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DEPARTMENT OF HEALTH & HUMAN SERVICES

5/27/97
2/2/97
**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: 29-53397

May 12, 1997

Arthur Stuyt
Richard Stuyt
Ansally Stuyt
21812 East Dodds Rd.
Escalon, California 95320

WARNING LETTER

Dear Messrs Stuyt and Mrs. Stuyt:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 10, 1997 by Food and Drug Administration (FDA) Investigator Alice Blair, have revealed serious violations of the Federal Food, Drug, and Cosmetic 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 of the Act. On January 14, 1997, you consigned a cull dairy cow (identified by USDA laboratory report number 384709) 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 antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver tissue at 0.42 parts per million (ppm) and in the muscle tissue at 1.01 ppm. The tolerance level for sulfadimethoxine in the edible tissue of cattle has been established at 0.1 ppm. USDA analysis of tissues from this animal also revealed the presence of penicillin in the kidney at 0.50 ppm. The tolerance level for penicillin in the edible tissues of cattle has been established at 0.05ppm.

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 determining the medication status of animals you offer for slaughter.
2. 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.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
4. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The Albon brand of sulfadimethoxine boluses that you used to treat your dairy cows are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(v) and are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with approved labeling. Labeling for Albon prescribes two boluses followed by one bolus per day for three to four days. The 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 cow you sold for food use.

Your use of the drug Duravet brand penicillin G procaine is not in conformance with its approved labeling directions. Labeling for penicillin G procaine requires a dose of 1 ml. per 100 pounds of body weight with no more than 10 mls. injected into one site. The labeling also requires a ten 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 penicillin in the tissues of the cow you sold for food use.

Failure to comply with the label instructions on the drugs you use presents the likely possibility that illegal residues will occur again and makes the drugs unsafe.

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.

S and S Stuyt Dairy
Escalon, California

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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.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, 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 include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to Alice A. Blair, Investigator, U.S. Food & Drug Administration, P.O. Box 1179, Stockton, CA 95201-1179.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc:

