



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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

Via Federal Express

Our Reference: 29-11452

September 17, 1999

Dan Figone, President  
Hunt & Behrens, Inc.  
30 Lakeville Street  
Petaluma, California 94952

**WARNING LETTER**

Dear Mr. Figone:

An inspection of your medicated feed manufacturing facility on August 24 and 25, 1999, by Food and Drug Administration (FDA) Investigator Karen L. Robles has revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (CFR), 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 Act). The deviations found during the inspection are as follows:

Your drug inventory records for Amprol 25% are incomplete and inaccurate. Drug inventory records do not show an actual balance. There is no comparison between actual amounts of drugs used in manufacture and theoretical drug usage. The drug inventory record theoretical balance does not agree with the physical inventory. In addition, drug inventory records are recorded in pencil.

You have failed to assay the first batch of medicated feed you ever manufactured using Amprol 25%. You have not performed the two additional assays required at periodic intervals during this calendar year for Amprol 25%, and you have no further plans to use this drug the remainder of this year. Three samples of all feeds that require licensing must be analyzed at periodic intervals during the calendar year.

The master record file for Amprol 25% is incomplete since it does not contain manufacturing instructions including mixing steps and times, appropriate control directions, and there is no signature or initial by a qualified person.

The production records for Amprol 25% are incomplete since they do not contain actual quantity of feed produced, they are not checked by a responsible individual at the end of the working day, and equipment flush is not documented.

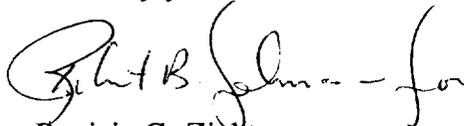
Causing the adulteration of drugs after receipt in interstate commerce and delivering for introduction into interstate commerce of any article in violation of Section 512 are violations of Section 301(k) of the Act.

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, 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, United States Food and Drug Administration, 801 I Street Room 443, Sacramento, California, 95814-2511.

Sincerely yours,



Patricia C. Ziobro  
Director  
San Francisco District