



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

December 20, 2002

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

W/L #14-03

Nyle A. "Tony" McAnally  
General Manager  
McAnally Enterprises LLC  
32710 Reservoir Road  
Lakeview, CA 92567

Dear Mr. McAnally:

An inspection of your licensed medicated feed mill located at 23489 Rider Street, Perris, CA, conducted October 11-23, 2002, found significant deviations from the Current Good Manufacturing Practice ("CGMP") regulations for licensed Medicated Feed manufacturers (Title 21, Code of Federal Regulations, Part 225). Such deviations cause feeds being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the "Act" henceforth).

Section 501(a)(2)(B) of the Act states that a drug shall be deemed adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with CGMP, to assure that such feed meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Our investigators documented that there is no assurance that the methods used in and the controls used for the manufacture of your medicated and non-medicated feeds are in conformity with CGMPs. These deviations from the regulations were reported to you in the Inspectional Observations, FDA-483, which was issued at the conclusion of the inspection and included the following:

- Failure to test on periodic basis feeds manufactured using a category II Type-A medicated article, as required by 21 C.F.R. § 225.58 (b)(1). Specifically, you did not conduct the required number of assays for medicated feeds containing [REDACTED] (Amprolium) during calendar 2002.

- Failure to compare your actual drug inventory with your theoretical drug inventory to determine if any discrepancies exist, as required by 21 C.F.R. § 225.42 (b)(7).
- Your firm lacks written procedures for the manufacture of medicated feeds, as required by 21 C.F.R. § 225.102 (b)(1).
- Failure to maintain production records for the required length of time. Specifically, your firm is not printing batch records for each batch of feed manufactured and therefore you do not have batch production records to maintain for the required period of not less than one year, as required by 21 C.F.R. § 225.102 (b)(2).
- It was further determined that you are using Type A medicated articles in a manner contrary to their approved labeling. Specifically, your use of [REDACTED] (Amprolium and Ethopabate) with [REDACTED] (Amprolium) in the manufacture of a medicated feed. Your use of any Type A medicated article in a manner other than as specifically approved for use in animal feeds is strictly forbidden. Use of Type A medicated articles in a manner other than as approved causes those drugs to be adulterated under Section 501(a)(6) of the Act because there is no approval for such use as required by Section 512 (a)(2)(A) of the Act.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your milling facility. As a producer of medicated and non-medicated feeds, you are responsible for assuring that your establishment is in compliance with all requirements of the applicable federal regulations. Several of the violations noted during this inspection are similar to those cited during previous inspections.

For your information we are concerned about the lack of required assays. Assays provide an indicator of your firm's ability to manufacture feeds of consistent quality and potency. Out-of-specification results are a potential indicator of mixer error, age and improper storage of the medication, mixing time, age and quality of equipment used, scale accuracy, sampling technique, physical characteristics of the equipment and commodities or human error. There are numerous resources available for additional guidance in this area. These include University out-reach/extension services, industry associations, private consultants and government agencies.

You should take prompt action to correct these deviations, and establish procedures to ensure compliance with the regulations and prevent future violations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action could include, but is not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license. This letter constitutes official notification under the law and provides you an opportunity to correct the observed violations.

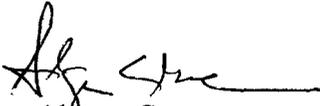
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Please notify this office in writing within (15) working days of receipt of this letter of the specific actions taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. Please include copies of any available documentation showing that corrections have been made. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. If you have any questions or clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at (949) 798-7739.

Please direct your written response to the attention of:

Thomas L. Sawyer  
Director, Compliance Branch  
United States Food and Drug Administration  
19900 MacArthur Blvd., Ste. 300  
Irvine, CA 92612

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza Cruse", with a long horizontal line extending to the right.

Alonza Cruse  
District Director