



CERTIFIED - RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300  
Irvine, California 92715-2445  
Telephone (714) 798-7600

WARNING LETTER

January 30, 1998

Mr. Kevin Kruse  
President  
O.H. Kruse Grain & Milling -  
11518 Road 120  
Pixley, CA 93256

WL-16-8

Dear Mr. Kruse:

During a recent inspection of your medicated feed mill, located at 1-821 Railroad Avenue, El Monte, California, our investigator documented serious deviations from current Good Manufacturing Practice (GMP) 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 (Act). In addition, your firm is adulterating a new animal drug within the meaning of Section 501(a)(5).

Our investigation found failure to review drug article labels to assure correct active drug ingredients are being used, failure to investigate out-of-specification results obtained from drug assays, failure to complete daily drug inventories, and failure to completely and consistently document complaints including investigation or other follow-up performed. Additional concerns reported include an excessive build-up of dust and ingredients from leaking equipment and incomplete labeling of sacked intermediate type B articles for in-house use.

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

You should be aware that the approved label claims for chlortetracycline products have changed. You have until April 1, 1998 to make these changes. Your products Verdemont Pig Grow Pellets Medicated No. 1, Verdemont Lamb Developer Medicated, and Calf Ration Medicated are affected by this change. You should review all of your labels to assure they comply with the approved indications and drug levels listed in Title 21, Code of Federal Regulations, but in particular, all chlortetracycline bearing

products.

You should take prompt action to correct these GMP violations, and you should establish and follow procedures to prevent the recurrence of such violations. Failure to promptly make corrections 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 your firm's facility license.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the 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 GMP 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:

Mary M. LoVetere  
Compliance Officer  
U.S. Food and Drug Administration  
19900 MacArthur Blvd., Suite 300  
Irvine, CA 92612-2445

Sincerely,

  
Elaine C. Messa  
District Director

cc: State of California  
Department of Food and Agriculture  
1220 N Street, Room A 372  
Sacramento, CA 95814