



T2096M

Food and Drug Administration  
Denver District Office  
Building 20 - Denver Federal Center  
P. O. Box 25087  
Denver, Colorado 80225  
TELEPHONE: 303-236-3000

October 2, 1998

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Steven L. Palmer  
President  
Intermountain Farmers Association  
1147 West 2100 South  
Salt Lake City, Utah 84119

**PURGED**

Ref. # - DEN-99-01

**WARNING LETTER**

Dear Mr. Palmer:

An inspection of your feed manufacturing facility located at 1071 E. Pioneer Road, Draper, Utah, conducted on June 9, 1998 by Consumer Safety Officer Jill A. Mielziner found deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds, Title 21, Code of Federal Regulations, Part 225 (21 CFR 225). Such deviations cause feed 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).

Our inspection found that your facility violated CGMPs in that the facility was not calibrating the scale used to weigh drug product. This is required by 21 CFR 225.30(b)(4), which requires that all scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently as may be necessary to insure their accuracy. In addition, batch production records are not reviewed at the end of the working day in which the product was manufactured to determine whether all required production steps have been performed, as required by 21 CFR 225.102(b)(4).

Further, analysis of your 15% Hog Grower Pellets, code 1182, Medicated, Lot 060998NB, showed the feed is adulterated within the meaning of Section 501(c) of the Act, in that its strength differs, or quality falls below that which is purports to possess. This feed is labeled to contain 30 g/ton Bacitracin Methylene Disalicylate.

Our original analysis of a composite of 10 subsamples showed the product contained 10.9 g/ton bacitracin, or 36.3% of declared. Check analysis of five individual subs showed 12.9, 15.9, 20.4, 14.4, and 17.1 g/ton bacitracin, or 43%, 53%, 68%, 48%, and 57% of declared, respectively.

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

You should take prompt action to correct these violations, and establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval for your Form FDA 1900s (Medicated feed Applications) under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

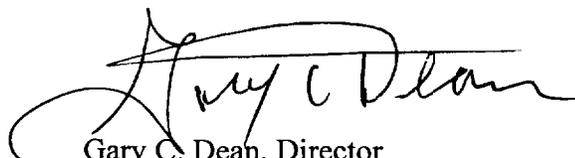
This letter constitutes official notification under the law. Based on the results of the June 9, 1998 inspection evaluated together with our sample analysis of 15% Hog Grower Pellets, code 1182, Medicated, Lot 060998NB, and the evidence before the FDA when the Form 1900s were approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies. Until the CGMP deficiencies are corrected and the corrections verified by FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

You should notify this office in writing within fifteen (15) days of the receipt of this letter of the steps 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 15 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 Ms. Shelly L. Maifarth, Compliance Officer, at the above address. She may be reached at (303) 236-3046 if you have any questions about this letter.

Sincerely,

**PURGED**

  
Gary C. Dean, Director  
Denver District