



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, California 94502-7070  
Telephone: 510-337-6700

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

Our Reference 29-13603

May 19, 1998

Craig Willardson  
Nulaid Foods, Inc.  
337 East Fourth Street  
Ripon, California 95366

**WARNING LETTER**

Dear Mr. Willardson:

An inspection of your medicated feed manufacturing facility on April 30 through May 5, 1998, by Food and Drug Administration (FDA) Investigator Karen L. Robles have revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated in conformity with Title 21 CFR, Code of Federal Regulations, Part 225. Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act. The deviations found during the inspection are as follows:

You have failed to complete the third of three required assays for 1997, for medicated feeds containing the following Category II drugs: Neo-Terramycin, Apralan, and Aureomix. Three samples of all feeds that require licensing must be analyzed at periodic intervals during the calendar year.

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You have failed to investigate and notify CVM of assay results from medicated feeds, containing Category II drugs, which were out of limit results. There were eight samples which showed out of limit results for at least one drug in combination.

Your drug inventory records for Category I and II drugs are incomplete. Drug inventory records do not show a theoretical balance. There is no comparison between actual amounts of drugs used in manufacture and theoretical drug usage.

Your master record files are incomplete since they do not contain a copy or description of labeling, manufacturing instructions including mixing steps and mixing times, appropriate control directions, and are not prepared checked and signed or initialed by a qualified person.

You have failed to label all feeds which contain or may contain prohibited material with the required cautionary statement: "Do not feed to cattle or other ruminants".

Causing the adulteration of drugs after receipt in interstate commerce and delivering for introduction into interstate commerce of any article in violation of Section 512 are violations of Section 301 (k) of the Act.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Should you fail to promptly correct these violations, the FDA is prepared to invoke regulatory and/or administrative sanctions provided under the law. These include but are not limited to seizure, injunction, and/or notice of an opportunity for a hearing on a proposal to withdraw approval of your medicated feed license under Section 512 (m)(4)(B)(ii) of the Act and 21 CFR 514.115 (c)(2).

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are met.

Within fifteen (15) days of the receipt of this letter, please notify our Sacramento resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Nulaid Foods, Inc.  
Ripon, CA.

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Sincerely yours,

*Charles D. Moss*  
*Acting District Director*

*for*

Patricia Ziobro  
District Director  
San Francisco District