



November 6, 1996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-03

Robert Fox, President and CEO
Foster Farms of California
1000 Davis Street
P.O. Box 457
Livingston, California 95334

WARNING LETTER

Dear Mr. Fox:

An inspection of Fircrest Farms, 33464 E. West Lane, Creswell, Oregon conducted by William C. Hughes on September 26, 1996, confirmed that you offered chickens for slaughter as food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On August 4, 1996, Fircrest Farms was responsible for offering for slaughter chickens that were being raised at the Little Feather Ranch, Brownsville, Oregon, operated by Mr. Richard Peel, to Lynden Farms, 6135 North Basin Avenue, Portland, Oregon (P495). U.S. Department of Agriculture (USDA) analysis of tissue collected found residues of arsenic at 2.26 parts per million (ppm) in the livers. A tolerance of 2.0 ppm has been established in livers of chickens [Title 21, Code of Federal Regulations, Part 556.60 (21 CFR 556.60)]. The presence of this drug above the tolerance causes the food to be adulterated.

This investigation also found that you hold chickens under conditions that are so inadequate that medicated chickens bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that medicated chickens have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissues. Foods from chickens held under such conditions are adulterated.

Additionally, an inspection of Del Mesa Farms, 11671 Ehlen Road, Aurora, Oregon, conducted by William C. Hughes on September 13 to October 4, 1996, revealed significant deviations from the Current Good Manufacturing Practices (CGMPs) for Medicated Feeds, 21 CFR

225, which cause the medicated feeds being manufactured to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The investigation at Del Mesa Farms, found:

failure to conduct assays at periodic intervals during the calendar year of medicated feeds formerly requiring a Medicated Feed Application. For example, no assays were conducted of [REDACTED] (with Roxarsone), yet production of this feed began on April 29, 1996 and ended on September 19, 1996;

failure to maintain a drug inventory by a daily comparison of the amount of drugs used versus the theoretical drug usage; and

failure to conduct daily reviews of production records.

The above is not intended to be an all-inclusive list of violations. As a producer of chickens which are offered for food and the manufacturer of medicated feeds, you are responsible for assuring that your overall operation and the foods you 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, 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 13 to October 4, 1996, inspection at Del Mesa Farms, the following determination was made. The methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed by your firm, 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.

A review of feed delivery records, feed transfer records, and kill records indicate that your firm slaughtered chickens, at either the Lynden or Fircrest slaughter facilities, on at least

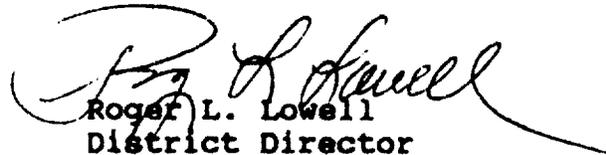
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twelve additional occasions, between August 5 and September 7, 1996, (besides the occurrence identified by USDA which originated at the Little Feather Ranch) which had been fed medicated feed containing Roxarsone before the five day withdrawal time had been observed.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the steps you have taken to bring your operation into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely,


Roger L. Lowell
District Director
Seattle District

cc: Lee E. Olmstead, N.W. Feed Manager
Del Mesa Farms
11671 Ehlen Road
Aurora, Oregon 97002

Leo Ciccolo, General Manager
Fircrest Farms
33464 E. West Lane
Creswell, Oregon 97426