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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Place Ste 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-47

March 12 1999

Thomas T. Rucks, President
United Feed Co-op, Inc.
201 N.W. 8th Street
Okeechobee, FL 34973

Dear Mr. Rucks:

An inspection of your medicated feed mill located in Okeechobee, FL, conducted by Food and Drug Administration investigator Michelle Dunaway on September 21-22, 1998 found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations, Part 225). Such deviations cause medicated 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 your mill lacked evidence to document that the equipment used to dispense Chlortetracycline is capable of producing medicated feeds of the intended potency. This observation is based on the fact that Chlortetracycline is added directly to each batch from a bulk storage tank, without being weighed, and the large monthly inventory discrepancies in the actual vs. theoretical usage of Chlortetracycline. Our review of the monthly inventory for Chlortetracycline showed for the month of April the inventory was 209 pounds short; for the month of May the inventory was 122 pounds short; for the month of June the inventory was 17 pounds over; for the month of July the inventory was 197 pounds short and for the month of August the inventory was 55 pounds short.

Our investigation also found at least four of the medicated cattle feeds manufactured by your mill contained the unapproved drug combination of Lasalocid and Chlortetracycline, e.g., Arbuckle Creek Ranch Heifer 9 mile grade, HW Rucks and Son Dairy Calf ration, Dry Lake Dairy Calf ration and Davie Dairy Calf ration. This drug combination is not approved for cattle or any other species per 21 CFR 558.311 and 558.128. The use of the above drug combination in the listed feeds causes the feeds to become adulterated within the meaning of Section 501(a)(6), because they are unsafe within the meaning of Section 512(a)(1)(A) of the Act.

Our investigation further found that your firm was using a label for Dry Lake Dairy Dry Cow Ration, which failed to list the drug ingredient Chlortetracycline. The use of this label causes the feed to be misbranded within the meaning of Section 502(e)(1)(A)(i) of the Act, because it fails to bear the established name of the drug active ingredient.

We acknowledge receipt of a letter from R. Grant Ridgeway, General Manager, dated September 28, 1998, responding to the FD-483 we issued to Mr. Ridgeway on September 22, 1998. The letter states the Chlortetracycline feeder has been recalibrated to correct the inventory deviations noted. If recalibration does not correct the problem, the Chlortetracycline will be weighed out for each lot. The formulas for the four dairy cattle rations above have been changed to remove Lasalocid, and the label for Dry Lake Dairy Dry Cow Ration has been corrected to include the active drug ingredient Chlortetracycline. If you have not already done so, you should examine all of your medicated feed formulas to ensure none of the remaining feeds contain unapproved drug combinations.

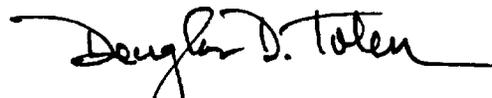
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with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

You should take prompt action to correct the above violations and establish procedures to ensure the violations do not recur. Failure to promptly correct these deviations may result in regulatory and/or administrative sanctions being initiated by the Food and Drug Administration without further notice. These sanctions include, but are not limited to, seizure and/or injunction. Based on the results of the September 21-22, 1998 inspection, 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 the 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.

You should notify this office in writing within fifteen (15) days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen days, state the reason for the delay and the time within which corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please reply to Kendall W. Hester, Compliance Officer, Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4730.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a long horizontal line extending to the right.

Douglas D. Tolen
Director, Florida District

bcc: HFR-SE200/EI JKT
HFR-SE240/KWH/LGL JKT/WL FILE
HFR-SE250
HFR-SE250/PRD
BCR-RP
✓ HFI-35 (PURGED)
HFA-224
HFC-210
HFC-240

approved by HFV-232 on 3/1/99
received: 3/12/99
final: 3/12/99 mrj