



SCD/HFI-35 11/17/97  
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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell WA 98041-3012

October 2, 1997

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Telephone: 206-486-8788  
Fax: 206-483-4996

In reply refer to Warning Letter SEA 98-01

Mr. Raymond E. Gerringa, Owner  
Carbon County Cattle Co.  
Box 156  
Boyd, Montana 59013

WARNING LETTER

Dear Mr. Gerringa:

An inspection of your commercial cattle feedlot and associated feed manufacturing facility at the above address was conducted on September 9, 1997. Investigator William C. Hughes observed and documented significant 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 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 investigation found: 1) failure to maintain records of potency assays on at least three representative samples of each feed requiring a Medicated Feed Application at periodic intervals during the calendar year, and 2) a significant discrepancy between the actual drugs on hand during this inspection compared to the amount listed on your Daily Drug Inventory.

The above is not intended to be an all-inclusive list of CGMP violations. 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.

We request that you take prompt action to correct the above violations and that you establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action, such as seizure and/or injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license to manufacture medicated feeds at this site under Section 512(m)(4)(B)(ii) of the Act. This letter constitutes official notification under the law.

Based on the result of the September 9, 1997 inspection, evaluated together with the evidence before FDA when the Forms FDA 1900 were approved, the following determination was made. The methods used in, or the facilities and controls used for, the manufacture, and processing of medicated feed by your firm, are inadequate to assure and preserve the identity, strength, quality,

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Raymond E. Gerringa  
Carbon County Cattle Co.  
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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 were issued Warning Letter SEA 95-16 dated 12/16/94 for similar violations of the law. Your response letter dated 12/22/94 stated that you would conduct potency assays. An inspection of your firm by the State of Montana 3/10/95 noted that you still had not conducted the required assays. During that inspection you stated that you would take the responsibility and collect the required assays. As of 9/9/97 you have not conducted the required assays even though you continue to manufacture medicated feeds that require periodic assays. We are very concerned that you have not taken the responsibility and steps to correct this violation of the law.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of 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 15 working days, state the reason for the delay and the time within which the correction will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food & Drug Administration, Seattle District Office, P.O. Box 3012, Bothell, WA 98041-3012, Attention: Richard S. Andros, Compliance Officer.

Sincerely,

  
Roger L. Lowell  
District Director