



UPDATED: July 10, 2018

TO: DATCP ACM ARM Environmental Enforcement Specialists

FROM: Feed Specialist

SUBJECT: Feed Program Inspections - Label drug levels vs. calculated drug level

Going forward, please use the following guidelines:

1. ATCP 42 defines the drug level statement as a guarantee. Guarantees must be met.
 - a. NOTE: If every one (Type A > Type B > Type C) is off, the final finished feed is going to be sub-potent and ineffectual or super-potent and a hazard.
2. Formulas can be adjusted and must be designed/formulated to meet the label guarantee.
3. If *any* medicated feed drug level is formulated to a drug level outside of the Federal drug approval, the drug level must be corrected. Example: Drug level formulated to 7.70 g/T Tylosin in a combination Monensin/Tylosin feed. The Tylosin drug approval for that combination is 8-10 g/T. The minimum calculation must be at least 8 g/T, and the maximum calculation cannot exceed 10 g/T.
4. Allowance, if any:
 - a. Type B Feeds must be within 0.5% of the guarantee.
 - b. Type C Feeds (as a finished feed) may be within 1% of the guarantee.

For example:

- Label guarantees 30 grams/ton, formula must be ± 0.3 grams.
- Label guarantees 0.003%, formula must be $\pm 0.00003\%$.
- Label guarantees 400 grams/ton, formula must be ± 4 grams.

When evaluating a firm's labels and formulas and discrepancies are identified, record it in the narrative and include it as an item of discussion with management at the conclusion of the inspection. A use of regulatory discretion would be appropriate regarding any enforcement action. Address discrepancy concerns with a direct supervisor or the Feed Specialist.