



Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
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November 25, 2003

**WARNING LETTER**  
**CIN-04-16951**

**Via Federal Express**

David A. Robertson, President  
Allen Robertson & Company, Inc.  
335 Baxter Ave.  
Louisville, KY 40204

Dear Mr. Robertson:

An inspection of your licensed medicated feed mill, located at the above address, conducted by Food and Drug Administration investigators, on 7/23-25/2003, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 CODE OF FEDERAL REGULATIONS, Part 225). Such deviations cause feeds being manufactured at this facility to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found:

- 1) failure to maintain equipment in a reasonably clean and orderly manner [21 CFR 225.30(b)(2)];

*Ribbons and shafts on both two-ton mixers had significant build-up of feed materials on them. The mixer operator indicated that both mixers were last cleaned about "three or four months ago".*

- 2) failure to have production record(s) for specific products which include the complete history of each batch or production run [21 CFR 225.102];

*You failed to adequately document the manufacturing of a medicated swine feed "Piggy 200". For example, the lot numbers on the bags do not match the "lot" numbers on the batch production record. Your procedures indicate that the mixer operator always prepares a batch slip for each medication used in the medicated feed. However, no batch slips were generated for the Mecadox 10, a Category 2, Type A drug source, or Mecadox 2.5 to indicate the amounts or date used.*

- 3) failure to maintain buildings in a reasonably clean and orderly manner [21 CFR 225.20(b)(2)];

*Numerous unlabeled bags (over 1000 lbs ) of feed and/or feed components were lying on the floor in the mixing area. The mixer operator had no idea what was in the bags and indicated they had been there since before he started. The mixing area had an appreciable amount of dust*

*on duct work and on bins containing drugs and minerals. The floor, in some areas, had over two inches of accumulated dust.*

- 4) failure to assure bulk drugs are identified and stored in a manner such that their identity, strength, quality, and purity will be maintained [21 CFR 225.42(b)(3)];
  - *The "working bin" containing [REDACTED] (pyrantel tartrate), a Category 2 Type "A" drug source, was stored in bulk form and had no bag or other labeling to identify the drug.*
  - *A bin containing [REDACTED] was observed in the drug room near the mixer. The most recent inventory record for this drug is 8/1/96. Your firm does not have any record documenting the expiration date of this product.*

- 5) failure to assure all employees involved in the manufacture of medicated feeds understand the manufacturing or control operations they perform [21 CFR 225.10(b)(1)];

*The person responsible for mixing medicated feed had been in that position for three months. He had not heard of the medicated feed Good Manufacturing Practices and was not aware of your "Drug Room and Mixing Rules". He also could not identify the drugs by name nor did he know what level of drug they contained.*

The above is not intended as an all-inclusive list of violations at your facility. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory action without further notice to you. These actions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2). This letter constitutes official notice under the law of CGMP violations.

We acknowledge receipt of your July 28, 2003, response to the FDA-483 observations made during the July 23-25, 2003 inspection. Our review of your response revealed the following inadequacies that you should address:

- (1) You indicate the Kentucky Division for Regulatory Services will assist you in verifying the adequacy of your mixer's uniformity for producing your medicated feeds. *However, you provide no details as to how this will be determined nor do you provide an expected date of completion of this study.*
- (2) Regarding observation 3, you state that you will work with the state in verifying the adequacy of your flushing procedure, yet *you provide no scheduled date that this will be completed.*
- (3) Regarding observation 4, you indicate that the person responsible for flushing will dispose of the flush material in the dumpster and will indicate this on the production sheet. *Please provide a copy of a current production record to show that this is being documented*
- (4) Regarding observation 5 about mixing production records, you indicate that errors and oversights resulted from a one or two day delay in reviewing these records. *The regulations*

*require these batch records be checked by a responsible person **at the end of each working day** in which the medicated feed was manufactured to determine whether all required steps have been performed and to investigate any significant discrepancies. See 21 CFR 225.102(b)(4). Your response also states that one batch record was not created because you mixed the medicated feed yourself. *Batch records are required regardless of who produces the medicated feed.**

- (5) In addition, during review of the "Drug Usage Inventory Records", attached to your response, it was noted that *these records fail to list entries in the column "WEIGH BACK"*. The regulations require that your inventory include the **actual quantity** of drug in inventory, to be determined by weighing, counting, or actual measurement, as appropriate, at the beginning and end of each work day. This actual amount of drug used must be compared to the theoretical drug usage (amount removed from inventory for each batch produced). Any significant discrepancy found in this drug inventory reconciliation must be investigated and corrective action taken. *These records must also include a lot or tracking number for each batch of feed in which the drugs were used.* See 21 CFR 225.42(b).

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of any further steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Charles S. Price Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097. If you have any questions regarding this letter, you may call Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,



Carol A. Heppe,  
District Director  
Cincinnati District