDA experts review the results of laboratory, animal, and human clinical testing done by manufacturers. If FDA grants an approval, it means the agency has determined that the benefits of the product outweigh the known risks for the intended use.

See the directory of approved and unapproved finished drugs on the market (/drugs/drug-approvals-and-databases/national-drug-code-directory).

FDA doesn’t approve compounded drugs.

Compounding is generally a practice in which a pharmacist or a doctor combines ingredients to create medications that meet the needs of individual patients, including those who are allergic to ingredients in FDA-approved medicines or who cannot swallow an FDA-approved pill. But consumers need to be aware that compounded drugs are not FDA approved. This means that FDA does not review applications for compounded drugs to evaluate their safety, effectiveness, or quality.

FDA uses a risk-based, tiered approach for regulating medical devices.

FDA classifies devices according to risk. The highest-risk devices (Class III), such as mechanical heart valves and implantable infusion pumps, generally require FDA approval of a premarket approval application before marketing. To receive FDA approval for these devices, manufacturers must demonstrate with sufficient, valid scientific evidence that there is a reasonable assurance that the devices are safe and effective for their intended uses.

Generally, FDA “clears” moderate-risk medical devices (Class II) (for example dialysis equipment and many types of catheters) for marketing once it has been demonstrated that the device is substantially equivalent to a legally marketed predicate device that does not require premarket approval.

Devices that present a low risk of harm to the user (Class I) (for example non-powered breast pumps, elastic bandages, tongue depressors, and exam gloves) are subject to general controls only, and most are exempt from premarket notification requirements.

FDA uses a risk-based approach for human cells and tissues.

All human cells and tissues intended for use in humans — collectively referred to as human cells, tissues, and cellular and tissue based products — are regulated to prevent the transmission of infectious disease. Those that pose an additional risk also require FDA approval before marketing. Examples of cells and tissues include bone, skin, corneas, ligaments, tendons, dura mater, heart valves, and reproductive tissue.

FDA doesn't approve tobacco products.

There's no such thing as a safe tobacco product, so FDA's safe and effective standard for evaluating medical products is not appropriate for tobacco products. Instead, FDA regulates tobacco products based on a public health standard that considers the product's risks to the population as a whole.

To legally sell or distribute a new tobacco product in the United States, manufacturers must receive a written order from FDA. There are three pathways are available to bring a tobacco product to market: premarket tobacco applications (/premarket-tobacco-applications), substantial equivalence applications (http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/default.htm), or exemption from substantial equivalence (http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ExemptionfromSubstantialEquivalence/default.htm).

A marketing order does not indicate that the tobacco product is either safe or "approved." It means that the manufacturer has complied with the requirements under the law to bring its product to market.

FDA approves food additives in food for people.

Although FDA does not have premarket approval of food products, it has the authority to approve certain ingredients before they are used in foods. Those include food additives, such as substances added intentionally to food, and color additives.

Companies that want to add new food additives to food are responsible for providing FDA with information demonstrating that the additives are safe. FDA experts review the results of appropriate tests done by companies to ensure that the food additive is safe for its intended use. An approved food additive must be used in compliance with its approved uses, specifications, and restrictions.

Some food additives are food contact substances that could migrate into food, such as coatings, plastics, paper and adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging. They undergo a different review process. The same safety standards still apply, but the food contact notification process is specific to the identified manufacturer or supplier. If at the end of the review period FDA does not object, the food contact notification becomes effective and the food contact substance may be legally marketed.

Certain food ingredients, such as those that are considered "generally recognized as safe" (GRAS) by scientific experts, do not require premarket approval as a food additive. FDA has a voluntary notification process under which a manufacturer may submit a conclusion that the use of an ingredient is GRAS.

FDA approves color additives used in FDA-regulated products.

This includes those used in food (including animal food), dietary supplements, drugs, cosmetics, and some medical devices. These color additives (except coal-tar hair dyes) are subject by law to approval by the agency, and each must be used only in compliance with its approved uses, specifications, and restrictions.

In the approval process, FDA evaluates safety data to ensure that a color additive is safe for its intended purposes.

FDA approves animal drugs and approves food additives for use in food for animals.

FDA is responsible for approving drugs for animals, including pets, livestock, and poultry. (Minor animal species include animals other than cattle, swine, chickens, turkeys, horses, dogs, and cats.)

Although FDA does not approve animal foods, including pet food, for marketing, it does approve food additives used in these products. FDA works to help ensure that food for animals (which includes livestock and poultry food, pet food and pet treats) is safe, made under sanitary conditions, and properly labeled.

The Preventive Controls for Animal Food rule, a new regulation mandated by the FDA Food Safety Modernization Act (FSMA), requires food companies to take steps to prevent foods from being contaminated and to use current good manufacturing practices (such as hygienic personnel practices, adequate sanitation practices, and proper equipment use) when making food for animals.

FDA does not approve cosmetics.

Examples of cosmetics are perfumes, makeup, moisturizers, shampoos, hair dyes, face and body cleansers, and shaving preparations. Cosmetic products and ingredients, and their labeling, do not require FDA approval before they go on the market. There's one exception: color additives (other than coal-tar hair dyes). Cosmetics must be safe for their intended use and properly labeled.

FDA doesn't approve medical foods.

A medical food is used for the dietary management of a disease or health condition that requires special nutrient needs. An example of a medical food is a food for use by persons with phenylketonuria, a genetic disorder. A person with this disorder may need medical foods that are formulated to be free of the amino acid phenylalanine. A medical food is intended for use under the supervision of a physician. It doesn't include products such as meal replacements or diet shakes, or products for the management of diseases like diabetes, which can be managed through modification of the normal diet.

Medical foods do not have to undergo premarket approval by FDA. But medical food companies must comply with other requirements, such as good manufacturing practices and registration of food facilities. Medical foods do not have to include nutrition information on their labels, and any claims in their labeling must be truthful and not misleading.

FDA doesn't approve infant formula.

FDA does not approve infant formulas before they can be marketed. But manufacturers of infant formula are subject to FDA's regulatory oversight.

Manufacturers must ensure that infant formula complies with federal nutrient requirements. Manufacturers must register with FDA and provide the agency with a notification before marketing a new formula.

FDA conducts yearly inspections of all facilities that manufacture infant formula and collects and analyzes product samples. FDA also inspects new facilities. If FDA determines that an infant formula presents a risk to human health, the manufacturer of the formula must conduct a recall.

FDA doesn't approve dietary supplements.

Unlike new drugs, dietary supplements are not reviewed and approved by FDA based on their safety and effectiveness. Unless an exception applies, dietary supplements that contain a new dietary ingredient (a dietary ingredient not marketed in the United States before Oct. 15, 1994) require a notification to FDA at least 75 days before marketing.

The notification must include the information that provides the manufacturer's or distributor's basis for concluding that the dietary supplement will reasonably be expected to be safe. When public health concerns arise about a dietary supplement after the product is on the market, FDA evaluates the product's safety through research and adverse event monitoring.

FDA doesn't approve the food label, including the Nutrition Facts panel.

FDA does not approve individual food labels before food products can be marketed. But FDA regulations require nutrition information to appear on most foods, including dietary supplements. Also, any claims on food products must be truthful and not misleading, and must comply with any regulatory requirements for the type of claim.

Manufacturers must provide the serving size of the food and specified information about the nutrient content of each serving on the "Nutrition Facts" panel of the food label (or on the "Supplement Facts" panel for dietary supplements).

FDA doesn't approve structure-function claims on dietary supplements and other foods.

Structure-function claims describe the role of a food or food component (such as a nutrient) that is intended to affect the structure or function of the human body. One example is "calcium builds strong bones."

Dietary supplement companies that make structure-function claims on labels or in labeling must submit a notification to FDA. This notification must be submitted no later than 30 days after first marketing the dietary supplement with the structure-function claim. Also, the notification must include the text of the claim, as well as other information, such as the name and address of the notifier. Structure-function claims on dietary supplements carry a disclaimer stating that the claim has not been reviewed by FDA, and that the product is not intended to diagnose, treat, cure, or prevent any disease.

FDA does not require conventional food manufacturers to notify FDA about their structure-function claims or to carry a disclaimer.

Misuse of FDA's logo may violate federal law.

FDA's logo is for official government use only. FDA's logo should not be used to misrepresent the agency or to suggest that FDA endorses any private organization, product, or service.

These are just some of the many ways FDA is responsible for protecting the public health.

Administration for Children and Families, Reports Clearance Officer, Roberta Katson at (202) 401–5756.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, (202) 395–7316.

Dated: April 10, 1996.

Roberta Katson,

Director, Office of Information Resource Management Services.

[FR Doc. 96–9750 Filed 4–19–96; 8:45 am]

BILLING CODE 4184–01–M

[Program Announcement No. ACF/ACYF/RHYP 96–2]

Runaway and Homeless Youth Program (RHYP): Fiscal Year (FY) 1996 Final Program Priorities, Availability of Financial Assistance for Fiscal Year 1996, and Request for Applications for FY 1996 and FY 1997

AGENCY: Family and Youth Services Bureau (FYSB), Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Extension of due date for receipt of applications for the Basic Center Program for Runaway and Homeless Youth (BCP) for FY 1996.

SUMMARY: This notice amends program announcement number ACF–ACYF–RHYP–96–2 published in the **Federal Register** on April 15, 1996 by extending the due date for submission of the BCP applications to June 7, 1996. This notice does not affect the due date for TLP applications. That date remains June 14, 1996.

FOR FURTHER INFORMATION CONTACT: Administration on Children, Youth and Families, Family and Youth Services Bureau, P.O. Box 1182, Washington, DC 20013; Telephone: 1–800–351–2293.

SUPPLEMENTARY INFORMATION: Under Part A of the Runaway and Homeless Youth Act, as amended, the overall purpose of the Basic Center Program is to provide financial assistance to establish or strengthen community-based centers that address the immediate needs (outreach, temporary shelter, food, clothing, counseling, aftercare, and related services) of runaway and homeless youth and their families.

(Catalog of Federal Domestic Assistance. Number 93.623, Basic Center Program for Runaway and Homeless Youth; Number 93.550)

Dated: April 16, 1996.

Olivia A. Golden,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 96–9861 Filed 4–19–96; 8:45 am]

BILLING CODE 4184–01–M

President's Committee on Mental Retardation; Notice of Meeting

AGENCY HOLDING THE MEETING: President's Committee on Mental Retardation.

TIME AND DATE: Full Committee Meeting, May 24, 1996, 10:00 a.m.–4:00 p.m.

PLACE: Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW., Washington, DC 20001.

STATUS: Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All locations are barrier free.

TO BE CONSIDERED: The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness.

THE PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs and services for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

CONTACT PERSON FOR MORE INFORMATION: Gary H. Blumenthal, Wilbur J. Cohen Building, Room 5325, 330 Independence Avenue, SW., Washington, DC 20201–0001, (202) 619–0634.

Dated: April 16, 1996.

Gary H. Blumenthal,

Executive Director, PCMR.

[FR Doc. 96–9860 Filed 4–19–96; 8:45 am]

BILLING CODE 4184–01–M

Food And Drug Administration

[Docket No. 95N–0308]

Inapplicability of the Dietary Supplement Health and Education Act to Animal Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing guidance regarding the inapplicability of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) to products intended for use in animals. The agency is issuing this notice in response to inquiries received on whether the DSHEA applies to products intended for use in animals.

DATES: Submit written comments by July 22, 1996.

ADDRESSES: Written comments may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Donny Dean, Center for Veterinary Medicine (HFV–236), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1726.

SUPPLEMENTARY INFORMATION: FDA has had inquiries concerning whether the DSHEA applies to products intended for use in animals. After examining the statutory language, intent, and legislative history, the agency has determined that the DSHEA does not apply to animal products.

On October 25, 1994, the DSHEA (Pub. L. 103–417) was signed into law. The DSHEA amends the Federal Food, Drug, and Cosmetic Act (the act) to create a new regulatory scheme for ''dietary supplements.'' The DSHEA, among other things, amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a ''dietary supplement,'' in part, as a product, other than tobacco, intended to supplement the diet that contains at least one or more of the following ingredients: A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the previously

mentioned ingredients (section 201(ff)(1) of the act). The DSHEA's main effect on the act was the removal of certain dietary supplement ingredients from regulation under 21 U.S.C. 321(s) and 348, two provisions of the act regulating the safety of food ingredients. In addition, the DSHEA permits certain limited claims to be made about dietary supplements without resulting in the supplement becoming a drug under 21 U.S.C. 321(g).

The definition of ''dietary supplement'' in the DSHEA does not explicitly state whether it includes or excludes products intended for use in animals other than man. The legislative record, which is extremely brief, is likewise silent about this issue. FDA has carefully examined the new law to determine if it should be applied to animal products, and believes that it should not. When the DSHEA is read as a whole, FDA believes it is evident that Congress was concerned only with human products and did not consider animal products. For this reason, the agency concludes that Congress did not intend the law to apply to animal products. Equally important, there are some critical differences between products intended for human use and products intended for animal use that strongly favor maintaining the status quo for animal products. Accordingly, FDA does not intend to apply the DSHEA to animal products.

There is much evidence in the DSHEA that Congress did not intend to apply the amendments to animal products. First, the extensive congressional findings in section 2 of the DSHEA focus strictly on the use of dietary supplements by humans. These findings begin by stating that ''improving the health status of United States *citizens* ranks at the top of the national priorities * * *,'' id., section 2(l) of the DSHEA (emphasis added); see also id., section 2(3)(A) and (2)(4) of the DSHEA (discussing the effect of supplements on human health conditions, such as ''cancer, heart disease, and osteoporosis'' and ''medical procedures, such as coronary bypass surgery or angioplasty.'') This strict focus on humans in the congressional findings reflects Congress' intent that the law apply only to humans. See *United States* v. *Solid Gold Holistic Animal Equine Nutrition Center* et al., No. CV 88–0473–GT, slip op. at 7–8 (S.D. Cal. March 2, 1995) (Ref. 1).

Next, although the definition of ''dietary supplement'' contains no explicit reference to products intended for use by animals, part of the definition does contain an explicit reference to products intended for use by humans (section 3 of the DSHEA (creating 21 U.S.C. 321(ff)(1)(E))). This is further evidence that Congress intended the law to apply to supplements used by humans, not supplements for other animals.

Furthermore, many of the changes made by the DSHEA apply only to supplements intended for human use because the sections of the act that were amended by the DSHEA apply only to human products—yet another strong signal that Congress was only concerned with human supplements. For example, when the DSHEA sets out the standards for determining whether a product that has been approved or investigated as a drug can also be sold as a dietary supplement, it cites only to the human drug provisions of the act, but not to any of the animal drug provisions. See 21 U.S.C. 321(ff)(3). Likewise, the changes to food labeling made by the DSHEA apply only to human food because the sections in the act that are amended are in 21 U.S.C. 343(r), which applies only to ''food for human consumption.''

Moreover, FDA believes the public health will be better protected if ingredients in animal dietary supplements are not subject to the special treatment provided for ingredients of human supplements by the DSHEA. Under the act's food additive provisions, 21 U.S.C. 321(s) and 348, before FDA can approve a product for use in a food producing animal, FDA must determine that the product will not leave harmful residues in food (21 U.S.C. 348(b)(2) and (c)(5), and 21 CFR part 570). If the compound or any of its metabolites induces cancer, the act imposes additional requirements on the approval of the compound (21 U.S.C. 348(c)(3)(A) and 21 CFR part 500, subpart E). However, nowhere in its revision of the regulation of ingredients in dietary supplements does the DSHEA address how the effect of supplements on food producing animals and human food safety is to be assessed. It seems unlikely that Congress would so alter the regulation of animal foods with no consideration—indeed, no mention—of the impact of the alteration on the safety of the nation's food supply.[1]

Not only are there human food safety concerns, but when compared with human use of supplements, there is less information on the safe use of dietary supplements in animals. Many substances that fall under the definition of dietary supplements for human consumption, such as herbs and other botanicals, have a history of use in humans that can be used to establish reasonably safe levels. However, the same is not true for use of many of these same ingredients in animals. As far as FDA is aware, very few substances that meet the criteria of 21 U.S.C. 321(ff)(1) and (ff)(2) have any established history of safe use in any animal. Moreover, each animal species requires different nutrients, absorbs and metabolizes nutrients differently, and can exhibit different toxic reactions to food and its components. The lack of information on the safe use of these kinds of substances in animals, and the fact that the animal population is not as homogenous as the human population are two more reasons why FDA has determined that the DSHEA should not apply to animal products.[2]

Finally, many drugs intended to increase the production of meat, milk, egg, or fiber (so-called production drugs) or otherwise affect animal performance could arguably be covered as dietary supplements under the DSHEA. Currently, products bearing such production claims are animal drugs under the act, and as such, can only be marketed after approval by FDA after the manufacturer conducts extensive scientific studies to show that the drug is both safe (in animals and humans) and effective (21 U.S.C. 360b). To allow new production drugs to be marketed under the provisions of the DSHEA not only raises exactly the same food safety concerns previously discussed about food additives, but would also be unfair to existing approved products, and would serve as a disincentive to develop and use legitimate drugs in the future.

In sum, although the DSHEA does not speak directly to the question, we think that the DSHEA was not intended to apply to animal products. Moreover, we

[1] The findings make clear that one underpinning of the new legislation was Congressional concern that consumers should have the freedom to make their own choices about whether to take dietary supplements. However, that critical element of consumer choice is lacking when the supplement (or its metabolite) ends up in the diet as an unidentified residue in meat, milk, or eggs.

[2] The law devotes no resources to the human and animal health issues raised by the use of supplements in animals. The DSHEA does mandate the establishment of an office within the National Institutes of Health to oversee scientific study of dietary supplements, as well as a seven-member commission to provide recommendations for the regulation of label claims for supplements. However, nothing in the law directs either new group to address the use of dietary supplements in animals. Thus, there will not be any independent resource from which the Center for Veterinary Medicine (CVM) can obtain unbiased information on benefits to animal health and production, safety to animals and humans consuming edible byproducts from treated animals, or the validity of claims for animal supplements. Lacking such a resource, FDA believes it is prudent for the burden to remain, as it is now, on the manufacturer to generate safety and effectiveness data and provide it to FDA for review in feed additive petitions and new animal drug applications.

believe that there are significant, complex scientific and regulatory issues relating to human and animal safety that would need to be resolved by Congress before a similar scheme for animal supplements could be put into place. Accordingly, FDA has concluded that animal dietary supplements are not covered by the DSHEA.

Interested persons may, on or before July 22, 1996, submit to the Dockets Management Branch (address above) written comments on this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 11, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–9780 Filed 4–19–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1995. FDA has announced the availability of previous lists, which are brought up-to-date monthly, identifying the drugs and biologicals granted orphan-drug designation pursuant to the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Peter Vaccari, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0983.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologicals. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologicals, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses. The cumulative list of compounds receiving orphan-drug designation through 1988 was published in the **Federal Register** of April 21, 1989 (54 FR 16294). This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify the docket number found in brackets in the heading of this document.

The list that is the subject of this notice consists of designated orphan drugs and biologicals through December 31, 1995, and, therefore, brings the March 2, 1993 (58 FR 12041), publication up-to-date.

The orphan-drug designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing an orphan drug or biological must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for these products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: April 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–9782 Filed 4–19–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Tentative Schedule of Meetings for 1996

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for the remainder of 1996. At the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. The IOM recommended that the agency publish an annual tentative schedule of its meetings in the **Federal Register**. In response to that recommendation, FDA is publishing its annual tentative schedule of meetings for the remainder of 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report, the IOM recommended that FDA adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the **Federal Register**. FDA has implemented this recommendation. A tentative schedule of forthcoming meetings will be published annually in the **Federal Register**. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. The schedule is tentative and amendments to this notice will not be published in the **Federal Register**. FDA will, however, publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, announcing the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for the remainder of 1996:

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	January 22, 2020
2) Requestor Name	M. Mace
3) Item Title for the Agenda	Process for approval of Guidance Documents
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	No
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	Guidance documents are taking up to a year to finalize using our current process of going to the board with a request, back with a draft for comments, and then back for more comments are finalization. This takes a minimum of 3 meetings of the full board, or 9months. We would like to discuss other process that would allow for review and comment between board meetings to expedite the creating and finalization of guidance documents.

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	Melissa Mace
3) Item Title for the Agenda	Veterinarian Dispensing Prescription - Guidance
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	ATT Ltr M. Mace - DATCP - Request for Guidance Dispensing Veterinary Rx Drugs - 5-6-19 Email: RE Prescription medication dispensing questions
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	WVMA submitted a request for guidance to be provided as the Statute is unclear on if a Veterinarian can dispense Veterinary Rx Drugs when the prescription is written by another veterinarian, and the dispensing veterinarian does not have a valid VCPR. Attached Letter provides background and sites relevant sections of Wis Stat § 89.02(6m) and 89.068(1)(c), also of interest not cited in the letter is Wis. Adm Code § VE 7.06 Prohibited Conduct sub (10) *Selling veterinary prescription drugs without establishing and maintaining a VCPR*. We have also received a couple real life question regarding this issue: 1. Attached is an email from a veterinarian dispensing in order to provide a discount to Shelter Staff for Rx medicine. 2. Received a phone call from a Veterinarian who has a seasonal client that brings up prescriptions to WI and the WI veterinarian is wondering if she can fill them.

DeWitt LLP Law Firm

Direct line: 608-252-9358
Email: jkl@dewittllp.com

May 6, 2019

VIA EMAIL Melissa.Mace@wisconsin.gov

Ms. Melissa Mace
Acting Executive Director
Veterinary Examining Board
Wisconsin Dept. of Agriculture, Trade & Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911

RE: Request for Guidance on Dispensing of Veterinary Prescription Drugs

Dear Ms. Mace:

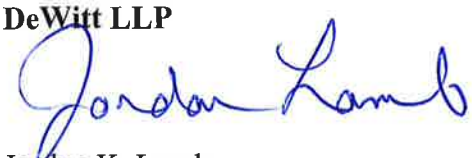
I write on behalf of the Wisconsin Veterinary Medical Association (WVMA) to request that the Veterinary Examining Board (VEB) issue formal guidance pursuant to Wis. Stat. § 227.112 regarding **the circumstances under which a veterinarian may dispense a drug for a patient of another veterinarian.** More specifically, WVMA seeks guidance from the VEB on the following questions interpreting Wis. Stat. §§ 89.02(6m) and 89.068(1)(c):

> Under what circumstances may a veterinarian licensed in Wisconsin dispense a prescription to a patient of another veterinarian?
>
> May a veterinarian dispense a drug for a patient if the dispensing veterinarian has never examined the patient and if the prescription was issued to the dispensing veterinarian by another veterinarian?

Please do not hesitate to contact me with any questions that may arise. Thank you for your attention to this important matter.

Very truly yours,

DeWitt LLP



Jordan K. Lamb

JKL:jav

cc: Ms. Kim Brown Pokorny, Executive Director, Wisconsin Veterinary Medical Assn.
Attorney J. Wesley Webendorfer, DeWitt LLP

Fisher, Angela H - DATCP

From: Mace, Melissa A - DATCP
Sent: Tuesday, January 7, 2020 12:29 PM
To: Laura Beck
Subject: RE: Prescription medication dispensing questions

This will likely result in a guidance document being drafted to clarify what is allowed regarding the dispensing of prescription drugs by a veterinarian that does not hold the VCPR. Given the board routinely meets quarterly this will not be a document that is published directly after the Jan meeting as it will need to be drafted and a final version approved by the board.

The best way for you to know the direction the VEB is going would be to reach back out to me after Jan. 22.

Melissa Mace
Director, Bureau of Field Services, Division of Animal Health
Executive Director Veterinary Examining Board
Wisconsin Department of Agriculture, Trade and Consumer Protection
Phone: 608-224-4883
Cell: 608-279-3861
Fax: 608-224-4903
Melissa.Mace@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: Laura Beck <laurabeckdvm@gmail.com>
Sent: Tuesday, January 7, 2020 12:22 PM
To: Mace, Melissa A - DATCP <Melissa.Mace@wisconsin.gov>
Subject: Re: Prescription medication dispensing questions

Thanks for your response, Melissa. Is there a way that I can be notified when a decision is made as to whether or not this is acceptable?

Dr. Beck

On Tue, Jan 7, 2020 at 12:19 PM Mace, Melissa A - DATCP <Melissa.Mace@wisconsin.gov> wrote:

> Dr. Beck;
>
> Wis. Stats §. 89.068 (1)(c)1. Requires the Veterinarian to have a valid VCPR in order to prescribe or dispense prescription drugs:

(c) Prescribing, dispensing and administering requirements for veterinarian. A veterinarian may not do any of the following:

89.068(1)(c)1. 1. Prescribe for or dispense to a client a veterinary prescription drug or a drug for extra-label use without personally examining the patient unless a veterinary-client-patient relationship exists between the veterinarian, client and patient and the veterinarian determines that the client has sufficient knowledge to administer the drug properly.

Part of the requirements for a valid VCPR requires that the **veterinarian has sufficient knowledge of the patient to initiate a general or preliminary diagnosis of the medical condition of the patient because the veterinarian has recently examined the patient** or has made medically appropriate and timely visits to the premises on which the patient is kept. (see below for full VCPR definition). As you can see there is no time specific, ex. seen in the last 12 months, it would be subject to the circumstance and action taken.

(8) "Veterinarian-client-patient relationship" means a relationship between a veterinarian, a client and the patient in which all of the following apply:

89.02(8)(a) (a) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the patient and the patient's need for medical treatment, and the client has agreed to accept those medical judgments and to follow the related instructions of the veterinarian.

89.02(8)(b) (b) The veterinarian has sufficient knowledge of the patient to initiate a general or preliminary diagnosis of the medical condition of the patient because the veterinarian has recently examined the patient or has made medically appropriate and timely visits to the premises on which the patient is kept.

89.02(8)(c) (c) The veterinarian is readily available for follow-up treatment of the patient if the patient has an adverse reaction to veterinary treatment.

This is a great and very timely question. On the agenda for the VEB's January 22 full board meeting is the discussion on if a veterinarian can fill a prescription written by another veterinarian, and if so under what circumstances.

Best Regards,

Melissa Mace

Director, Bureau of Field Services, Division of Animal Health

Executive Director Veterinary Examining Board

Wisconsin Department of Agriculture, Trade and Consumer Protection

Phone: 608-224-4883

Cell: 608-279-3861

Fax: 608-224-4903

Melissa.Mace@Wisconsin.gov

Please complete this brief survey to help us improve our customer service. Thank you for your feedback!

From: DATCP VEB <datcpveb@wisconsin.gov>
Sent: Monday, January 6, 2020 11:34 AM
To: Mace, Melissa A - DATCP <Melissa.Mace@wisconsin.gov>
Subject: FW: Prescription medication dispensing questions

From: Laura Beck <laurabeckdvm@gmail.com>
Sent: Sunday, January 5, 2020 8:17 PM
To: DATCP VEB <datcpveb@wisconsin.gov>
Subject: Prescription medication dispensing questions

Hello,

I am a small animal veterinarian and recently made the transition from private practice to shelter medicine. I have some questions regarding the legalities of prescription dispensing in a couple situations.

First, the shelter is interested in giving employees the option to purchase prescription medications through the shelter (as an employee benefit for cost savings), if their personal veterinarian provides a written script for the medication. If a script is provided, is this something that can legally be done? If not...another part of employee benefits is one annual wellness exam by me as the shelter vet. If I have seen the employee's pet for a wellness exam in the past 12 months (and therefore technically have a VCPR), can I then legally fill a script through the shelter if the script is provided by an outside veterinarian (i.e., not prescribed by me but filled through the shelter as long as I've done a wellness exam on the pet within the year?)

The second question is in regards to shelter animals. The shelter has a wonderful program which covers the cost of prescription medications for animals with pre-existing health conditions for a period of one year from

the date of adoption. I'd prefer that, beyond the initial script from me, those animals get a written script from their new veterinarian who is managing that pet's condition after adoption. Similar to the question above...if an animal I've seen within the year is adopted out and then brings a script (from their new vet) to the shelter to be filled, can we fill it?

Thanks for any guidance you can provide!

Laura Beck, DVM

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	January 22, 2020
2) Requestor Name	M. Mace
3) Item Title for the Agenda	WVMA Requesting Guidance Regarding Telemedicine
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	• WVMA ltr to VEB - Telehealth Suggested Guidance - Request for Guidance - 12-19-19 • Compiled Responses from AAVSB Member Board Question - Telehealth Telemedicine • AAVSB Other States with Guidance • Questions about Telehealth_Telemedicine
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	**WVMA, and the VEB, have been getting questions on what type of telemedicine or telehealth options are legally available for WI licensed veterinarians to participate in. In response to the inquiries on telehealth/medicine the WVMA convened a telehealth task force. The results of this task force have been complied into the attached WVMA Telehealth suggested guidance created by Jordan Lamb on behalf of the WVMA for the VEB to consider. It is attached for your review and consideration.** **This was a big topic at the AAVSB in 2018 and they did publish recommended guidelines on telehealth technologies. This guidance is included in the WVMA Telehealth Suggested Guidance.** **I am also including the following to provide additional information:** **1. The compiled responses from other states based on a question submitted by Dr. Tod Schadler, Executive Director for the North Carolina Veterinary Medical Board in January 2019 where he inquired if licensing boards had any rules or regulations regarding telehealth/telemedicine.** **2. A very recent set of AAVSB compiled responses regarding states managing telehealth/telemedicine by guidance. Question submitted Dec 2019.** **2. A question that was recently submitted regarding telemedicine/video exams, as a potential point of discussion.**

DeWitt LLP Law Firm

Direct line: 608-252-9358
Email: jkl@dewittllp.com

December 19, 2019

VIA U.S. MAIL AND EMAIL TO:
Melissa.Mace@wisconsin.gov

Veterinary Examining Board
Dept. of Agriculture, Trade and Consume Protections
C/O Melissa Mace, VEB Executive Director
PO Box 8911
Madison, WI 53708-8911

RE: WVMA Suggested Guidance and Request for Guidance on the Use of Telehealth in Veterinary Medicine

Dear Chairman Forbes and Members of the Veterinary Examining Board:

Emerging and developing technology and advancements in communication have created the opportunity for improving the accessibility of veterinary medical care using telehealth technologies. Telehealth allows veterinarians to utilize electronic communication, information technology and other means to interact with patients who are located in a different physical location from the treating veterinarian. However, the WVMA believes that client/patient safety concerns must be carefully evaluated, and strategies must be developed to allow for the delivery of veterinary care via telehealth in a way that is protective of both animal health and public health.

Accordingly, the WVMA formed a Telehealth Task Force that worked this fall to develop the enclosed *suggested* guidelines for the Wisconsin Veterinary Examining Board (VEB) to consider and review. We urge the VEB to use our Task Force recommendations to develop telehealth guidance for Wisconsin-licensed veterinarians.

These guidelines should not be construed to alter the scope of practice of any veterinarian or veterinary technician or to authorize the delivery of veterinary medical services in a setting or in a manner that is not otherwise authorized by Wisconsin law. These guidelines support a consistent standard of care and veterinarians and veterinary technicians must review and understand the laws, regulations, and policies of each jurisdiction where they practice.

The WVMA believes that it is critical that the veterinarian must employ sound professional judgment to determine whether using telehealth is suitable each time veterinary services are provided and should only furnish medical advice or treatment via telemedicine when it is medically appropriate.

For reference, we have also enclosed a copy of the "AAVSB Recommended Guidelines for The Appropriate Use of Telehealth Technologies in the Practice of Veterinary Medicine" (2018).

If you have any questions regarding our suggestions or our request for telehealth guidance, please contact me directly at (608) 252-9358 or jkl@dewittllp.com.

Very truly yours,

DeWitt LLP

Jordan K. Lamb

JKL:jav

Enclosures

cc. Kim Pokorny, Executive Director, WVMA (*via email only / with enclosures*)
WVMA Telehealth Task Force Members (*via email only / with enclosures*)

WVMA Suggested Guidance for the Use of Telehealth Technologies in Veterinary Medicine

December 2019

I. Definitions

Consultation means advice given to a Wisconsin licensed veterinarian that is delivered in person, telephonically, electronically, or by any other method of communication from a veterinarian licensed in this or any other jurisdiction, or another person whose expertise, in the opinion of the licensed veterinarian, would benefit a patient. The licensed veterinarian receiving the consultation maintains the veterinarian-client-patient-relationship. Consultation is not considered telehealth.

Prescription means "a written, oral or electronic order from a veterinarian to a pharmacist or to another veterinarian that authorizes the pharmacist or other veterinarian to dispense a drug, or from a veterinarian to a client that authorizes the client to make extra-label use of a drug." Wis. Stat. § 89.02(6m)

Telehealth means a mode of delivery of veterinary medicine through telecommunications systems including but not limited to, video and digital technologies used to facilitate the assessment, diagnosis, treatment, or care management of an animal's medical care while the client/patient is located at a different site from the provider. The term includes synchronous interactions and store-and-forward transfers.

Telehealth technologies means technologies and devices enabling secure electronic communications and information exchange between a licensee in one location and a client/patient in another location with or without an intervening veterinarian.

Teletriage means emergency Animal care, including Animal poison control services, for immediate, potentially life-threatening Animal health situations (e.g., poison exposure mitigation, Animal CPR instructions, other critical lifesaving treatment or advice).

Veterinary Client-Patient Relationship ("VCPR") has the meaning set forth at s. 89.02 (8), Stats., which reads as follows:

(8) "Veterinarian-client-patient relationship" means a relationship between a veterinarian, a client and the patient in which all of the following apply:

(a) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the patient and the patient's need for medical treatment, and the client has agreed to accept those medical judgments and to follow the related instructions of the veterinarian.

(b) The veterinarian has sufficient knowledge of the patient to initiate a general or preliminary diagnosis of the medical condition of the patient because the veterinarian has recently examined the patient or has made medically appropriate and timely visits to the premises on which the patient is kept.

(c) The veterinarian is readily available for follow-up treatment of the patient if the patient has an adverse reaction to veterinary treatment.

II. Guidelines for Use of Telehealth in Veterinary Medicine

A. Licensure

Providers who evaluate, treat or prescribe through telehealth technologies are practicing veterinary medicine. The practice of veterinary medicine occurs where the patient is located at the time telehealth technologies are used. Therefore, a provider must be licensed to practice veterinary medicine in the State of Wisconsin in order to evaluate or treat patients located in Wisconsin utilizing telehealth technologies or otherwise.

B. Establishment of a Veterinarian-Client-Patient Relationship ("VCPR") for Purposes of Telehealth

1. **VCPR Required.** Veterinary services may only be provided using telehealth technologies where a VCPR is established. If an existing VCPR relationship is present, then telehealth technologies may be used as long as the VCPR is maintained in accordance with Wis. Stat. s. 89.02 (8) and the requirements in this Section. If an existing VCPR relationship is not present, then a veterinarian must take appropriate steps to establish a VCPR consistent with Wis. Stat. s. 89.02 (8) and the requirements in this Section.

2. **Establishing an Initial VCPR for Telehealth.** For purposes of establishing an initial VCPR prior to engaging in the practice of veterinary medicine using telehealth technologies, the veterinarian must meet the requirements of Wis. Stat. s. 89.02 (8) and:

    a. For livestock, (food and fiber animals), the veterinarian must have either conducted an in-person physical examination of the patient or must have visited the premises on which the patient is kept at least once in the immediate six (6) months prior to engaging in any telehealth treatment or services.

    b. For companion animals and equine animals, the veterinarian must have conducted an in-person physical examination of the patient at least once in the immediate six (6) months prior to engaging in any telehealth treatment or services.

3. **Maintaining a VCPR for Telehealth.** Once a VCPR is established, for purposes of maintaining that VCPR and engaging in the ongoing practice of veterinary medicine using telehealth technologies, the veterinarian must meet the requirements of Wis. Stat. s. 89.02 (8) and:

    a. For livestock (food and fiber animals), the veterinarian must either conduct an in-person physical examination of the patient or must visit the premises on which the patient is kept at least once every six (6) months.

    b. For companion animals and equine animals, the veterinarian must conduct an in-person physical examination of the patient at least once every twelve (12) months.

4. **Documentation Required.** Documentation of all physical examinations or visits to the premises on which the patient is kept must be maintained in a reproducible form and be available for inspection as provided in Section G. and Wis. Admin. Code. s. VE 7.03.

C. Evaluation and Treatment of the Patient

An appropriate medical evaluation and review of relevant clinical history, commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided, should be performed prior to providing treatment, including issuing prescriptions, electronically or otherwise. Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional in-person settings.

D. Informed Consent

Appropriate informed consent should be obtained for a telehealth encounter including those elements required by law and generally accepted standards of practice. Evidence documenting appropriate patient informed consent for the use of telehealth services must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following:

- Identification of the client, patient, veterinarian, and the veterinarian's credentials including Wisconsin license registration number;
- Types of activities permitted using telehealth services, which may include prescription refills, appointment scheduling and patient education;
- Agreement by the client that it is the role of the veterinarian to determine whether the condition being diagnosed and/or treated is appropriate for a telehealth encounter;
- Discussion with the client the available diagnostic and treatment options, a risk assessment, and prognosis; and
- Consent, by the client, to the recommended treatment.

E. Continuity of Care

Licensed veterinarians should adhere to generally accepted standards of practice as it relates to continuity and coordination of care.

An animal owner should be able to easily seek follow-up care or information from the veterinarian who conducts an encounter while using telehealth technologies. The veterinarian must ensure that the client is aware of the veterinarian's identity, location, licensure status, and the privacy and security issues involved in accessing veterinary care via telehealth technologies as provided in this document.

F. Referrals for Emergency Services and Teletriage

An emergency plan should be provided by the provider to the client when the care provided using telehealth technologies indicates that a referral to an acute care or emergency facility for treatment is necessary for the safety of the patient.

Teletriage may be performed by a Veterinarian or Veterinary Technician without establishing a VCPR or obtaining Informed Consent to provide emergency, potentially life-saving Telemedicine services.

G. Medical Records

In addition to the specific documentation required in Section B., all medical records must be maintained with regard to telehealth visits consistent with the requirements provided in Wis. Admin. Code s. VE 7.03. The medical record should include, if applicable, copies of all patient-related electronic communications including VCPR communication, prescriptions, laboratory and test results, evaluations and consultations, records of past care, and instructions obtained or produced in connection with the utilization of telehealth technologies. Informed consents obtained in connection with an encounter involving telehealth technologies should be maintained in accordance with best practices in the medical record. The patient record established during the use of telehealth technologies must be accessible and documented for both the provider and the client, consistent with all established laws and regulations governing veterinary medicine in the State of Wisconsin.

H. Privacy and Security of Veterinary Records & Exchange of Information

Providers should meet or exceed applicable requirements for maintaining veterinary records, including but not limited to Wis. Admin. Code s. VE 7.03. Written policies and procedures related to treatment and prescribing medications using telehealth technologies should be maintained at the same standard as traditional in-person encounters for documentation, maintenance, and transmission of the records of the encounter using telehealth technologies.

In accordance with Wis. Admin. Code. s. 11.16 (4), patient health care records are confidential under s. 146.82, Stats., and shall not be made available to the public without the informed consent of the patient or of a person authorized by the patient or as provided under s. 146.82 (2), Stats.

I. Disclosures and Functionality for Providing Online Services

Disclosures and advertising should be made in accordance with all applicable state and federal laws.

J. Prescribing Medications Via Telehealth

Prescribing medications via telehealth technologies requires a VCPR and is at the professional discretion of the provider. The indication, appropriateness, and safety considerations for each telehealth visit that results in the issuance of a prescription must be evaluated by the provider in accordance with current standards of practice and, consequently, carries the same professional accountability as prescriptions delivered during an in-person visit. However, where such measures

are upheld, and the appropriate clinical consideration is carried out and documented, providers may exercise their judgment and prescribe medications as part of telehealth encounters. In addition, prescribing medications must be done in accordance with all applicable state and federal laws including Wis. Stat. s. 89.068 (1) (b).

K. Delegation of Surgical Procedures is Prohibited

Notwithstanding the delegation provisions under Wis. Admin. Code. s. VE 7.02 (4), no veterinary surgery, as defined under Wis. Admin. Code s. 1.02 (9), including those procedures identified in Wis. Admin. Code s. VE 1.02 (9) (b), may be delegated using telehealth technologies.

L. Parity of Professional and Ethical Standards

There should be parity of ethical and professional standards applied to all aspects of a provider's practice. A provider's professional discretion as to the diagnoses, scope of care, or treatment should not be limited or influenced by non-clinical considerations of telehealth technologies or by payment terms, incentives or other monetary influences related to use of telehealth technologies. Provider remuneration or treatment recommendations should not be materially based on the delivery of patient-desired outcomes (*i.e.* a prescription or referral) or the utilization of telehealth technologies.

AAVSB
AMERICAN ASSOCIATION OF VETERINARY STATE BOARDS

AAVSB RECOMMENDED GUIDELINES FOR THE APPROPRIATE USE OF TELEHEALTH TECHNOLOGIES IN THE PRACTICE OF VETERINARY MEDICINE

Introduction

When telehealth is used within the confines of state and provincial regulations, it provides valuable tools to augment the delivery and availability of high quality veterinary care. According to the Center for Connected Health Policy, "Telehealth encompasses a broad variety of technologies and tactics to deliver virtual medical, health, and education services. Telehealth is not a specific service, but a collection of means to enhance care and education delivery."[1] Advancements in communication and information technology provide opportunities for new approaches to the delivery of veterinary medicine.

The American Association of Veterinary State Boards (AAVSB) charged the AAVSB Regulatory Policy Task Force to draft proactive guidelines that provide an appropriate balance between enabling access to veterinary care while ensuring patient safety. This document provides guidance to AAVSB Member Boards for regulating the use of telehealth technologies in the practice of veterinary medicine. Key components of the document include: definitions, veterinarian-client-patient relationship (VCPR), licensure, evaluation and treatment of the patient, continuity of care, medical records, emergency services, prescribing medication, and telemedicine service requirements.

Veterinary medical boards face complex regulatory challenges and patient and public safety concerns in adapting regulations and standards historically intended for the hands-on provision of veterinary medical care to new delivery models involving telehealth technologies. Challenges include determining when a VCPR is established, assuring confidentiality and privacy of client and patient data, guaranteeing creation and maintenance of appropriate medical records, proper diagnosis and treatment of the patient, and limiting the prescribing and dispensing of certain medications.

These guidelines should be used in conjunction with the AAVSB Practice Act Model and in no way be construed to alter the scope of practice of any veterinarian or veterinary technician or

[1] The Center for Connected Health Policy (www.cchpca.org)

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380 West 22nd Street
Suite 101
Kansas City, MO 64108

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authorize the delivery of veterinary medical services in a setting or in a manner that is not otherwise authorized by law. In fact, these guidelines support a consistent standard of care and scope of practice. Veterinarians and veterinary technicians must review and understand the laws, regulations, and policies of each jurisdiction where they practice.

The veterinarian must employ sound professional judgment to determine whether using telehealth is suitable each time veterinary services are provided and only furnish medical advice or treatment via telemedicine when it is medically appropriate. A veterinarian using telemedicine must take appropriate steps to establish the VCPR, obtain informed consent from the client, and conduct all necessary patient evaluations consistent with currently acceptable standards of care. Some patient presentations are appropriate for the utilization of telemedicine as a component of, or in lieu of, hands-on medical care, while others are not.

Definitions

When used in these guidelines, these words and phrases shall be capitalized and are defined as follows:

- **Animal** means any member of the animal kingdom other than humans, whether living or dead.
- **Client** means a Person who has entered into an agreement with a Veterinarian for the purposes of obtaining veterinary medical services in-person or by any means of communication.
- **Consultation** means when a Veterinarian receives advice or assistance in-person, or by any method of communication, from another veterinarian or other Person whose expertise, in the opinion of the Veterinarian, would benefit a Patient. Under any circumstance, the responsibility for the welfare of the Patient remains with the Veterinarian receiving Consultation.
- **Informed Consent** means the Veterinarian has informed the Client or the Client's authorized representative, in a manner understood by the Client or representative, of the diagnostic and treatment options, risk assessment, and prognosis, and the Client has consented to the recommended treatment.
- **General Advice** means any advice provided by a Veterinarian or Veterinary Technician via any method of communication within or outside of an established VCPR that is given in general terms and is not specific to an individual Animal, group of Animals, diagnosis, or treatment.
- **Jurisdiction** means any commonwealth, state, or territory, including the District of Columbia, of the United States of America, or any province of Canada.
- **Patient** means any Animal or group of Animals receiving veterinary care from a Veterinarian or Veterinary Technician.

- **Person** means any individual, firm, partnership, association, joint venture, cooperative, corporation, governmental body, or any other group, legal entity or combination acting in concert; and whether or not acting as a principal, trustee, fiduciary, receiver, or as any kind of legal or personal representative, or as the successor in interest, assignee, agent, factor, servant, employee, director, officer, or any other representative of such Person.
- **Telehealth** is the overarching term that encompasses all uses of technology geared to remotely deliver health information or education. Telehealth encompasses a broad variety of technologies and tactics to deliver virtual medical, health, and education services. Telehealth is not a specific service, but a collection of tools which allow Veterinarians to enhance care and education delivery. Telehealth encompasses both Telemedicine and General Advice.
- **Telemedicine** is the remote delivery of healthcare services, such as health assessments or consultations, over the telecommunications infrastructure. It allows Veterinarians to evaluate, diagnose and treat patients without the need for an in-person visit.
- **Teletriage** means emergency Animal care, including Animal poison control services, for immediate, potentially life-threatening Animal health situations (e.g., poison exposure mitigation, Animal CPR instructions, other critical lifesaving treatment or advice).
- **Veterinarian** means an individual who is duly licensed to practice Veterinary Medicine under the Jurisdiction's practice act. When not capitalized, means an individual who is duly licensed to practice Veterinary Medicine in another Jurisdiction.
- **Veterinarian-Client-Patient Relationship (VCPR)** exists when:
  1) Both the Veterinarian[2] and Client agree for the Veterinarian to assume responsibility for making medical judgments regarding the health of the Animal(s); and
  2) The Veterinarian has sufficient knowledge[3] of the Animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the Animal(s); and
  3) The practicing Veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.
- **Veterinary Technician** means an individual who is duly licensed to practice Veterinary Technology under the Jurisdiction's practice act.

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[2] AAVSB recommends that each jurisdiction promulgate appropriate regulations clarifying who may be included within the scope of a single VCPR such as a Veterinarian or another Veterinarian within the same practice group with access to medical records, or a veterinarian with whom he/she is consulting.

[3] AAVSB recommends that each jurisdiction promulgate appropriate regulations defining how to establish sufficient knowledge, including the following:

A. A recent examination of the Animal or group of Animals, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; or
B. Through medically appropriate and timely visits to the premises at which the Animal or group of Animals are kept.

Guidelines for the Appropriate Use of Telehealth Technologies in Veterinary Medical Practice

Licensure

A Veterinarian or Veterinary Technician must be licensed by, or under the authority of, the Board of Veterinary Medicine in the Jurisdiction where the VCPR is established (location of Patient at time of VCPR establishment)[4].

Any veterinarian who is licensed in another Jurisdiction, or any Person whose expertise, in the opinion of the Veterinarian with an established VCPR, would benefit an Animal, and who is consulting with the Veterinarian, is exempt from licensure in this Jurisdiction, provided such service is limited to such Consultation.

Evaluation and Treatment of the Patient(s)

The Veterinarian must employ sound professional judgment to determine whether using Telehealth is suitable each time veterinary services are provided and only furnish medical advice or treatment via Telemedicine when it is medically appropriate. A Veterinarian using Telemedicine must take appropriate steps to establish the VCPR, obtain Informed Consent from the Client, and conduct all necessary Patient evaluations consistent with currently acceptable standards of care. Some Patient presentations are appropriate for the utilization of Telemedicine as a component of, or in lieu of, hands-on medical care, while others are not.

The Veterinarian must take appropriate precautions to safe guard the confidentiality of a Client's or Patient's records. Such includes ensuring that technology and physical settings used as part of Telemedicine services are compliant with Jurisdictional or federal requirements.

The Veterinarian must ensure that the Client is aware of the Veterinarian's identity, location and Jurisdiction's license number and licensure status. Evidence documenting Informed Consent for the use of Telemedicine must be obtained and maintained in the medical record.

Continuity of Care/Medical Records

Veterinarians must maintain appropriate medical records[5] that contain sufficient information for continued care and are compliant with Jurisdictional requirements. Documentation of the Telemedicine encounter should be readily available upon request by the Client.

[4] Arguments can also be made that identify the location of practice under these circumstances as occurring in both Jurisdictions; that is where the Patient is located and where the Veterinarian is located.

[5] See the AAVSB Practice Act Model Article V for suggested language.

Emergency Services

Teletriage may be performed by a Veterinarian or Veterinary Technician without establishing a VCPR or obtaining Informed Consent to provide emergency, potentially life-saving Telemedicine services.

Prescribing Medications

Prescribing medications in-person or via Telemedicine requires a VCPR and is at the professional discretion of the Veterinarian. The indication, appropriateness, and safety considerations for each prescription issued in association with Telemedicine services must be evaluated by the Veterinarian in accordance with all Jurisdictional and federal laws[6] and standards of care.

Telemedicine Service Requirements

A provider of Telemedicine services must ensure that the Client is aware of the Veterinarian's identity, location and Jurisdiction's license number and licensure status, and should provide to Clients a clear mechanism to:

1. Access, supplement and amend Client-provided contact information and health information about the Patient; and
2. Register complaints with the appropriate Board of Veterinary Medicine or other regulatory body.

[6] The Federal definition of the VCPR must be followed when issuing prescriptions in accordance with the Veterinary Feed Directive (VFD) and Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994.

A Query from an AAVSB Member Board

Telehealth/Telemedicine Regulations

On January 17, 2019 Dr. Tod Schadler, Executive Director for the North Carolina Veterinary Medical Board, asked if licensing boards had any rules or regulations regarding telehealth/telemedicine.

AAVSB – The membership of the AAVSB voted to approve the changes to the AAVSB Practice Act Model at the 2018 Annual Meeting which included reference to the Guidelines for Telehealth. This document has been created by the AAVSB Regulatory Policy Task Force after 2-years of extensive research, to serve as a guide for our Member Boards that are having conversations around veterinary telehealth. The Regulatory Policy Task Force is composed of 12 individuals representing various AAVSB member jurisdictions. Should you need additional information, we can put you in touch with the chair of the Task Force. A link to the document is at the bottom of the page on our website below: https://www.aavsb.org/board-services/member-board-resources/practice-act-model/

Arkansas – Arkansas does not at this time, but we have talked about looking into it soon.

Florida – Florida does not specifically address Telehealth or Telemedicine in statute or rule.

Georgia – Telehealth and telemedicine is not specifically addressed within the Board statutes and rules. In the state of Georgia, the Veterinary Practice Act allows for consultation telephonically, electronically or by any other method of communication from a veterinarian licensed in this or any other state or other person whose expertise, in the opinion of the licensed veterinarian, may benefit an animal patient [O.C.G.A.§ 43-50-3(18)&(29)]. It also allows for indirect supervision by a licensed veterinarian when such licensed veterinarian has given either written or oral instructions for the treatment of the animal patient and is readily available by telephone or other forms of immediate communication. That being said, the rules stipulate that a veterinarian/client/patient relationship cannot be established solely by telephone, computer or other electronic means [BR 700-8-.01(d).

Idaho – Idaho's Practice Act, and specifically the VCPR section, is worded in such a way that it does not exclude the possibility of a telemedicine consultation. Subsequently, we did not need to change our statutes or rules to accommodate the practice of telemedicine/telehealth; however, we did adopt some of the AAVSB and AVMA model language when crafting our telemedicine policy.
https://adminrules.idaho.gov/rules/current/46/460101.pdf Section 150
https://bovm.idaho.gov/Office%20Policies/Policy%20Statement-2018-2%20Telemedicine.pdf

Maryland – Maryland has not addressed the issue. (We've talked about it, but we haven't addressed it.)

Mississippi – From the definitions in the Mississippi Veterinary Practice act:
(v) "Veterinarian-client-patient relationship" means that all of the following are required:
(i) The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
(ii) The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal because the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal either by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animal is kept.
and
SECTION 5. Section 73-39-59, Mississippi Code of 1972, is reenacted as follows:
73-39-59. (1) No person may practice veterinary medicine in the state who is not a licensed veterinarian or the holder of a valid temporary permit issued by the board unless otherwise exempt under this chapter.
(2) No person may practice veterinary medicine in the state except within the context of a veterinarian-client-patient relationship.
(3) A veterinarian-client-patient relationship cannot be established solely by telephonic or other electronic means.

Nebraska – We are currently in legislative session where a bill has been introduced to allow for Telehealth. I can update Lainie as the bill progresses. I don't foresee opposition outside of groups that may were excluded.

New Hampshire – At this time I am not aware of any.

New Jersey – In NJ we do NOT have any statutes or regulations regarding telehealth/telemedicine.

New Mexico – The New Mexico Board of Veterinary Medicine has the following rule. I have attached the New Mexico Veterinary Practice Act for the citation referenced in the rule.

16.25.9.8 GENERAL STANDARDS:
A. The delivery of veterinary care shall be provided in a competent and humane manner.
B. Veterinary medicine shall be performed in a manner compatible with current veterinary medical practice.
C. A valid veterinarian-client-patient relationship (VCPR) must be established when delivering veterinary care. See VCPR as defined by the New Mexico Veterinary Practice Act 61-14-2-J (1), (2), (3), and (4).
(1) A VCPR cannot be established by telephonic, computer, internet or other .electronic communications; however, a New Mexico-licensed veterinarian may provide or arrange for consulting services for their clients using the described electronic communication methods.

See Attachment 1 starting on page 4.

New York – In NYS, we do not have any specific statutes or regulations regarding veterinary telemedicine. All laws and regulations regulating the practice of veterinary medicine and veterinary technology apply to any telemedicine scenario. The Veterinary Medicine Board is discussing this issue, which may at some point result in a guidance document.

Ohio – Ohio does not have rules regarding telehealth/telemedicine, but the Board did just adopt a Position Statement at their January board meeting:
http://www.ovmlb.ohio.gov/pdfs/Telelmed%20position.pdf

Oklahoma – We have a position statement that was passed last October by the Board, it is attached starting on page 29.

Utah - https://le.utah.gov/xcode/Title26/Chapter60/26-60.html See attached starting on page 31.

Vermont - Vermont does not currently have any rules regarding tele-medicine.

Washington - In Washington, the board does not yet have rules that guide telehealth for veterinarians. The legislature enacted a law in 2015 that defines telemedicine (RCW 48.43.735 – see (8)(f) and (g)). Many professions have adopted guidelines, but the veterinary board of governors has not yet gotten there. Telehealth is a strategic priority for the board in 2019, so they may have guidelines near the end of the year. I think we're a ways away from adopting rules on the subject.

West Virginia - WV Board of Veterinary Medicine does not have any rules nor regulations on telehealth/telemedicine.

Wisconsin - Wisconsin has no laws specific to telehealth or telemedicine.

61-14-1. Short title. (Repealed effective July 1, 2024.)

Chapter 61, Article 14 NMSA 1978 may be cited as the "Veterinary Practice Act".
History: 1953 Comp., § 67-11-12, enacted by Laws 1967, ch. 62, § 1; 2011, ch. 30, § 2.

61-14-2. Definitions. (Effective July 1, 2018.)(Repealed effective July 1, 2024.)

As used in the Veterinary Practice Act:

A. "animal" means any animal other than man;

B. "animal shelter":

(1) means:

(a) a county or municipal facility that provides shelter to animals on a regular basis, including a small animal impound facility; and

(b) a private humane society or a private animal shelter that temporarily houses stray, unwanted or injured animals through administrative or contractual arrangements with a local government agency; and

(2) does not include a municipal zoological park;

C. "euthanasia" means to produce a humane death of an animal by standards deemed acceptable by the board as set forth in its rules;

D. "euthanasia agency" means a facility that provides shelter to animals on a regular basis, including a small animal impound facility, a humane society or a public or private shelter facility that temporarily houses stray, unwanted or injured animals, and that performs euthanasia;

E. "practice of veterinary medicine" means:

(1) the diagnosis, treatment, correction, change, relief or prevention of animal disease, deformity, defect, injury or other physical or mental condition, including the prescription or administration of any drug, medicine, biologic, apparatus, application, anesthetic or other therapeutic or diagnostic substance or technique and the use of any procedure for artificial insemination, testing for pregnancy, diagnosing and treating sterility or infertility or rendering advice with regard to any of these;

(2) the representation, directly or indirectly, publicly or privately, of an ability and willingness to do any act mentioned in Paragraph (1) of this subsection; or

(3) the use of any title, words, abbreviation or letters in a manner or under circumstances that induce the belief that the person using them is qualified to do any act mentioned in Paragraph (1) of this subsection;

F. "veterinarian" means a person having the degree of doctor of veterinary medicine or its equivalent from a veterinary school or a person who has received a medical education in veterinary medicine in a foreign country and has thereafter entered the United States and fulfilled the requirements and standards set forth by the American veterinary medical association and has passed all examinations required by the board prior to being issued any license to practice veterinary medicine in this state;

G. "licensed veterinarian" means a person licensed to practice veterinary medicine in this state;

H. "veterinary school" means any veterinary college or any division of a university or college that is approved for accreditation by the American veterinary medical association;

I. "board" means the board of veterinary medicine;

J. "veterinary technician" means a skilled person certified by the board as being qualified by academic and practical training to provide veterinary services under the supervision and direction of the licensed veterinarian who is responsible for the performance of that technician;

K. "committee" means the veterinary technician examining committee;

L. "direct supervision" means the treatment of animals on the direction, order or prescription of a licensed veterinarian who is available on the premises and who has established a valid veterinarian-client-patient relationship;

M. "sheltering committee" means the animal sheltering committee;

N. "valid veterinarian-client-patient relationship" means:

(1) the veterinarian has assumed responsibility for making medical judgments regarding the health of an animal being treated and the need for and the course of the animal's medical treatment;

(2) the client has agreed to follow the instructions of the veterinarian;

(3) the veterinarian is sufficiently acquainted with an animal being treated, whether through examination of the animal or timely visits to the animal's habitat for purposes of assessing the condition in which the animal is kept, to be capable of making a preliminary or general diagnosis of the medical condition of the animal being treated; and

(4) the veterinarian is reasonably available for follow-up treatment; and

O. "veterinary medicine" means veterinary surgery, obstetrics, dentistry and all other branches or specialties of veterinary medicine.

History: 1953 Comp., § 67-11-13, enacted by Laws 1967, ch. 62, § 2; 1975, ch. 96, § 1; 1977, ch. 236, § 1; 1993, ch. 163, § 1; 2017, ch. 44, § 1.

61-14-3. Criminal offender's character evaluation. (Repealed effective July 1, 2024.)

The provisions of the Criminal Offender Employment Act [28-2-1 through 28-2-6 NMSA 1978] shall govern any consideration of criminal records required or permitted by the Veterinary Practice Act.

History: 1953 Comp., § 67-11-13.1, enacted by Laws 1974, ch. 78, § 19.

61-14-4. Board created; terms; compensation; finance. (Repealed effective July 1, 2024.)

A. The "board of veterinary medicine" is created. The board shall consist of seven members who are citizens of the United States and residents of New Mexico. Veterinary members shall have been licensed to practice veterinary medicine in the state for five years preceding their appointment to the board.

B. Members of the board and their successors shall be appointed by the governor. Five of the members shall be licensed veterinarians, and these appointments may be made from a list of five names for each professional vacancy, submitted to the governor by the New Mexico veterinary medical association. Two members shall represent the public and shall not have been licensed as veterinarians or have any significant financial interest, whether direct or indirect, in the occupation regulated.

C. Members shall be appointed to staggered terms of four years each. Appointments shall be made in such manner that the terms of no more than two board members expire on July 1 of each year. All board members shall hold office until their successors are appointed and qualified. Appointments to vacancies shall be for the unexpired terms. Board members shall not serve more than two consecutive four-year terms.

D. A majority of the members of the board constitutes a quorum for the transaction of business, except that the vote of four members is required for suspension or revocation of a license. The board shall elect a chairman and other necessary officers prescribed by regulation of the board.

E. Members of the board shall receive per diem and mileage as provided in the Per Diem and Mileage Act [10-8-1 through 10-8-8 NMSA 1978] and shall receive no other compensation, perquisite or allowance. This reimbursement and all other expenses involved in carrying out the Veterinary Practice Act shall be paid exclusively from fees received pursuant to provisions of the Veterinary Practice Act. The board shall deposit all fees received pursuant to provisions of the Veterinary Practice Act with the state treasurer for the exclusive use of the board, and money shall be expended only upon vouchers certified by a majority of the board.

F. Any board member failing to attend, after proper notice, three consecutive meetings, either regular or special, shall automatically be removed as a member of the board.

History: 1953 Comp., § 67-11-14, enacted by Laws 1967, ch. 62, § 3; 1975, ch. 96, § 2; 1979, ch. 76, § 1; 1991, ch. 189, § 21; 1993, ch. 163, § 2; 1995, ch. 154, § 1.

61-14-4.1. Protected actions; communication. (Repealed effective July 1, 2024.)

A. No current or former member of the board, officer, administrator, staff member, committee member, examiner, representative, agent, employee, consultant, witness or any other person serving or having served the board shall bear liability or be subject to civil damages or criminal prosecutions for any action or omission undertaken or performed within the scope of the board's duties.

B. All written and oral communications made by any person to the board relating to actual or potential disciplinary action shall be confidential communications and are not public records for the purposes of the Inspection of Public Records Act [Chapter 14, Article 2 NMSA 1978]. All data, communications and information acquired by the board relating to actual or potential disciplinary action shall not be disclosed except to the extent necessary to carry out the board's purposes or in a judicial appeal from the board's actions.

C. The board shall make available to interested members of the public information about a disciplinary action taken by the board pursuant to Section 61-14-13 NMSA 1978, including the name of the licensee, the nature of the violation of the Veterinary Practice Act and the disciplinary action taken.

D. No person or legal entity providing information to the board, whether as a report, a complaint or testimony, shall be subject to civil damages or criminal prosecutions.

History: Laws 1999, ch. 243, § 6.

61-14-5. Board; duties. (Effective July 1, 2018.)(Repealed effective July 1, 2024.)

The board shall:

A. examine and determine the qualifications and fitness of applicants for a license to practice veterinary medicine in New Mexico and issue, renew, deny, suspend or revoke licenses;

B. regulate artificial insemination and pregnancy diagnosis by establishing standards of practice and issuing permits to persons found qualified;

C. establish a schedule of license and permit fees based on the board's financial requirements for the ensuing year;

D. conduct investigations necessary to determine violations of the Veterinary Practice Act and discipline persons found in violation;

E. employ personnel necessary to carry out its duties;

F. promulgate and enforce rules necessary to establish recognized standards for the practice of veterinary medicine and to carry out the provisions of the Veterinary Practice Act. The board shall make available to interested members of the public copies of the Veterinary Practice Act and all rules promulgated by the board;

G. examine applicants for veterinary technician certification purposes. Such examination shall be held at least once a year at the times and places designated by the board;

H. establish a five-member veterinary technician examining committee;

I. adopt rules establishing continuing education requirements as a condition for license renewal;

J. regulate the operation of veterinary facilities, including:

(1) establishing requirements for operation of a veterinary facility in accordance with recognized standards for the practice of veterinary medicine;

(2) issuing permits to qualified veterinary facilities; and

(3) adopting standards for inspection of veterinary facilities.

For purposes of this subsection, "veterinary facility" means a building, mobile unit, vehicle or other location where services included within the practice of veterinary medicine are provided;

K. perform the duties imposed on the board pursuant to the Animal Sheltering Act; and

L. establish a five-member sheltering committee.

History: 1953 Comp., § 67-11-15, enacted by Laws 1967, ch. 62, § 4; 1975, ch. 96, § 3; 1977, ch. 167, § 1; 1993, ch. 163, § 3; 1995, ch. 154, § 2; 1999, ch. 243, § 1; 2017, ch. 44, § 2.

61-14-5.1. Impaired veterinarian. (Repealed effective July 1, 2024.)

A. The board may appoint an impaired-veterinarian committee to organize and administer a program that will:

(1) serve as a diversion program to which the board may refer licensees in lieu of or in addition to other disciplinary action under terms set by the board; and

(2) be a confidential source of treatment or referral for veterinarians who, on a voluntary basis and without the knowledge of the board, desire to avail themselves of treatment for emotionally based or chemical-dependence impairments.

B. The impaired-veterinarian committee shall:

(1) provide evaluations for veterinarians who request participation in the diversion program;

(2) review and designate treatment facilities and services to which veterinarians in the diversion program may be referred;

(3) receive and review information concerning the status and progress of participants in the diversion program;

(4) publicize the diversion program in coordination with veterinary professional associations; and

(5) prepare and provide reports at least annually to the board.

C. Each veterinarian referred to the diversion program by the board shall be informed of the procedures applicable to the diversion program, of the rights and responsibilities associated with participation in the diversion program and of the possible consequences of failure to participate in the diversion program. Failure to comply with any treatment requirement of the diversion program may result in termination of diversion program participation; termination of diversion program participation shall be reported to the board by the impaired-veterinarian committee. Participation in the diversion program shall not be a defense against, but may be considered in mitigating, any disciplinary action taken by the board. The board is not precluded from commencing a disciplinary action against a veterinarian who is participating in the diversion program or has been terminated.

D. No member of the board or the impaired-veterinarian committee shall be liable for civil damages because of acts or omissions that occur in administering the provisions of this section.

History: Laws 1993, ch. 163, § 11.

61-14-6. Veterinary technician examining committee; membership; terms; compensation. (Repealed effective July 1, 2024.)

A. The "veterinary technician examining committee" shall consist of five members appointed by the board of veterinary medicine. The committee shall consist of two licensed veterinarians, one member of the board and two registered veterinary technicians.

B. Committee members shall serve for terms of four years except the board member on the committee shall be appointed for one year. With the exception of the board member on the committee, the terms of committee members shall be staggered by one year. Committee members shall serve until their successors have been appointed and qualified. Any vacancy shall be filled by appointment by the board of veterinary medicine for the remainder of the unexpired term.

C. Members of the committee shall receive per diem and mileage as provided in the Per Diem and Mileage Act [10-8-1 through 10-8-8 NMSA 1978] and shall receive no other compensation, perquisite or allowance.

History: 1953 Comp., § 67-11-15.1, enacted by Laws 1975, ch. 96, § 4; 1993, ch. 163, § 4.

61-14-7. Duties of the veterinary technician examining committee. (Repealed effective July 1, 2024.)

A. The committee shall evaluate qualifications of education, skill and experience for certification of a person as a veterinary technician and provide forms and procedures for the board for certificates of qualification and for annual registration of employment.

B. The committee shall assist the board in the examination of applicants for veterinary technician certification. Such examination shall be held at least once a year at the times and places designated by the board.

History: 1953 Comp., § 67-11-15.2, enacted by Laws 1975, ch. 96, § 5.

61-14-7.1. Animal sheltering committee; duties. (Effective July 1, 2018.)(Repealed effective July 1, 2024.)

The sheltering committee shall:

A. develop a voluntary statewide dog and cat spay and neuter program in conjunction with animal shelters andeuthanasia agencies;

B. develop criteria for individuals, nonprofit organizations, animal shelters and euthanasia agencies to receive assistance for dog and cat sterilization from the animal care and facility fund; and

C. recommend to the board the disbursements of money from the animal care and facility fund to qualifying individuals, nonprofit organizations, animal shelters and euthanasia agencies.

History: Laws 2017, ch. 44, § 3.

61-14-8. Application for license. (Repealed effective July 1, 2024.)

A. Any person desiring a license to practice veterinary medicine in this state may make written application to the board showing that he:

(1) has reached the age of majority; and

(2) is a person of good moral character.

The application shall contain other information and proof as required by regulation of the board and shall be accompanied by an application fee established by the board.

B. If the board finds that the applicant possesses the proper qualifications, it shall admit him to the next examination. If an applicant is found unqualified to take the examination, the board shall immediately notify the applicant in writing of its findings and the grounds for them.

History: 1953 Comp., § 67-11-16, enacted by Laws 1967, ch. 62, § 5; 1973, ch. 49, § 1; 1993, ch. 163, § 5.

61-14-9. Examination. (Repealed effective July 1, 2024.)

The board shall conduct at least one examination each calendar year following public notice of the time and place. Examinations shall be prepared and conducted under regulations promulgated by the board, and shall be designed to test the applicant's knowledge and proficiency in the practice of veterinary medicine. Immediately after the results of each examination are determined, the board shall notify each applicant of the results of his examination and issue a license to those applicants successfully completing it. Any applicant failing an examination shall be admitted to any subsequent examination upon payment of another application fee.

History: 1953 Comp., § 67-11-17, enacted by Laws 1967, ch. 62, § 6.

61-14-10. License by endorsement. (Repealed effective July 1, 2024.)

A. Pursuant to its regulations, the board may issue a license without written examination, except an examination on state laws and other state and federal regulations related to the practice of veterinary medicine, to any qualified applicant who furnishes satisfactory evidence that he is a veterinarian and has for the five years next prior to filing his application, been a practicing veterinarian and licensed in a state, territory or district of the United States having license requirements at the time the applicant was first licensed that were substantially equivalent to the requirements of the Veterinary Practice Act.

B. Pursuant to its regulations, the board may issue, with examination, a limited practice license in veterinary medicine, which limited practice license shall describe adequately that area of veterinary medicine that the licensee is entitled to practice.

C. At its discretion, the board may examine, orally or practically, any person qualifying for a license under this section.

D. The board may issue without examination a temporary permit to practice veterinary medicine to:

(1) a qualified applicant for a license pending examination, provided the applicant is a graduate veterinarian and employed by and working under the direct supervision of a licensed veterinarian provided:

(a) the temporary permit shall expire the day after the notice of results of the first examination given after the permit is issued;

(b) a qualified applicant for a license pending examination may, at the board's discretion, be exempted from the requirement of working under the direct supervision of a licensed veterinarian, provided the applicant submits a written request for such exemption; and

(c) no additional temporary permit shall be issued to an applicant who has failed the required components of the New Mexico examination in this or any other state or any other territory, district or commonwealth of the United States; or

(2) a nonresident veterinarian validly licensed and in good standing with the licensing authority in another state, territory, district or commonwealth of the United States; provided that the temporary permit shall be issued for a period lasting no more than sixty days and that not more than one permit shall be issued to such a person during each calendar year. No more than two temporary permits shall be issued to any one individual.

E. A temporary permit to practice veterinary medicine may be summarily revoked by a majority vote of the board without a hearing.

History: 1953 Comp., § 67-11-18, enacted by Laws 1967, ch. 62, § 7; 1975, ch. 96, § 6; 1993, ch. 163, § 6; 1995, ch. 154, § 3.

61-14-11. Certification as veterinary technician; annual registration of employment; employment change; fees. (Repealed effective July 1, 2024.)

A. No person shall perform or attempt to perform as a veterinary technician without first applying for and obtaining a certificate of qualification from the board of veterinary medicine as a veterinary technician and having his employment registered in accordance with board regulation.

B. A veterinary technician shall perform only those acts and duties assigned him by a supervising licensed veterinarian that are within the scope of practice of such supervising veterinarian, not to include diagnosis, prescription or surgery.

C. An applicant for a certificate of qualification as a veterinary technician shall complete application forms as supplied by the board of veterinary medicine, successfully complete an examination conducted by the board and pay a fee to defray the cost of processing the application and administering the examination, which fee is not returnable.

D. Each certified veterinary technician shall annually register his employment with the board of veterinary medicine, stating his name and current address, the name and office address of both his employer and supervising licensed veterinarian and such additional information as the board deems necessary. Upon any change of employment as a veterinary technician, such registration shall automatically be void. Each annual registration or registration of new employment shall be accompanied by fees set by the board for use by the board in defraying the cost of administering the Veterinary Practice Act.

History: 1953 Comp., § 67-11-18.1, enacted by Laws 1975, ch. 96, § 7; 1993, ch. 163, § 7.

61-14-12. License, permit and registration renewal. (Effective July 1, 2018.)(Repealed effective July 1, 2024.)

A. All licenses, permits and registrations issued pursuant to the Veterinary Practice Act may be renewed by payment of the renewal fee and submission of proof of completion of continuing education requirements as established by regulation of the board. Not later than thirty days prior to expiration, the board shall mail a notice to each licensed veterinarian, registered veterinary technician and holder of an artificial insemination or pregnancy diagnosis permit that the license, registration or permit will expire and provide a renewal application form.

B. Except as provided in Subsections C and D of this section, a person may reinstate an expired license, registration or permit, issued pursuant to the Veterinary Practice Act, within five years of its expiration by making application to the board for renewal and paying the current renewal fee along with all delinquent renewal fees and late fees. After five years have elapsed since the date of expiration, a license, registration or permit may not be renewed and the holder shall apply for a new license, registration or permit and take the required examination.

C. A person shall not have the person's license, issued pursuant to the Veterinary Practice Act, reinstated in New Mexico if, during the time period in which the person's license lapsed, the person's license in another state or jurisdiction was suspended or revoked for reasons for which the license would have been subject to suspension or revocation in New Mexico.

D. A person who, during the time period in which the person's license, issued pursuant to the Veterinary Practice Act, lapsed, was subject to any disciplinary proceedings resulting in action less than suspension or revocation in another state or jurisdiction, may, at the discretion of the board, have the person's license to practice in New Mexico reinstated on a probationary status for up to two years. Upon request by the applicant for reinstatement, the board shall determine under what circumstances the probationary status shall be continued or removed or the application for reinstatement denied.

E. The board may provide by regulation for waiver of payment of any renewal fee of a licensed veterinarian during any period when the veterinarian is on active duty with any branch of the armed services of the United States for the duration of a national emergency.

History: 1953 Comp., § 67-11-19, enacted by Laws 1967, ch. 62, § 8; 1975, ch. 96, § 8; 1977, ch. 167, § 2; 1993, ch. 163, § 8; 1995, ch. 154, § 4; 2017, ch. 44, § 4.

61-14-13. Denial, suspension or revocation of license. (Repealed effective July 1, 2024.)

A. In accordance with the procedures contained in the Uniform Licensing Act [61-1-1 through 61-1-31 NMSA 1978], the board may deny, suspend for a definite period or revoke a license, certificate or permit held or applied for under the Veterinary Practice Act, or may reprimand, place on probation, enter a stipulation with or impose an administrative penalty in an amount not to exceed five thousand dollars ($5,000) on a holder of a license, certificate or permit, upon a finding by the board that the licensee, certificate or permit holder, or applicant:

(1) has committed an act of fraud, misrepresentation or deception in obtaining a license or permit;

(2) has been adjudicated insane or manifestly incapacitated;

(3) has used advertising or solicitation that is false, misleading or is otherwise deemed unprofessional under rules promulgated by the board;

(4) has been convicted of a felony or other crime involving moral turpitude;

(5) is guilty of dishonesty, incompetence, gross negligence or other malpractice in the practice of veterinary medicine;

(6) has a professional association with or employs any person practicing veterinary medicine unlawfully;

(7) is guilty of fraud or dishonesty in the application or reporting of any test for disease in animals;

(8) has failed to maintain his professional premises and equipment in a clean and sanitary condition in compliance with facility permit rules promulgated by the board;

(9) is guilty of habitual or excessive use of intoxicants or drugs;

(10) is guilty of cruelty to animals;

(11) has had his license to practice veterinary medicine revoked by another state, territory or district of the United States on grounds other than nonpayment of license or permit fees;

(12) is guilty of unprofessional conduct by violation of a rule promulgated by the board pursuant to provisions of the Veterinary Practice Act;

(13) has failed to perform as a veterinary technician under the direct supervision of a licensed veterinarian;

(14) has failed as a licensed veterinarian to reasonably exercise direct supervision with respect to a veterinary technician;

(15) is guilty of aiding or abetting the practice of veterinary medicine by a person not licensed, certified or permitted by the board;

(16) has used any controlled drug or substance on any animal for the purpose of illegally influencing the outcome of a competitive event;

(17) has willfully or negligently administered a drug or substance that will adulterate meat, milk, poultry, fish or eggs;

(18) has failed to maintain required logs and records;

(19) has used a prescription or has sold any prescription drug or prescribed extra-label use of any over-the-counter drug in the absence of a valid veterinarian-client-patient relationship;

(20) has failed to report, as required by law, or has made a false report of any contagious or infectious disease;

(21) has engaged in an unfair or deceptive practice; or

(22) has engaged in the practice of veterinary medicine on any animal or group of animals in the absence of a valid veterinarian-client-patient relationship.

B. Disciplinary proceedings may be instituted by sworn complaint by any person and shall conform with the provisions of the Uniform Licensing Act.

C. Any person whose license, certificate or permit is suspended or revoked by the board pursuant to provisions of this section may, at the discretion of the board, be relicensed or reinstated by the board at any time without examination upon written application to the board showing cause to justify relicensing or reinstatement.

History: 1953 Comp., § 67-11-20, enacted by Laws 1967, ch. 62, § 9; 1975, ch. 96, § 9; 1993, ch. 163, § 9; 1995, ch. 154, § 5; 1998, ch. 55, § 75; 1999, ch. 243, § 2.

61-14-14. Exemptions. (Effective July 1, 2018.)(Repealed effective July 1, 2024.)

Provisions of the Veterinary Practice Act do not apply to:

A. employees of federal or state governments performing official duties;

B. regular students in a veterinary school performing duties or actions assigned by an instructor or working under direct supervision of a licensed veterinarian during a school vacation period;

C. reciprocal aid of neighbors in performing routine accepted livestock management practices;

D. a veterinarian licensed in a foreign jurisdiction consulting with a licensed veterinarian;

E. a merchant or manufacturer selling at the merchant's or manufacturer's regular place of business any medicine, feed, appliance or other product used in the prevention or treatment of animal disease;

F. the owner of an animal and the owner's consignees and their employees while performing routine accepted livestock management practices in the care of animals belonging to the owner;

G. a member of the faculty of a veterinary school performing the member's regular functions or a person lecturing or giving instruction or demonstration at a veterinary school or in connection with a continuing education course or seminar for licensed veterinarians, veterinary technicians or persons holding or training for valid permits for artificial insemination or diagnosing pregnancy;

H. a person selling or applying any pesticide, insecticide or herbicide; or

I. a person engaging in bona fide scientific research that reasonably requires experimentation involving animals.

History: 1953 Comp., § 67-11-21, enacted by Laws 1967, ch. 62, § 10; 1975, ch. 96, § 10; 1993, ch. 163, § 10; 1999, ch. 243, § 3; 2017, ch. 44, § 5.

61-14-15. Persons previously licensed. (Repealed effective July 1, 2024.)

The board shall issue a license to any person holding a valid license to practice veterinary medicine in this state on the effective date of the Veterinary Practice Act.

History: 1953 Comp., § 67-11-22, enacted by Laws 1967, ch. 62, § 11.

61-14-16. Responsibility. (Repealed effective July 1, 2024.)

Every veterinarian using, supervising or employing a registered veterinary technician shall be individually responsible and liable for the performance of the acts and omissions delegated to the veterinary technician. Nothing in this section shall be construed to relieve the veterinary technician of any responsibility and liability for any of his own acts and omissions.

History: 1953 Comp., § 67-11-22.1, enacted by Laws 1975, ch. 96, § 11; 1995, ch. 154, § 6.

61-14-17. Inoculation records; confidentiality. (Repealed effective July 1, 2024.)

Animal inoculation records maintained by any state or local public agency may be used only in protecting the public health and welfare or by any other government agency and are not public records open to inspection or duplication. Upon request, the agency shall verify, or deny, as the case may be, that the records reflect that a particular animal has received inoculations within the next preceding twelve months.

History: 1978 Comp., § 61-14-17, enacted by Laws 1995, ch. 154, § 7.

61-14-18. Practicing without license; penalty. (Effective July 1, 2018.)(Repealed effective July 1, 2024.)

A. It is a misdemeanor punishable pursuant to Section 31-19-1 NMSA 1978 for a person to practice veterinary medicine without complying with the provisions of the Veterinary Practice Act and without being the holder of a license entitling the person to practice veterinary medicine in New Mexico.

B. If the board finds that a person or entity has practiced veterinary medicine without a license, the board may:

(1) impose a fine not to exceed five thousand dollars ($5,000);

(2) assess the person or entity for administrative costs, including investigative costs and the cost of conducting a hearing; and

(3) impose any other sanction as provided pursuant to board rules.

History: 1953 Comp., § 67-11-24, enacted by Laws 1967, ch. 62, § 13; 1999, ch. 243, § 4; 2017, ch. 44, § 6.

61-14-19. Injunction. (Repealed effective July 1, 2024.)

The board or any person may bring an action in the district court to enjoin any person who is not a licensed veterinarian from engaging in the practice of veterinary medicine. If the court finds that the defendant is violating or threatening to violate the Veterinary Practice Act, it shall enter an order restraining him from the violation. Any person so enjoined who violates the injunction may be punished for contempt of court. This remedy by injunction shall be in addition to any remedy provided for criminal prosecution of the offender.

History: 1953 Comp., § 67-11-25, enacted by Laws 1967, ch. 62, § 14; 1999, ch. 243, § 5.

61-14-20. Termination of agency life; delayed repeal. (Repealed effective July 1, 2024.)

The board of veterinary medicine is terminated on July 1, 2023 pursuant to the Sunset Act. The board shall continue to operate according to the provisions of Chapter 61, Article 14 and Chapter 77, Article 1B NMSA 1978 until July 1, 2024. Effective July 1, 2024, Chapter 61, Article 14 and Chapter 77, Article 1B NMSA 1978 are repealed.

History: 1978 Comp., § 61-14-20, enacted by Laws 1979, ch. 76, § 2; 1981, ch. 241, § 27; 1985, ch. 87, § 12; 1991, ch. 189, § 22; 1993, ch. 163, § 12; 1997, ch. 46, § 16; 2005, ch. 208, § 10; 2011, ch. 30, § 3; 2017, ch. 44, § 7.

OKLAHOMA STATE BOARD OF
VETERINARY MEDICAL EXAMINERS
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POSITION STATEMENT

Telemedicine/Telehealth

In the interest of protecting the health, safety and welfare of the public, the Oklahoma State Board of Veterinary Medical Examiners (Board) at its regularly scheduled public meeting on October 5, 2018, approved issuing this position statement regarding Telemedicine/Telehealth. It is the position of the Board that veterinarians should use the following guidelines regarding the use of Telemedicine/Telehealth in their veterinary practices. (American Association of Veterinary State Boards, AAVSB)

A veterinarian using telehealth technologies must take appropriate steps to establish the VCPR and conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation. As such, some situations and patient presentations are appropriate for the utilization of telehealth technologies as a component of, or in lieu of, hands-on medical care, while others are not.

Pursuant to Title 59 O.S. §698.2 (13) "Veterinarian-client-patient relationship" means when: a. the licensed veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal or animals and the need for medical treatment, and the client, owner or other caretaker has agreed to follow the instructions of the licensed veterinarian; and b. there is sufficient knowledge of the animal or animals by the licensed veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal or animals in that: 1. the licensed veterinarian has recently seen or is personally acquainted with the keeping and care of the animal or animals, or 2. the licensed veterinarian has made medically necessary and timely visits to the premises where the animal or animals are kept or both, and c. the licensed veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy, or has arranged for emergency medical coverage, and d. the licensed veterinarian's actions would conform to applicable federal law and regulations;

Telehealth is a reasonable option for patients who lack regular access to veterinary care. It also enhances opportunities to access emergency or specialty veterinary expertise in geographic areas where no other options are available.

The veterinarian accepts that he or she cannot prescribe drugs when practicing via telehealth alone, unless the veterinarian has sufficient knowledge of the animal or group of animals by virtue of a

history and inquiry, and either physical examination or medically appropriate and timely visits to the premises where the animal or group of animals is kept.

Appropriate medical records must be maintained in a secure and confidential manner. The medical record should include, but not be limited to, if applicable, copies of all patient related electronic communications, including prescriptions, laboratory and test results, evaluations and consultations, and instructions obtained or produced in connection with the utilization of telehealth technologies.

An animal owner should be able to seek, with relative ease, follow-up care or information from the veterinarian (or veterinarian's designee) who conducts an encounter using telehealth technologies. The veterinarian must ensure that the client is aware of the veterinarian's identity, location, licensure status, and the privacy and security issues involved in accessing veterinary care via telehealth technologies. Evidence documenting appropriate animal owner consent for the use of telehealth technologies must be obtained and maintained.

A veterinarian must be licensed, or under the jurisdiction of, the veterinary board of the jurisdiction where the patient is located. The practice of medicine occurs where the patient is located at the time telehealth technologies are used. Veterinarians who treat or prescribe through online services sites are practicing veterinary medicine and must possess appropriate licensure in all jurisdictions where patients receive care.

Consultation is not considered telehealth and means when a licensed veterinarian received advice in person, telephonically, electronically, or by any other method of communication from a veterinarian licensed in this or any other jurisdiction or other person whose expertise, in the opinion of the licensed veterinarian, would benefit a patient. The licensed veterinarian receiving consultation maintains the veterinarian-client-patient-relationship.

These guidelines should not be construed to alter the scope of practice of any veterinarian or veterinary technician or authorize the delivery of veterinary medical services in a setting or in a manner that is not otherwise authorized by law. These guidelines support a consistent standard of care and veterinarians and veterinary technicians must review and understand the laws, regulations, and policies of each jurisdiction where they practice. The veterinarian must employ sound professional judgment to determine whether using telehealth is suitable each time veterinary services are provided and only furnish medical advice or treatment via telemedicine when it is medically appropriate.

This Position Statement is issued as of the 5th day of October 2018, by unanimous approval of the Board members.

Oklahoma State Board of Veterinary Medical Examiners

By: Clint J Gardner DVM

Clint J. Gardner, DVM, Board President

Attachment #3 - Utah

R156-1-602. Telehealth - Scope of Telehealth Practice.

(1) This rule is not intended to alter or amend the applicable standard of practice for any healthcare field or profession. The provider shall be held to the same standards of practice including maintaining patient confidentiality and recordkeeping that would apply to the provision of the same health care services in an in-person setting.

(2) In accordance with Section 26-60-103 and Subsection 26-60-104(1), a provider offering telehealth services shall, prior to each patient encounter:

(a) verify the patient's identity and originating site;

(b) obtain informed consent to the use of telehealth services by clear disclosure of:

(i) additional fees for telehealth services, if any, and how payment is to be made for those additional fees if they are charged separately from any fees for face-to-face services provided to the patient in combination with the telehealth services;

(ii) to whom patient health information may be disclosed and for what purpose, including clear reference to any patient consent governing release of patient-identifiable information to a third-party;

(iii) the rights of patients with respect to patient health information;

(iv) appropriate uses and limitations of the site, including emergency health situations;

(v) information:

(A) affirming that the telehealth services meet industry security and privacy standards, and comply with all laws referenced in Subsection 26-60-102(8)(b)(ii);

(B) warning of potential risks to privacy notwithstanding the security measures;

(C) warning that information may be lost due to technical failures, and clearly referencing any patient consent to hold the provider harmless for such loss; and

(D) disclosing the website owner/operator, location, and contact information; and

(c) allow the patient an opportunity to select their provider rather than being assigned a provider at random, to the extent possible;

(d) ensure that the online site from which the provider offers telehealth services does not restrict a patient's choice to select a specific pharmacy for pharmacy services.

(3) In accordance with Subsection 26-60-103(1)(b), it is not an acceptable standard of care for a provider offering telehealth services to establish a diagnosis and identify underlying conditions and contraindications to a recommended treatment based solely on an online questionnaire, except as specifically provided in Title 58, Chapter 83, the Online Prescribing, Dispensing and Facilitation Licensing Act.

(4) In accordance with Subsection 26-60-103(1)(c), a provider offering telehealth services shall be available to the patient for subsequent care related to the initial telemedicine services, by:

(a) providing the patient with a clear mechanism to:

(i) access, supplement, and amend patient-provided personal health information;

(ii) contact the provider for subsequent care;

(iii) obtain upon request an electronic or hard copy of the patient's medical record documenting the telemedicine services, including the informed consent provided; and

(iv) request a transfer to another provider of the patient's medical record documenting the telemedicine services;

(b) if the provider recommends that the patient needs to be seen in person, such as where diagnosis requires a physical examination, lab work, or imaging studies:

(i) arranging to see the patient in person, or directing the patient to the patient's regular provider, or if none, to an appropriate provider; and

(ii) documenting the recommendation in the patient's medical record; and

(c) upon patient request, electronically transferring to another provider the patient's medical record documenting the telemedicine services, within a reasonable time frame allowing for timely care of the patient by that provider.

(5) In accordance with Subsection 26-60-103(1)(d), a provider offering telehealth services shall be familiar with available medical resources, including emergency resources near the originating site.

(6) In settings and circumstances where an established provider-patient relationship is not present, a provider offering telehealth services shall establish a provider-patient relationship during the patient encounter, in a manner consistent with standards of practice including providing the provider's licensure and credentials.

(7) Nothing in this section shall prohibit electronic communications consistent with standards of practice applicable in traditional health care settings, including those:

(a) between a provider and a patient with a preexisting provider-patient relationship;

(b) between a provider and another provider concerning a patient with whom the other provider has a provider-patient relationship;

(c) in on-call or cross coverage situations in which the provider has access to patient records;

(d) in broader practice models where multiple providers provide care as a team, including, for example:

(i) within an existing organization; or

(ii) within an emergency department; or

(e) in an emergency, which as used in this section means a situation in which there is an occurrence posing an imminent threat of a life-threatening condition or severe bodily harm.

A Query from an AAVSB Member Board

Implemented telehealth vs. guidelines/policy

On December 18, 2019, Lucy Richards, Executive Officer for the Montana Board of Veterinary Medicine asked the following:

Has your jurisdiction implemented telehealth/medicine statutes as opposed to just guidelines, policy, etc.?

If so, please share those regulations as well as any data you have regarding the use of telehealth/telemedicine and impacts on practice and regulation (positive or negative).

Alaska
The need for telemedicine regulations is on the Alaska Board's radar, but no regulations have been adopted yet. This is especially important in Alaska due to the vast remoteness of many communities around the state. This will likely be linked in some way to the upcoming VCPR regulations. 2020 will be a busy regulatory year for the board.

Alaska does require that telehealth practitioners be licensed and registered with the State, but the regulations are fairly vague and definitely not specific to veterinary medicine.

Arizona
No

Arkansas
Telehealth/telemedicine was discussed at our December board meeting in light of this FDA guidance document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals. Currently, Arkansas does not have the statutory authority to promulgate telehealth/telemedicine rules, but that is something we might be looking into. It was discussed whether introducing telehealth/telemedicine rules would help producers in rural areas gain better access to veterinarians, as the last of the antibiotics available OTC at feed stores will likely be coming off of the shelves and only be available by prescription (if FDA follows through with its plan per the guidance document, or at least that is my understanding). I am very interested to see what responses you get on this subject.

California
The Board's recently made changes to their current regulations to address telehealth. Those regulations can be found here and are effective on January 1, 2019.

Hawaii
Hawaii does not address telehealth in the Veterinary Practice statute or rules. However, it is defined in the Physician statute: HRS **§453-1.3 Practice of telehealth.**

https://www.capitol.hawaii.gov/hrscurrent/Vol10_Ch0436-0474/HRS0453/HRS_0453-0001_0003.htm

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Maine
Maine does not.

Maryland
Maryland has not implemented any guidelines or regulations related to telehealth or telemedicine.

Minnesota
Minnesota has not implemented any new statutes or rules as their position that a valid VCPR is required is already supported in current statutes.

Nevada
We're in the process of workshopping regs. I have attached our most recent draft. (See pages 5-12).

New Mexico
The New Mexico Board of Veterinary Medicine has not instituted statutes or rules addressing telemedicine specifically; however, the following Board rule is expected when providing telemedicine services:

16.25.9.8 GENERAL STANDARDS:

C. A valid veterinarian-client-patient relationship (VCPR) must be established when delivering veterinary care. See VCPR as defined by the New Mexico Veterinary Practice Act 61-14-2-J (1), (2), (3), and (4).

(1) A VCPR cannot be established by telephonic, computer, internet or other electronic communications; however, a New Mexico-licensed veterinarian may provide or arrange for consulting services for their clients using the described electronic communication methods.

The Board does not currently have data on the telehealth/telemedicine impacts on practice and regulation in New Mexico.

North Carolina
NC has granted the NCVMB regulatory authority to draft language pertaining to Telehealth. Our legislative committee has been hard at work and hopes to have formal language available early in 2020.

Nova Scotia
Nova Scotia developed a telemedicine guide to the professional practice standard in July 2019.

Ohio
Ohio does not have telehealth statutes for veterinarians, only a Guidance policy.

Oklahoma
We just implemented guidelines no regulations as of today. However, we are proposing the following language for next year's legislative session as a definition of telemedicine/telehealth.

18. **"Telemedicine - Telehealth"** ~~shall mean the transmission of diagnostic images such as, but not limited to, radiographs, ultrasound, cytology, endoscopy, photographs and case information over ordinary or cellular phone lines to a licensed veterinarian or board-certified medical specialist for the purpose of consulting regarding case management with the primary care licensed veterinarian who transmits the cases;~~
means the practice of veterinary medicine including diagnosis, consultation, evaluation and treatment, transfer of medical data or exchange of information by means of a two-way, real-time interactive communication, between a client/patient and a veterinarian with access to and reviewing the patient's relevant information prior to the telemedicine visit. Does not include consultations provided by telephone audio-only communication. A veterinarian using telehealth technologies must take appropriate steps to establish the VCPR and conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation.A veterinarian must be licensed, or under the jurisdiction of, the veterinary board of the jurisdiction where the patient is located. The practice of medicine occurs where the patient is located at the time telehealth technologies are used.

Oregon
We have proposed the attached rules, may be adopting them in February. (See page 13)

Vermont
Vermont has not adopted telehealth statutes.

Virginia
The Virginia Board of Veterinary Medicine considers telemedicine to be a method of delivery. Therefore, all current laws and regulations applicable to the practice of veterinary medicine apply. The Code of Virginia requires a license if the person is doing anything to an animal located in Virginia that constitutes the practice of veterinary medicine. There are several exceptions to this statutory requirement which are provided below:
§ 54.1-3801. Exceptions.
This chapter shall not apply to:
1. The owner of an animal and the owner's full-time, regular employee caring for and treating the animal belonging to such owner, except where the ownership of the animal was transferred for the purpose of circumventing the requirements of this chapter;

2. Veterinarians licensed in other states called in actual consultation with veterinarians licensed in the Commonwealth who do not open an office or appoint a place to practice within the Commonwealth;

3. Veterinarians employed by the United States or by the Commonwealth while actually engaged in the performance of their official duties, with the exception of those engaged in the practice of veterinary

medicine, pursuant to § 54.1-3800, as part of a veterinary medical education program accredited by the American Veterinary Medical Association Council on Education and located in the Commonwealth;

4. Veterinarians providing free care in underserved areas of Virginia who (i) do not regularly practice veterinary medicine in Virginia, (ii) hold a current valid license or certificate to practice veterinary medicine in another state, territory, district, or possession of the United States, (iii) volunteer to provide free care in an underserved area of the Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) file copies of their licenses or certificates issued in such other jurisdiction with the Board, (v) notify the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi)
acknowledge, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any veterinarian whose license has been previously suspended or revoked, who has been convicted of a felony, or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a veterinarian who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state; or
5. Persons purchasing, possessing, and administering drugs and biological products in a public or private animal shelter as defined in § 3.2-6500, provided that such purchase, possession, and administration is in compliance with § 54.1-3423.

Washington
In Washington, we have not.

Wisconsin
WI has not made changes to our regulations regarding telehealth.

PROPOSED REGULATION OF THE NEVADA STATE BOARD

OF VETERINARY MEDICAL EXAMINERS

LCB File No. R*-19**

September 4, 2019

EXPLANATION – Matter in ***italics*** is new; matter in brackets ~~[omitted material]~~ is material to be omitted.

AUTHORITY: §§1-5, 7 and 8, NRS 638.070; §6, NRS 638.070 and 638.147.

[NOTE: Many of the concepts and much of the language contained herein derives from "AAVSB Recommended Guidelines for the Appropriate Use of Telehealth Technologies in the Practice of Veterinary Medicine" published September 2018.]

A REGULATION relating to veterinary medicine; allowing veterinarians to provide telemedicine and teletriage services and conditions related thereto.

Legislative Counsel's Digest:

Existing law. . .

Section 1. Chapter 638 of NAC is hereby amended by adding thereto the provisions set forth as section 2 of this regulation.

Sec. 2. ***"Consultant" means a veterinarian who does not have a veterinarian-client-patient relationship with a patient and who consults with a treating veterinarian.***

Sec. 3. ***"Telemedicine" means the remote delivery of healthcare services for patients, such as health assessments or consultations, over the telecommunications infrastructure and by which a veterinarian may evaluate, diagnose, treat, create a veterinary-client-patient***

relationship, and provide health information or education related to patients to other veterinarians or clients.

Sec. 4. ***"Teletriage" means emergency patient care, including animal poison control services, for immediate, potentially life-threatening animal health situations such as, but not limited to, poison exposure mitigation, animal CPR instructions, or other critical lifesaving treatment or advice.***

Sec. 5. ***"Treating veterinarian" is a veterinarian who:***

1. Practices veterinary medicine in a location in Nevada;

2. Has a veterinarian-client-patient relationship with an animal located in Nevada; and

3. Sees and treats the animal in-person at a location in Nevada.

Sec. 6. ***1. A veterinarian may provide telemedicine or teletriage services to clients and patients in Nevada where:***

(a) The veterinarian is licensed with the Board;

(b) The veterinarian is licensed in good standing in the state from which he or she will be providing the telemedicine or teletriage services;

(c) The veterinarian has established a veterinary-client-patient relationship with a patient; and

(d) The veterinarian provides the telemedicine or teletriage services in conformance with this section.

2. A consultant who is licensed in another state and only consults with a treating veterinarian related to an animal being treated by the treating veterinarian and who does not establish a veterinarian-client-patient relationship with the animal is exempt from licensure under this section. If a veterinarian who is licensed in another state speaks with or otherwise

communicates directly with a client, then that veterinarian is not a consultant and must be licensed in Nevada.

Sec. 7. ***1. A veterinarian who provides telemedicine or teletriage to an animal and a client located in Nevada must for each encounter:***

(a) Allow the encounter to commence only through means of a website or application, and at the commencement of the encounter, inform the patient in writing and orally of the veterinarian's name, location from which he or she is providing the telemedicine or teletriage, and the veterinarian's license number in Nevada and the state from which he or she is providing telemedicine;

(b) Evaluate and assess the animal by whatever technological means and consistent with currently acceptable standards of care;

(c) Determine that the animal and client are appropriate candidates for the utilization of teletriage and telemedicine will be adequate to address the presentation, and if the animal and client are not appropriate candidates for the utilization of teletriage or telemedicine, so inform the client, provide contact information for the nearest available and appropriate Nevada veterinarian, and terminate the encounter;

(d) If the veterinarian determines that the animal and client are appropriate candidates for the utilization of teletriage or telemedicine, establish a veterinarian-client-patient relationship;

(e) If the veterinarian determines that the animal and client are appropriate candidates for the utilization of telemedicine or teletriage, obtain written evidence by paper, e-mail, or other technological means of the informed consent of the client to receiving telemedicine or teletriage services related to the animal;

(f) In all cases, make a medical record related to the encounter;

(g) In all cases where the client has an established treating veterinarian located in Nevada, provide the medical records generated in the telemedicine encounter to the treating veterinarian located in Nevada;

(h) In all cases, assure that the encounter is conducted and maintained confidentially.

2. Where, in the judgment of the veterinarian, the providing of advice regarding or guidance in the treatment of the animal is emergent and that the life or well-being of the animal is in imminent threat, the veterinarian may act and advise as he or she deems necessary and may assure compliance with any or all of subsections (a), (e), (f), or (g) after the emergency is resolved with the animal.

3. The website or application through which the client initiated the encounter must contain:

(a) A method by which the client may access, supplement, and amend contact and health information the client provided related to the animal;

(b) A method by which the client may request the medical records and other related records made and maintained by the veterinarian related to the care of the animal; and

(c) Information about how the client may file a complaint about the care provided to the Nevada board and the board of the state from which the veterinarian is providing the telemedicine or teletriage.

Sec. 8. *1. All written medical records made regarding a telemedicine or teletriage encounter involving a patient and client located in Nevada must comply with NAC 638.0475. All such records must be made available upon request to the client or the Board within three business days of the request.*

2. If the veterinarian records the encounter by video or aural means, the veterinarian shall:

(a) Inform the client that the recording will be made and obtain the client's consent to the recording before the recording can commence;

(b) Maintain the recording as part of the medical record; and

(c) Assure that the substance of the recording is written into the medical record within 24 hours of the encounter.

Sec. 9. *If the veterinarian determines that a prescription drug is appropriate and necessary as part of a telemedicine or teletriage encounter, the veterinarian may:*

1. Call in or provide an electronic prescription to a pharmacy of the client's choice;

2. Not prescribe more than a three-day supply of a controlled substance;

3. Not dispense the drug to the patient from his or her own veterinary facility unless the veterinary facility is located in Nevada and the client picks up the drug in person at the veterinary facility.

Sec. 10. *1. For the purposes of providing telemedicine or teletriage services, a veterinarian-client-patient relationship exists when:*

(a) Both the veterinarian and client agree for the veterinarian to assume responsibility for making medical judgments regarding the health of the animal; and

(b) The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal; and

(c) If the client has a treating veterinarian, that he or she is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy ordered by the veterinarian who provided the telemedicine or teletriage services.

2. The veterinarian who will provide telemedicine or teletriage services may establish that he has sufficient knowledge of an animal by or through:

(a) A recent examination of the animal, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically and in real time to the veterinarian;

(b) A physical examination and assessment performed at the veterinarian's direction by a veterinary technician employed by the veterinarian who is physically present with the animal; or

(c) Through medically appropriate and timely visits to the premises at which the animal is kept.

Sec. 11. NAC 638.0197 shall be amended to read as follows:

1. For the purposes of this chapter, a veterinarian shall be deemed to have a "veterinarian-client-patient relationship" concerning a nonhuman animal if the veterinarian ***satisfies Section 10 of this regulation or*** all of the following conditions:

(a) The veterinarian assumes the responsibility for making medical judgments concerning the health of the animal and the need for medical treatment of the animal.

(b) The veterinarian has knowledge of the present care and health of the animal sufficient to provide at least a general or preliminary diagnosis of the medical condition of the animal. This knowledge must be acquired by:

(1) Conducting a physical examination of the animal; [~~or~~]

(2) Visiting the premises where the animal is kept in a timely manner that is appropriate to the medical condition of the animal [~~.~~] ***; or***

(3) Compliance with Section 10 of this regulation.

(c) The veterinarian obtains the informed consent of the client for medical treatment of the animal.

(d) The veterinarian obtains the agreement of the client to follow the instructions provided by the veterinarian for the care and medical treatment of the animal.

2. As used in this section, "informed consent" means that the client, after having been informed in a manner that would be understood by a reasonable person, of the diagnostic and treatment options, risk assessment and prognosis for the animal and of an estimate of the fees expected for provision of veterinary services to be rendered to the animal, has consented to the recommended treatment.

Sec. 12. NAC 638.0435 shall be amended to read as follows:

NAC 638.0435. 1. ***Except as provided in subsection 3,*** [~~In~~] ***in*** addition to the requirements of NRS 638.100, an applicant for a license to practice veterinary medicine must submit to the Executive Director of the Board proof that the applicant has passed, within the 5 years immediately preceding the date on which he or she submitted his or her application:

(a) The North American Veterinary Licensing Examination of the National Board of Veterinary Medical Examiners; or

(b) Any other examination approved for this purpose by the Board pursuant to NRS 638.110.

2. In addition to the requirements of subsection 1, an applicant for a license to practice veterinary medicine who is a graduate of a school of veterinary medicine that is not accredited by the Council on Education of the American Veterinary Medical Association must submit to the Board a verified copy of the educational certificate required pursuant to paragraph (b) of subsection 2 of NRS 638.100.

3. A veterinarian is not required to comply with subsection 1 where the veterinarian:

(a) Has been licensed in and has practiced veterinary medicine in another state for at least five years preceding his or her application; and

(b) Has not been disciplined in any other state for the five years preceding his or her application.

PROPOSED 10/26/2019
MINIMUM STANDARDS FOR VETERINARY TELEMEDICINE
OAR 875-015-0035

Minimum Standards for Veterinary Telemedicine (VTM)

(1) Veterinary Telemedicine (VTM) occurs in Oregon when either the animal who is receiving the care is located in Oregon when receiving VTM or the person providing the care to the animal is located in Oregon when providing VTM.

(2) VTM may be used when a veterinarian has a VCPR only when:

(a) A physical examination of the patient has been conducted within the last year; and

(b) If it is possible to make a diagnosis and create a treatment plan without a new physical exam.

(3) At the discretion of the veterinarian, VTM may be used by a veterinarian who has not personally physically examined the animal within the last year only under the following circumstances:

(a) The veterinarian has reviewed the records of another licensed veterinarian who has seen the animal within the previous year; and

(b) Only if it is possible to make a diagnosis and create a treatment plan without a physical examination.

(4) VTM may be used with an existing client when there has not been a previous physical examination for the purpose of prescribing sedation for an aggressive or fractious patient prior to an initial visit.

(5) Prescriptions may only be issued when VTM occurs if the veterinarian has evaluated the safety of doing so via VTM, and in compliance with all state and federal laws.

(6) A veterinarian shall not substitute VTM for a physical exam when a physical exam is warranted or necessary for an accurate diagnosis of any medical condition or creation of an appropriate treatment plan.

(7) When practicing VTM in Oregon, licensees must conform to all minimum standards of practice and applicable laws. Licensees are fully responsible and accountable for their conduct when using VTM under the Board's statutes and rules.

(8) Whenever VTM is practiced in Oregon, a veterinarian must:

(a) Ensure that any technology used in the provision of VTM is sufficient and of appropriate quality to provide accuracy of remote assessment and diagnosis.

(b) Ensure that medical information obtained via VTM is recorded completely in the patient medical record and meets all applicable requirements of OAR 875-015-0030(1).

(9) A veterinarian may only delegate the provision of VTM to a Certified Veterinary Technician who is acting under direct or indirect supervision and in accordance with OAR 875-030-0040. A valid VCPR established by a physical examination conducted by the veterinarian must exist for the CVT to provide VTM services.

(10) Veterinarians and CVTs providing VTM shall at the time of service provide their contact information to the client or practice using the service. All VTM records shall be provided to the client or another veterinarian pursuant to the provisions of OAR 875-011-0010 (12), (13).

From:	DATCP VEB
To:	Mace, Melissa A - DATCP
Subject:	FW: Questions about Telehealth/Telemedicine
Date:	Tuesday, January 7, 2020 8:18:21 AM
Attachments:	image001.png

From: Susan Krebsbach, DVM <DrSusan@CreatureCounseling.com>
Sent: Monday, January 6, 2020 8:51 PM
To: DATCP VEB <datcpveb@wisconsin.gov>
Subject: Questions about Telehealth/Telemedicine

To Whom It May Concern:

I have a couple of questions about veterinarians practicing telehealth in the state of Wisconsin, specifically telemedicine (as defined by the American Veterinary Medical Association (AVMA) on their web page "Veterinary telehealth: The basics").

I frequently receive referrals from other veterinarians throughout the state of Wisconsin to perform behavioral consultations for their clients. As part of my services, I ask to review the medical record of the patient for the past two years or so. For those clients who are not within driving distance for me to do a home behavioral consultation for them, is it acceptable to conduct the behavioral consultation via video conference as long as the referring veterinarian is involved (e.g., is made aware of the recommendations, would be the prescribing veterinarian if medication is used, etc.)?

I look at my services as an extension of the veterinary clinic. The ability to do video conferencing is especially important for veterinary clinics that do not have local access to a veterinarian who works on animal behavior. This type of arrangement is really no different than a veterinarian who works at the same clinic as the referring veterinarian, but who has not physically examined the pet, yet still provides recommendations to the client in the absence of the referring veterinarian (for example, over the telephone).

Thank you in advance for your guidance.

Sincerely,

Susan B. Krebsbach, DVM
Creature Counseling
Veterinary Animal Behavior Consulting Services
1000 Wesley Road
Oregon, WI 53575-2686
Phone: 608-835-5104
Fax: 608-835-5185
Email: DrSusan@CreatureCounseling.com
Website: www.CreatureCounseling.com

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Election of Officers Appointment of Liaisons Appointment of Committees
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	"2020 Elections & Appointments"
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	Election of officers must occur at the first VEB meeting of every calendar year. The full Board elects the chair, vice chair, and secretary. Then the Board discusses and the chair appoints the liaisons and committees. The attachment lists the offices, liaisons, and committees that have been used in past years with draft descriptions of what these roles have been used for. The Board may discuss making changes to this list, such as whether to add/remove/change the categories of liaisons, and discuss how they would like to define each role.

State of Wisconsin

Veterinary Examining Board

2811 Agriculture Drive • PO Box 8911 • Madison, WI 53708-8911 • Wisconsin.gov

2020 Elections and Appointments

2020 Election Results		
Office	**Description of Role**	**Member Name**
Board Chair	Highest ranking officer. Manages meetings. Delegated authority to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair has the ability to delegate this signature authority to the Board's Executive Director for purposes of facilitating the completion of assignments during or between meetings.	
Vice Chair	Serves as backup for the Board Chair.	
Secretary	(required by Statute)	

2020 Liaison Appointments		
Liaison	**Description of Role**	**Member Name**
Education and Exams Liaison	(Do we need this liaison)	Primary:
		Alternate:
Continuing Education Liaison	Consultation on CE questions	Primary:
		Alternate:
Legislative Liaison	(Do we need this liason)	Primary:
		Alternate:
Administrative Rules Liaison	Could this be made into a committee and used to answer rule applicability questions and/or assist in developing guidance documents)	Primary:
		Alternate:
Monitoring	(is this used)	Primary:
		Alternate:

2020 Committee Appointments		
Committee	**Description of Role**	**Member Name**
Screening	Delegated authority to open cases for	Chair:

Committee	investigation or closes cases inappropriate for further action. Delegated authority to consider questions related to scope of practice of veterinary medicine and veterinary technicians. The Committee may choose to approve or reject a particular practice, or bring the matter to the full Board. Chair manages Committee meetings.	Member:
		Member:
		Member:
		Member:
Credentialing Committee	Delegated authority to address all issues related to credentialing matters, except potential denial decisions should be referred to the full Board for final determination. Delegated authority to employ a "passive review" process for background checks, whereby if no Committee member requests a meeting on the materials within five business days after receiving them, the application would be considered cleared to proceed through the process. Chair manages Committee meetings.	Chair:
		Member:
		Member:

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Delegated Authority Motions
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	"Delegated Authority Motions" "Roles and Authorities Delegated to the Monitoring Liaison"
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	These are motions to delegate VEB authority to officers, liaisons, and department staff. These motions occur at the first Board meeting of every calendar year.

State of Wisconsin

Veterinary Examining Board

2811 Agriculture Drive • PO Box 8911 • Madison, WI 53708-8911 • Wisconsin.gov

Delegated Authority Motions

Delegated Authority – Urgent Matters

MOTION: (*Board Member*) moved, seconded by (*Board Member*), that in order to facilitate the completion of assignments between meetings, the Board delegates authority by order of succession to the Chair, highest ranking officer, or longest serving member of the Board, to appoint liaisons to the Department to act in urgent matters, to fill vacant appointment positions, where knowledge or experience in the profession is required to carry out the duties of the Board in accordance with the law.

Delegated Authority - Screening Committee

MOTION: (*Board Member*) moved, seconded by (*Board Member*), that the Board delegates authority to the Screening Panel to open cases for investigation or close cases inappropriate for further action.

MOTION: (*Board Member*) moved, seconded by (*Board Member*), that the Board delegates authority to the Screening Panel to consider questions related to scope of practice of veterinary medicine and veterinary technicians. The Screening Committee may choose to approve or reject a particular practice, or bring the matter to the full Board.

Delegated Authority - Credentialing Committee

MOTION: (*Board Member*) moved, seconded by (*Board Member*), that the Board delegates authority to the Credentialing Committee to address all issues related to credentialing matters, except potential denial decisions should be referred to the full Board for final determination.

MOTION: (*Board Member*) moved, seconded by (*Board Member*), that the Board delegates authority to the Credentialing Committee to employ a "passive review" process for background checks, whereby if no Committee member requests a Committee meeting on the materials within five (5) business days after receiving them, the application would be considered cleared to proceed through the process.

Delegated Authority - Document Signatures

MOTION: (*Board Member*) moved, seconded by (*Board Member*), that the Board delegates authority to the Chair to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair has the ability to delegate this signature authority to the Board's Executive Director for purposes of facilitating the completion of assignments during or between meetings.

Delegated Authority - Monitoring Liaison and Department Monitor

MOTION: (*Board Member*) moved, seconded by (*Board Member*), to adopt the "Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor" document.

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Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor

The Monitoring Liaison is a board designee who works with department monitors to enforce the Board's orders as explained below.

Current Authorities Delegated to the Monitoring Liaison

The Liaison may take the following actions on behalf of the Board:

1. Grant a temporary reduction in random drug screen frequency upon Respondent's request if he/she is unemployed and is otherwise compliant with Board order. The Department Monitor will draft an order and sign on behalf of the Liaison. The temporary reduction will be in effect until Respondent secures employment in the profession.

2. Grant a stay of suspension if Respondent is eligible per the Board order. The Department Monitor will draft an order and sign on behalf of the Liaison.

3. Remove the stay of suspension if there are repeated violations or a substantial violation of the Board order. The Department Monitor will draft an order and sign on behalf of the Liaison.

4. Grant or deny approval when Respondent proposes continuing/remedial education courses, treatment providers, mentors, supervisors, change of employment, etc. unless the order specifically requires full-Board approval. The Department Monitor will notify Respondent of the Liaison's decision.

5. Grant a maximum 90-day extension, if warranted and requested in writing by Respondent, to complete Board-ordered CE, pay proceeding costs, and/or pay forfeitures upon Respondent's request.

Current Authorities Delegated to the Department Monitor

The Department Monitor may take the following actions on behalf of the Board, draft an order and sign:

1. Grant full reinstatement of licensure if CE is the sole condition of the limitation and Respondent has submitted the required proof of completion for approved courses.

2. Suspend the license if Respondent has not completed Board-ordered CE and/or paid costs and forfeitures within the time specified by the Board order. The Department Monitor may remove the suspension and issue an order when proof completion and/or payment have been received.

Clarification

1. In conjunction with removal of any stay of suspension, the Liaison may prohibit Respondent from seeking reinstatement of the stay for a specified period of time. (This is consistent with current practice.)

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	January 22, 2020
2) Requestor Name	M. Mace
3) Item Title for the Agenda	Follow-up from Oct. 23, 2019 mtg
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	No
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	1. WTCS – CVT Outreach (Lyn Shuh and Melissa Mace met with WTCS CVT program to discuss barriers to certification) 2. Strategic Planning: Getting a presenter/training on Strategic Planning. 3. VEB outreach to the WI School of Vet Medicine on Licensing/VEB education. – Discuss WSOV interest in having the Board educate third year students on licensing and what the VEB does.

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	Jan 22, 2020
2) Requestor Name	M Mace
3) Item Title for the Agenda	Establishing a VCPR
4) Should the Item be in Open or Closed Session?	Open
5) Are there Attachments? (If yes, include file names)	No
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	**Question from a veterinarian at an Emergency Clinic:** **To establish a VCPR does the veterinarian need to meet in person with the client or can it be done thru the CVT or unlicensed technician discussing treatment and findings (routine) with client. Veterinarian would still do an exam but may not discuss findings with client.**

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Administrative Code Items
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	"VEB Rules Status"
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	The attachment shows the rule process timelines for VE 7 (CAITs) and VE 1-11 (Reorganization). VE 7 CAITs was referred to the Joint Committee for Review of Administrative Rules (JCRAR) on 12/23/19. JCRAR has a 30-day passive review period that may be extended to 60 days. No Board action is required. VE 1-11 requires Board action to approve the preliminary public hearing and comment period, which is detailed on a separate form.

DAH Rules Estimated Timelines

Future dates are estimates for the purposes of work planning.

Last Updated: 1/9/19

Key	
White	Estimated date
Blue	Actual date
Yellow	Estimated date requires revision
Red	Projection exceeds deadline (scope expires)

					Statement of Scope											Hearing Draft									Final Draft												
					Initiate	Governor			Preliminary Hearing[1]					Board		EIA[2]		Board		Clearinghouse		Hearing			Board		Governor		Legislature[3]					Adopt			
Rule	Topic	Scope #	DATCP Docket #	Clearing-house #	Begin Scope	Scope to Governor	Governor Approve Scope	Scope Publish in Register	Materials to OS	Board Approve Hearing	Notice Publish in Register	Hearing Date(s)	Record Open Until	Materials to OS	Board Approve Scope	Posted for Comment	Record Open Until	Materials to OS	Board Approve Draft	Refer to CH	Receive CH Comment	Notice Publish in Register	Hearing Date(s)	Record Open Until	Materials to OS	Board Approve Final	Final to Governor	Governor Approve Final	Refer to Legis.	Refer to Comm.	Comm. Review Ends	Refer to JCRAR	JCRAR Review Ends	Rule to LRB	Deadline to Refer to Legis. (Scope Expires)	Rule Effective Date
VE 7	CAITs	SS 025-16	16-VER-7	CR 17-084	x	3/16/16	4/15/16	4/18/16	x	x	x	x	x	x	4/27/16	x	x	x	10/25/17	11/30/17	12/19/17	12/11/17	1/10/18, 1/11/18, 1/12/18, 1/9/18	1/31/18	x	2/13/18	3/2/18	10/3/19	10/24/19	10/31/19; 11/7/19	11/30/19; 12/9/19	12/2/19; 12/23/19	2/21/20	2/27/20	2/4/20	4/1/20
VE 1-11	Reorg	SS 125-19			5/17/19	10/25/19	12/5/19	12/23/19	1/7/20	1/22/19, 1/30/19	2/10/20	2/17/20	2/24/20	2/28/20	3/5/20	6/3/20	8/2/20	9/30/20	10/21/20	10/28/20	11/17/20	11/21/20	12/1/20	12/15/20	4/7/21	4/28/21	5/5/21	8/3/21	8/17/21	8/27/21	10/26/21	11/5/21	1/4/22	1/18/22	6/23/22	3/1/22

Rule Process Step:	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10	Step 11	Step 12	Step 13	Step 14	Step 15	Step 16	Step 17	Step 18	Step 19	Step 20	Step 21	Step 22	Step 23	Step 24	Step 25	Step 26	Step 27	Step 28	Step 29	Step 30	Expiration	Step 31
General Projection Assumptions: (specific projections may vary)	Begin process of drafting scope	90 days after Step 1	90 days after Step 2	14 days after Step 3	21 days before Step 6	30 days after Step 4	10 days after Step 6	7 days after Step 7	7 days after Step 8	21 days before Step 11	30 days after Step 9	90 days after Step 11	60 days after Step 12	21 days before Step 15	60 days after Step 13	7 days after Step 15	20 days after Step 16	10 days before Step 19	14 days after Step 17	14 days after Step 19	21 days before Step 22	90 days after Step 20	7 days after Step 22	90 days after Step 23	14 days after Step 24	10 days after Step 25	60 days after Step 25	10 days after Step 26	60 days after Step 28	14 days after Step 29	30 months after Step 4	1-2 months after Step 30
Notes:					7 days OS + 14 days Board	Or next Board meeting		At least 3 days after publish in register		7 days OS + 14 days Board	Or next Board meeting		14, 30, or 60 days	7 days OS + 14 days Board	Or next Board meeting				At least 10 days after publish in register		7 days OS + 14 days Board	Or next Board meeting				Or next session if referred after March in even year	30 days, can be extended to 60 days (+ more if hearing)		30 days, can be extended to 60 days (+ more if hearing)			1st of month after 1 full month

[1]JCRAR may require a preliminary public hearing for the scope statement.

[2]JCRAR may require a separate, independent economic analysis any time between the EIA posting and the Governor's approval of the final draft.

[3]The standing committees and/or JCRAR may take actions, including requiring a meeting/hearing, making germane changes, recalling the rule, and introducing legislation.

Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	VE 1-11 – Reorganization – Board Approval of Preliminary Public Hearing and Comment Period
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	"VE 1-11 Preliminary Public Hearing Notice" "VE 1-11 Statement of Scope" "VE 1-11 Governor 12.5.2019 Approval letter"
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	The Governor approved scope statement SS 125-19 on December 5, 2019. On December 30, 2019, the Joint Committee for Review of Administrative Rules directed the VEB to hold a preliminary public hearing and comment period, pursuant to Wis. Stat. § 227.136 (1). This preliminary hearing and comment period will need to be approved by both the VEB and the DATCP Boards. The preliminary hearing and comment period will need to be held before either board can approve the statement of scope. Wis. Stat. s. 89.03 authorizes the VEB to promulgate rules regarding veterinarians and veterinary technicians. However, the authority to determine fees for veterinarians and veterinary technicians is vested in DATCP, pursuant to Wis. Stat. s. 89.063. In addition to VEB approval, the Department will request that the DATCP Board approve this notice at the January 30, 2020, DATCP Board meeting. After the public hearing and comment period, the scope statement will need to go to both boards for approval. The department anticipates bringing the scope statement to the March 5th DATCP Board meeting. The next VEB meeting is scheduled for April 29th but the Board may discuss the possibility of scheduling a teleconference call in early March to keep the rule package moving.

State of Wisconsin
Department of Agriculture, Trade and Consumer Protection
Veterinary Examining Board

NOTICE OF PUBLIC HEARING AND COMMENT PERIOD FOR SS 125-19

Permanent Rule Regarding Licensing, Practice Scope, and Standards of Practice for Veterinarians and Veterinary Technicians

The Wisconsin Department of Agriculture, Trade and Consumer Protection (Department) and Wisconsin Veterinary Examining Board (VEB) announces that, pursuant to Wis. Stat. § 227.136 (1), it has been ordered by the Joint Committee for the Review of Administrative Rules to hold a preliminary public hearing and comment period on its proposed revised statement of scope pertaining to Wis. Admin. Code chs. VE 1-11 regarding licensing, practice scope, and standards of practice for veterinarians and veterinary technicians.

The Department and VEB will hold the public hearing at the time and place shown below. The Department and VEB invites the public to attend the public hearing on the proposed statement of scope or to provide comments on the proposed statement of scope no later than Monday, February 24, 2020. Written public comments may be sent to the Division of Animal Health, Department of Agriculture, Trade and Consumer Protection, P.O. Box 8911, Madison, WI 53708-8911 or by e-mail to Angela.Fisher1@wisconsin.gov.

Hearing Date and Location:

Monday, February 17, 2020
Commencing at 2:00 PM
Board Room 106, Prairie Oaks State Office Building
Department of Agriculture, Trade and Consumer Protection
2811 Agriculture Drive
Madison, WI 53718

You may obtain a copy of the Statement of Scope for this proposed rule by contacting the Wisconsin Department of Agriculture, Trade and Consumer Protection, Office of the Secretary, P.O. Box 8911, Madison, Wisconsin 53708-8911. You may also obtain a copy by contacting the division policy analyst, Angela Fisher, at Angela.Fisher1@wisconsin.gov or by calling (608) 224-4890. Copies will also be available at the hearing or you can view the statement of scope online at: https://docs.legis.wisconsin.gov/code/register/2019/768A4/register/ss/ss_125_19/ss_125_19.

Hearing-impaired persons may request an interpreter for this hearing. Please make reservations for a hearing interpreter by February 14, 2020, by writing, calling, or emailing Angela Fisher. The hearing facility is handicap accessible.

Dated this ____day of January, 2020

STATE OF WISCONSIN,
VETERINARY EXAMINING BOARD

By _____

Dr. Robert Forbes, DVM, Chair

Dated this ____day of January, 2020

STATE OF WISCONSIN,
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____

Randy Romanski, Interim Secretary

STATEMENT OF SCOPE

Veterinary Examining Board

Rule No.: Chs. VE 1 to 11, Wis. Admin. Code (Revised)

Relating to: Licensing, Practice Scope, and Standard of Practice for Veterinarians and Veterinary Technicians

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only):

Not applicable.

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to make chs. VE 1 through 11 easier to access and understand quickly.

Fee amounts would not be changed as a part of this proposal. However, the Veterinary Examining Board (VEB) will propose that existing fee amounts be stated in rule to make this information easier to access.

The VEB may propose that the existing eleven rule chapters be consolidated into as few as three chapters, to make it easier to access information for veterinarians, veterinary technicians, and the veterinary professional assistance program.

The VEB proposes that a new chapter be added, to include procedures on discipline that were part of Department of Safety and Professional Services (DSPS) rules pertaining to all DSPS boards but were not transferred to the Department of Agriculture, Trade and Consumer Protection (DATCP) in chs. VE 1 through 11.

The VEB proposes to evaluate rule provisions and language for clarity, consistency, and ease of use, including evaluating procedures and processes, technical changes and updates, delegation of veterinary medical acts, references to relevant statutory requirements, and terminology.

The VEB proposes to evaluate rule language to fulfill the requirements in Wis. Stat. s. 89.078 (2), which requires the VEB to determine by rule what information and documentation a credential holder shall include with a written notice of a conviction.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Existing Policies Relevant to the Rule

- The current rules, consisting of chs. VE 1 through 11, are denominated as follows:
  1. Authority and Definitions
  2. Examinations
  3. Licensure by Examination for Veterinarians
  4. Licensure by Endorsement for Veterinarians
  5. Practice Related to Veterinary Schools
  6. Temporary Consulting Permits

7. Standards of Practice and Unprofessional Conduct for Veterinarians
8. Certification for Veterinary Technicians
9. Standards of Practice and Unprofessional Conduct for Veterinary Technicians
10. Continuing Veterinary Education for Veterinarians and Veterinary Technicians
11. Veterinary Professional Assistance Program

- 2015 Wisconsin Act 55 transferred the VEB from DSPS to DATCP. However, most of the general licensing requirements did not transfer to DATCP in the current chs. VE 1 through 11. This includes rules specifying the procedures and requirements for all boards under DSPS, as well as the fee amounts for VEB fees.

- Current rules refer to the fees required under Wis. Stat. ch. 440, which is the DSPS portion of the statutes, and does not list the dollar amounts of the fees. DATCP has continued to use the same fee amounts that DSPS used, but these amounts are not stated in chs. VE 1 through 11.

- Wis. Stat. s. 89.03 (1) requires the VEB to review the rules at least once every 5 years to determine whether they are consistent with current practice.

New Policies Proposed to be Included in the Rule

- Evaluating whether to state the current fee amounts in rule. Fee amounts would not change.

- Evaluating whether to consolidate the existing eleven chapters.

    - This could include evaluating whether to consolidate the existing rules into as few as three chapters: one for veterinarians, one veterinary technicians, and one for the professional assistance program. Consolidation could make the rules easier to access quickly.

- Evaluating whether to add a chapter for relevant disciplinary procedures that did not transfer in rule from DSPS to DATCP in chs. VE 1 through 11.

- Evaluating whether to make changes regarding procedures and processes.

    - For example, evaluating whether to document a review process for the annual review of colleges and technical schools referenced in ss. VE 1.02 (1e) and 8.01 (1), remove the reference to the review being annual, or make no change.

    - For example, evaluating whether to expand the process under s. VE 3.05 to include applicants who are scheduled to take or are awaiting results from the examination on state laws and rules, document a separate process, or make no change.

- Evaluating whether to make technical changes and updates.

    - For example, evaluating whether to add the denial of a license to the list of reasons for a temporary permit to expire under s. VE 3.05 (6).

    - For example, evaluating whether to permit the electronic submission of the certification of graduation through an online system managed by the American Association of Veterinary State Boards.

    - For example, evaluating whether to provide additional direction in the rules to assure the requirements for access to health care records required in Wis. Stat. s. 89.075 are clear and consistently applied.

- Evaluating whether to allow licensed veterinarians to delegate any additional veterinary medical acts to certified veterinary technicians and/or unlicensed assistants.

- For example, evaluating whether to modify s. VE 7.02 to allow unlicensed assistants to administer an IV catheter under the direct supervision of a veterinarian present on the premises, per requests from stakeholders.

- Evaluating for consistency and ease of use the places in which rule requirements repeat, or refer to requirements under Wis. Stat. ch. 89. This could include evaluating whether to remove repetitive rule language, refer to the relevant section of statute within the rule text, use notes to alert the reader to related requirements in the statute, or make no change.

  - For example, unprofessional conduct is listed in Wis. Stat. s. 89.07 and Wis. Admin. Code s. VE 7.06. The rule language repeats some of the items that are listed in statute, but not all. For items that are not repeated, the rule does not refer the reader to the statute through either the rule text or a note. This partial repetition and partial absence can make the rule unnecessarily complex to understand.

- Evaluating whether to modify terminology for clarity and consistency.

  - For example, evaluating whether to rename temporary permits (s. VE 3.05) and/or temporary consulting permits (ch. VE 6) to make it easier to distinguish between the different types of permits.

  - For example, evaluating whether to use the word "dispense" rather than "sell" to be more consistent with statutory language and definitions.

- Evaluating new language to fulfill the requirements of Wis. Stat. s. 89.078 (2), which requires the VEB to determine by rule what information and documentation a credential holder shall include with a written notice of a conviction. The rules do not currently state what information and documentation is required.

Analysis of Policy Alternatives

- Rule Proposal: The existing rules would be evaluated for clarity and ease of use. The fee amounts would remain the same but could be stated in rule to make them readily accessible. Restructuring the chapters could make the rules easier to read and reference quickly. Adding a chapter for relevant procedures could make those procedures clearer and more accessible for credential holders. Evaluating procedures and processes, technical changes and updates, delegation of veterinary medical acts, references to relevant statutory requirements, and terminology could make the rules more consistent and easier to understand. Adding rule language to determine what information and documentation is required in a written notice of conviction from a credential holder would fulfill the requirements of Wis. Stat. s. 89.078 (2). The rule proposal could reduce the burden to veterinarians, veterinary technicians, and consumers of veterinary services, as the rules may become easier to read and understand quickly.

- No Change: Should the VEB not modify the existing rules, the rules would remain unnecessarily difficult to understand. The amounts of fees would continue to be unspecified in rule. Current requirements relating to veterinarians and veterinary technicians would remain scattered across multiple rule chapters. Some of the board's procedures and processes would remain unclear. The board would not be able to evaluate technical changes and updates or the delegation of veterinary medical acts. References to relevant statutory requirements would remain inconsistent. Some terminology would continue to be unclear and confusing. The rules would continue to not state what information and documentation is required in a written notice of conviction from a credential holder as required by Wis. Stat. s. 89.078 (2). Each of these concerns makes the current rules unnecessarily difficult to understand.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

Section 89.03, Stats., authorizes the VEB to promulgate rules as follows:

89.03 Rules.

(1) The examining board shall promulgate rules, within the limits of the definitions under s. 89.02 (6), establishing the scope of practice permitted for veterinarians and veterinary technicians and shall review the rules at least once every 5 years to determine whether they are consistent with current practice. The examining board may promulgate rules relating to licensure qualifications, denial of a license, certification, or temporary permit, unprofessional conduct, and disciplinary proceedings.

(2) The examining board shall promulgate rules requiring training and continuing education sufficient to assure competency of veterinarians and veterinary technicians in the practice of veterinary medicine, except that the board may not require training or continuing education concerning the use, handling, distribution, and disposal of pesticides other than for disciplinary purposes.

(3) The examining board shall promulgate rules specifying a procedure for addressing allegations that a person licensed or certified by the veterinary examining board under this chapter has practiced as a veterinarian or veterinary technician while impaired by alcohol or other drugs or that his or her ability to practice is impaired by alcohol or other drugs, and for assisting a person licensed by the veterinary examining board under this chapter who requests to participate in the procedure or who requests assistance in obtaining mental health services. In promulgating rules under this subsection, the examining board shall seek to facilitate early identification of chemically dependent veterinarians or veterinary technicians and encourage their rehabilitation. The rules promulgated under this subsection may be used in conjunction with the formal disciplinary process under this chapter. The examining board may contract with another entity to administer the procedure specified under the rules promulgated under this subsection.4

Section 89.063, Stats., authorizes the Department to determine by rule the fees as follows:

89.063 Fees. The department shall determine by rule the fees for each initial license, certification, and permit issued under ss. 89.06, 89.072, and 89.073, and, if applicable, for renewal of the license, certification, or permit, including late fees, based on the department's administrative and enforcement costs under this chapter. The department shall notify the holder of each such license, certification, or permit of any fee adjustment under this subsection that affects that license, certification, or permit holder.

Section 89.078 (2), Stats., authorizes the VEB to determine by rule what information and documentation a credential holder shall include with a written notice of a conviction:

89.078 (2) A person holding a license, certification, or permit issued under s. 89.06, 89.072, or 89.073 who is convicted of a felony or misdemeanor anywhere shall send a notice of the conviction by 1st class mail to the examining board within 48 hours after the entry of the judgement of conviction. The examining board shall by rule determine what information and documentation the person holding the credential shall include with the written notice.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

The Department estimates that it will use approximately .5 FTE staff to develop this rule. That calculation includes time required for investigation and analysis, drafting the rule, preparing related documents, coordinating advisory committee meetings, holding public hearings, and communicating with affected persons and groups. The Department will use existing staff to develop this rule.

6. List with description of all entities that may be affected by the proposed rule:

The proposed rule would directly affect Wisconsin licensed veterinarians and certified veterinary technicians. Most veterinary practices are small businesses. Current fee amounts would not change.

The proposed rule may indirectly affect pet and livestock owners who are consumers of veterinary services.

Adjustments to make rule language and structure clearer, and to simplify processes where possible, may reduce the burden to each of these affected entities by making the rules easier to access and understand quickly.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

Pursuant to 9 CFR 160 to 162, a veterinarian must be specifically authorized by the United States Department of Agriculture – Animal and Plant Health Inspection Service to perform animal disease eradication and control functions under federal animal health laws.

Licensure requirements to practice veterinary medicine are established by each state and should not be affected by federal requirements.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

The Department expects the proposed rule to have minimal to no economic impact. No fee amounts will be changed in the proposed rule.

Most veterinary practices are small businesses. Adjustments to make rule language and structure clearer may reduce the burden to veterinarians, veterinary technicians, and consumers of veterinary services, as the rules may become easier to access and understand quickly.

Contact Person: Melissa Mace, Acting Executive Director, Veterinary Examining Board; (608) 224-4883

Signed this 23rd day of October 2019

Robert Forbes DVM

Dr. Robert Forbes, DVM
Chair
State of Wisconsin Veterinary Examining Board

Signed this 24 day of October 2019

Bradley M. Pfaff

Bradley M. Pfaff
Secretary
State of Wisconsin Department of Agriculture,
Trade and Consumer Protection

Tony Evers
Office of the Governor | State of Wisconsin

December 5, 2019

By Electronic Mail Only

Dear Secretaries and Agency Heads:

On this day, I approved the following statements of scope pursuant to Wis. Stat. § 227.135(2):

- A statement of scope by the Department of Health Services, submitted September 12, 2019, relating to Division of Medicaid Services biennial review (Wis. Admin. Code chs. DHS 90, 103, 104, 105, 106, 107, 109, 152, 250, and 251); and
- A statement of scope by the Department of Children and Families, submitted October 14, 2019, relating to technical changes to update Wisconsin Works rules (Wis. Admin. Code ch. DCF 101); and
- A statement of scope by the Department of Public Instruction, submitted November 7, 2019, relating to expanding the assessment of pedagogical knowledge in educator preparation programs (Wis. Admin. Code ch. PI 34); and
- A statement of scope by the Department of Agriculture, Trade, and Consumer Protection, submitted October 24, 2019, relating to Licensing, Practice Scope, and Standard of Practice for Veterinarians and Veterinary Technicians (Wis. Admin. Code chs. VE 1-11); and
- A statement of scope by the Department of Natural Resources, submitted July 30, 2019, relating to the administration, procedures, and enforcement of the Wisconsin Wetland and Waterway regulatory program (Wis. Admin. Code chs. NR 300, 301, 305 and 310); and
- A statement of scope by the Department of Natural Resources, submitted August 20, 2019, relating to Wastewater Discharges from Dental Offices to Sanitary Sewers (Wis. Admin. Code ch. NR 211); and
- A statement of scope by the Department of Natural Resources, submitted September 9, 2019, relating to Well Construction and Pump Installation (Wis. Admin. Code ch. NR 812); and
- A statement of scope by the Department of Natural Resources, submitted November 13, 2019, relating to Establishing the 2020 migratory bird season framework and regulations (Wis. Admin. Code ch. NR 10); and
- A statement of scope by the Office of the Commissioner of Insurance, submitted November 13, 2019, relating to step therapy protocols for prescription drug coverage (Wis. Admin. Code ch. Ins 18); and

- A statement of scope by the Department of Agriculture, Trade and Consumer Protection, submitted October 3, 2019, relating to recreational and educational camps (Wis. Admin. Code ch. ATCP 78); and
- A statement of scope by the Parole Commission, submitted October 25, 2019, relating to parole procedure (Wis. Admin. Code ch. PAC 1).

On this day, I approved the following proposed administrative rules pursuant to Wis. Stat. § 227.185:

- A proposed rule by the Office of the Commissioner of Insurance, submitted on October 15, 2019, relating to holding company supervision amendments and corporate governance disclosure requirements (Wis. Admin. Code chs. Ins 40 and 53); and
- A proposed rule by the Office of the Commissioner of Insurance, submitted on October 7, 2019, relating to the Wisconsin Insurance Plan (Wis. Admin. Code ch. Ins 4); and
- A proposed rule by the Department of Natural Resources, submitted on June 26, 2019, relating to Best Management Practices and Cost Share Rates (Wis. Admin. Code ch. NR 154); and
- A proposed rule by the Department of Natural Resources, submitted on September 26, 2019, relating to Air Permit Streamlining (Wis. Admin. Code chs. NR 406 and 407); and
- A proposed rule by the Department of Natural Resources, submitted on October 24, 2019, relating to Surface Water Grant Program (Wis. Admin. Code chs. NR 190, 191, 192, 195, and 198); and
- A proposed rule by the Department of Natural Resources, submitted on November 7, 2019, relating to Test methods for examining water and wastewater (Wis. Admin. Code ch. NR 538); and
- A proposed rule by the Department of Health Services, submitted on November 1, 2019, relating to Immunization of Students (Wis. Admin. Code ch. DHS 144); and
- A proposed rule by the Department of Natural Resources, submitted on November 12, 2019, relating to Federal hazardous waste regulation (Wis. Admin. Code ch. NR 600); and
- A proposed rule by the Department of Agriculture, Trade and Consumer Protection, submitted on November 13, 2019, relating to animal disease movement and animal markets, dealers and truckers, and affecting small businesses (Wis. Admin. Code chs. ATCP 10 and 12); and
- A proposed rule by the Department of Agriculture, Trade and Consumer Protection, submitted on September 5, 2019, relating to milk, food and water testing laboratories (Wis. Admin. Code ch. ATCP 77); and
- A proposed rule by the Department of Veterans Affairs, submitted on November 5, 2019, relating to the educational assistance program (Wis. Admin. Code ch. VA 18).

Please direct any questions about this letter to my chief legal counsel, Ryan Nilsestuen.

Sincerely,

Tony Evers
Governor

Cc: Ryan Nilsestuen, chief legal counsel (ryan.nilsestuen1@wisconsin.gov)
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Veterinary Examining Board
Agenda Request Form

1) Meeting Date	1/22/20
2) Requestor Name	Angela Fisher
3) Item Title for the Agenda	Legislative Update
4) Should the Item be in Open or Closed Session?	Open Session
5) Are there Attachments? (If yes, include file names)	"VEB Legis Update" "AB 130" "SB 654"
6) Is a Public Appearance Anticipated?	No
7) Description of the Agenda Item	The attachment shows the status of legislation regarding Wis. Stat. ch. 89. This is an informational update. No Board action is needed.

DAH Relevent Statutes Current Status

2019-2020 Legislative Session
Last Updated: 1/9/20

Agency	Ch.	Citation	Topic	Description	LRB #	Bill #	Status Notes
DATCP	89	89.063	Initial Fees	Would remove initial license fees for veterinarians and veterinary technicians.	2457/1, 1925/1	AB-130, SB-140	7/18/19 AB & SB fiscal estimate received. 3/28/19 SB introduced, referred to committee. 3/25/19 AB introduced, referred to committee.
		89.073	Reciprocal	Would expand reciprocal credentials for service members, former service members, and their spouses.	4162/1	AB-731, SB-654	1/8/20 SB introduced, referred to committee. 12/13/19 Co-sponsorship due.

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-2457/1
MCP:cdc

2019 ASSEMBLY BILL 130

March 25, 2019 - Introduced by Representatives KURTZ, BRANDTJEN, BROOKS, KNODL, SKOWRONSKI, THIESFELDT and TITTL, cosponsored by Senator JACQUE. Referred to Committee on Regulatory Licensing Reform.

AN ACT ***to amend*** 89.063 of the statutes; **relating to:** eliminating first-time license fees for veterinary licenses and veterinary technician certificates.

Analysis by the Legislative Reference Bureau

This bill exempts applicants for veterinary licenses and veterinary technician certificates from the fee for an initial license or certification.

For further information see the ***state*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 89.063 of the statutes is amended to read:

89.063 Fees. The department may not charge a fee for an initial license, certification, or permit issued under s. 89.06, 89.072, or 89.073. The department shall determine by rule the fees for ~~each initial~~ renewal of a license, certification, ~~and~~ or permit issued under ss. 89.06, 89.072, and 89.073~~,~~ and~~, if applicable, for renewal of the license, certification, or permit, including~~ late fees~~,~~. The department shall

determine the fees under this section based on the department's administrative and enforcement costs under this chapter. The department shall notify the holder of each such license, certification, or permit of any fee adjustment under this subsection that affects that license, certification, or permit holder.

(END)

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-4162/1
KP:cdc

2019 SENATE BILL 654

January 8, 2020 - Introduced by Senators KAPENGA, JACQUE, BERNIER, CRAIG, DARLING, KOOYENGA, LEMAHIEU, MARKLEIN, NASS, OLSEN, STROEBEL and TESTIN, cosponsored by Representatives VANDERMEER, SKOWRONSKI, BALLWEG, FELZKOWSKI, GUNDRUM, KNODL, KUGLITSCH, MURSAU, SPIROS, STEFFEN and TUSLER. Referred to Committee on Public Benefits, Licensing and State-Federal Relations.

AUTHORS SUBJECT TO CHANGE

AN ACT ***to repeal*** 89.073 (2) (e) and 440.09 (2) (e); ***to renumber and amend*** 89.073 (1) and 440.09 (1); ***to amend*** 89.073 (title), 89.073 (2) (intro.), 89.073 (2) (a), 89.073 (2) (b), 89.073 (3), 440.09 (title), 440.09 (2) (b) and 440.09 (3); and ***to create*** 89.073 (1) (a), 89.073 (2) (f), 89.073 (4), 89.073 (5), 440.09 (1) (a), 440.09 (2) (f), 440.09 (4) and 440.09 (5) of the statutes; **relating to:** reciprocal credentials for service members, former service members, and their spouses and granting rule-making authority.

Analysis by the Legislative Reference Bureau

This bill enables service members, former service members, and the spouses of former service members who reside in this state to obtain reciprocal credentials to practice a profession granted by the Department of Safety and Professional Services, the boards attached to DSPS, and the Veterinary Examining Board. To obtain a reciprocal credential under the bill, a person must hold an analogous credential in another jurisdiction, and the bill applies to former service members discharged from the armed forces under conditions other than dishonorable within four years of applying for a reciprocal credential. Under current law, the spouse of a service member may obtain a reciprocal credential granted by DSPS, the boards attached to DSPS, and the Veterinary Examining Board.

The bill also provides that a reciprocal credential granted to a service member, former service member, or the spouse of a service member or former service member

expires on the same renewal date as the credential that corresponds to the reciprocal credential, and that the reciprocal credential may be renewed by paying the applicable fee and satisfying the requirements that apply to renewing the corresponding credential. Current law provides that a reciprocal credential granted to the spouse of a service member expires after 180 days unless DSPS or the applicable board extends the reciprocal credential. Also, under the bill, DSPS, the boards attached to DSPS, and the Veterinary Examining Board may promulgate rules necessary to implement the bill.

For further information see the ***state*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 89.073 (title) of the statutes is amended to read:

89.073 (title) **~~Temporary reciprocal~~ Reciprocal credentials for ~~the spouses of~~ service members, former service members, and their spouses.**

SECTION 2. 89.073 (1) of the statutes is renumbered 89.073 (1) (intro.) and amended to read:

89.073 **(1)** (intro.) In this section~~, "service member"~~:

(b) "Service member" means a member of the U.S. armed forces, a reserve unit of the U.S. armed forces, or the national guard of any state.

SECTION 3. 89.073 (1) (a) of the statutes is created to read:

89.073 **(1)** (a) "Former service member" means a person who was discharged from the U.S. armed forces under conditions other than dishonorable within 4 years of the date on which the service member or the spouse of the service member applies for a license, certification, or permit under this section.

SECTION 4. 89.073 (2) (intro.) of the statutes is amended to read:

89.073 **(2)** (intro.) The examining board shall grant a ~~temporary~~ license, certification, or permit specified under s. 89.06 to an individual who the examining board determines meets all of the following requirements:

SECTION 5. 89.073 (2) (a) of the statutes is amended to read:

89.073 **(2)** (a) The individual applies for a ~~temporary~~ credential under this section on a form prescribed by the examining board.

SECTION 6. 89.073 (2) (b) of the statutes is amended to read:

89.073 **(2)** (b) The individual is a service member, a former service member, or the spouse of a service member or former service member and ~~the spouse and service member temporarily reside~~ resides in this state ~~as a result of the service member's service in the U.S. armed forces, a reserve unit of the U.S. armed forces, or the national guard of any state~~.

SECTION 7. 89.073 (2) (e) of the statutes is repealed.

SECTION 8. 89.073 (2) (f) of the statutes is created to read:

89.073 **(2)** (f) The individual is in good standing with the governmental authorities in every jurisdiction outside this state that have granted the individual a credential that qualifies the individual to perform acts authorized under the appropriate credential specified under s. 89.06.

SECTION 9. 89.073 (3) of the statutes is amended to read:

89.073 **(3)** A ~~temporary~~ credential granted under this section expires ~~180 days after the date the examining board issues it unless, upon application by the holder of the credential, the examining board extends the credential~~ on the renewal date specified in s. 89.062 (1). The examining board shall grant a renewed license, certification, or permit specified under s. 89.06 to an applicant who pays the renewal fee specified under s. 89.063 and satisfies the renewal requirements under s. 89.062.

SECTION 10. 89.073 (4) of the statutes is created to read:

89.073 **(4)** The examining board shall expedite the issuance of a license, certification, or permit granted under this section.

SECTION 11. 89.073 (5) of the statutes is created to read:

89.073 **(5)** The examining board may promulgate rules necessary to implement this section.

SECTION 12. 440.09 (title) of the statutes is amended to read:

440.09 (title) **Reciprocal credentials for ~~the spouses of~~ service members, former service members, and their spouses.**

SECTION 13. 440.09 (1) of the statutes is renumbered 440.09 (1) (intro.) and amended to read:

440.09 **(1)** (intro.) In this section~~, "service member"~~:

(b) "Service member" means a member of the U.S. armed forces, a reserve unit of the U.S. armed forces, or the national guard of any state.

SECTION 14. 440.09 (1) (a) of the statutes is created to read:

440.09 **(1)** (a) "Former service member" means a person who was discharged from the U.S. armed forces under conditions other than dishonorable within 4 years of the date on which the service member or the spouse of the service member applies for a reciprocal credential under this section.

SECTION 15. 440.09 (2) (b) of the statutes is amended to read:

440.09 **(2)** (b) The individual is a service member, a former service member, or the spouse of a service member~~,~~ or former service member and ~~the spouse and service member temporarily reside~~ resides in this state ~~as a result of the service member's service in the U.S. armed forces, a reserve unit of the U.S. armed forces, or the national guard of any state~~.

SECTION 16. 440.09 (2) (e) of the statutes is repealed.

SECTION 17. 440.09 (2) (f) of the statutes is created to read:

440.09 **(2)** (f) The individual is in good standing with the governmental authorities in every jurisdiction outside this state that have granted the individual a license, certification, registration, or permit that qualifies the individual to perform acts authorized under the appropriate credential granted by the department or credentialing board.

SECTION 18. 440.09 (3) of the statutes is amended to read:

440.09 **(3)** A reciprocal credential granted under this section expires ~~180 days after the date the department or credentialing board issues the reciprocal credential unless, upon application by the holder of the reciprocal credential, the department or credentialing board extends the reciprocal credential~~ on the applicable renewal date specified in s. 440.08 (2) (a). The department or credentialing board, as appropriate, shall grant a renewed reciprocal credential to an applicant who pays the renewal fee specified under s. 440.05 (2) and satisfies the requirements that apply for renewing that credential.

SECTION 19. 440.09 (4) of the statutes is created to read:

440.09 **(4)** The department or credentialing board, as appropriate, shall expedite the issuance of a reciprocal credential granted under this section.

SECTION 20. 440.09 (5) of the statutes is created to read:

440.09 **(5)** The department or credentialing board, as appropriate, may promulgate rules necessary to implement this section.

SECTION 21. Initial applicability.

(1) APPLICATIONS FOR VETERINARY RECIPROCAL CREDENTIALS. The treatment of s. 89.073 (2) (b), (e), and (f) first applies to an application for a license, certification, or permit specified in s. 89.06 received by the veterinary examining board on the effective date of this subsection.

(2) EXPIRATION OF VETERINARY RECIPROCAL CREDENTIALS. The treatment of s. 89.073 (3) first applies to a license, certification, or permit granted under s. 89.073 that is valid on the effective date of this subsection.

(3) APPLICATIONS FOR RECIPROCAL CREDENTIALS. The treatment of s. 440.09 (2) (b), (e), and (f) first applies to an application for a reciprocal credential, as defined in s. 440.01 (2) (d), received by the department of safety and professional services on the effective date of this subsection.

(4) EXPIRATION OF RECIPROCAL CREDENTIALS. The treatment of s. 440.09 (3) first applies to a reciprocal credential, as defined in s. 440.01 (2) (d), that is valid on the effective date of this subsection.

(END)