



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
m2379n

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

Via Federal Express

Reference: 29-54169

February 10, 1999

Steve H. Nash, President
Nash Farms, Inc.
4225 East Conejo Avenue
Selma, California 93662

WARNING LETTER

Dear Mr. Nash

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 8, 1999, by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On November 16, 1998, you consigned a dairy cow (identified by USDA laboratory report Number 273743) for sale for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver at 0.22 parts per million (ppm) and in the muscle at 0.22 ppm. The tolerance level for sulfadimethoxine in the edible tissues of cattle has been established at 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to

health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
2. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
3. You lack an adequate inventory system for determining the quantities of drugs used to medicate yours cows.

The Albon brand of sulfadimethoxine that you use to treat your cows is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Labeling for Albon prescribes two boluses followed by one bolus per day for three to four days. Labeling also requires a seven day withdrawal period prior to slaughter for food use. Failure to adhere to the prescribed withdrawal time is likely the cause of the presence of violative levels of sulfadimethoxine in the tissues of the animal you sold for food use.

You are using the drug Maxim 100 brand oxytetracycline hydrochloride in a manner not in conformance with its approved labeling. Labeling for oxytetracycline hydrochloride specifies it is to be administered only to non-lactating dairy animals. Your practice of administering it to your lactating dairy animals is an unapproved use for which safety and efficacy have not been established.

You are using the drug Bimeda brand of penicillin in a manner not in conformance with its approved labeling. Labeling for penicillin specifies it is to be administered at a maximum rate of 1cc per 100 pounds of body weight. Your practice of administering 30 to 35 cc's per treatment of lactating catttle

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is an unapproved use for which safety and efficacy have not been established.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Within fifteen (15) 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 Robert J. Anderson, Investigator, P.O. Box 169, Fresno, CA 93707

Sincerely yours

Charles D. Moss
Acting District Director

for

Patricia C. Ziobro
District Director
San Francisco District

cc:

