



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3818n

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

Via Federal Express

Our Reference: 2915203

May 26, 2000

Robert Fox, CEO
Foster Poultry Farms
843 Davis Street
Livingston, California 95334

WARNING LETTER

Dear Mr. Fox:

An inspection of your medicated feed manufacturing facility located at 11245 West Swanson, Burrel, California, 93607, on April 4 through 10, 2000, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed 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 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:

Failure to sequence, flush, or otherwise physically clean manufacturing and delivery equipment between batches of medicated feed to ensure that cross contamination does not occur, as required by 21 CFR 225.65.

Failure to perform three assays at periodic intervals on feeds containing Rofenaid 40 (Sulfadimethoxine and Ormetoprim) in 1999, as required by 21 CFR 225.58.

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.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These

sanctions include, but are not limited to, seizure and/or injunction. Based on the result of the April 2000 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed 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.

Within fifteen days of the receipt of this letter, please notify this 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 Suzanne Schenck, Compliance Officer, at the above address.

Sincerely yours,



District Director
San Francisco District

cc: Larry D. Schuman, Plant Manager
Foster Farms
11245 West Swanson
Burrel, California 93607