



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

4/5/98
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San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50793

December 3, 1997

Jean P. Petrissans
George Petrissans
Petrissans Dairy
5111 Bear Mountain Boulevard
Bakersfield, California 93313

WARNING LETTER

Dear Messrs. Petrissans:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 29 through November 4, 1997, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon 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 August 1, 1997, you consigned a cull dairy calf (identified by USDA laboratory report number 391401) to be slaughtered as human food. This calf which was delivered for introduction into interstate commerce by your firm was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of gentamicin in the kidney at 0.49 parts per million (ppm); and sulfamethoxazole in the liver at 0.95 ppm and in the muscle at 1.58 ppm. A tolerance level for gentamicin and sulfamethoxazole has not been established for the edible tissues of cattle.

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 animals have been treated only with drugs which have been approved for use in their class of animal or species.
4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Fermenta brand of gentamicin sulfate within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with prescribed labeling. Your veterinarian prescribed the gentamicin sulfate for treatment of pneumonia in your calves. Your practice of mixing the gentamicin with five mLs. of Vita-Ject Vitamin B and five mLs. of Tylan 200 for use in your calves is an unapproved use for which safety and efficacy have not been proven and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval. Labeling on the drug includes a prescribed withdrawal time of eighteen months prior to slaughter. Failure to comply with the labeling instructions, coupled with an inadequate withdrawal time, is likely the cause of the gentamicin residues in the calf you sold for slaughter.

You are using the drug Oxymycin 100 brand of oxytetracycline hydrochloride in a manner not in conformance with its approved labeling. Labeling for oxytetracycline hydrochloride specifically states it is to be used to treat non-lactating dairy cattle by intravenous administration only. Your practice of using Oxymycin 100 oxytetracycline as a uterine infusion to medicate your cows

is an unapproved use for which safety and efficacy have not been established and requires the submission of a New Animal Drug Application for FDA approval.

Your use of the drug Ellsworth's Calf Supplement brand of oxytetracycline hydrochloride and neomycin sulfate is not in conformance with its approved labeling. You are using one tablespoon per two quarts of milk. The product labeling states that one tablespoon per gallon of milk is to be used.

Your use of the drug Spectam Scour-Halt brand of spectinomycin is not in conformance with its approved labeling. You are using Spectam Scour-Halt to treat your calves for scours. Spectam Scour-Halt is not approved for use in cattle.

Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe for use.

We request that you take prompt action to ensure that dairy cows and calves 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 into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of September 18, 1986, through August 1, 1997, your firm sold fourteen dairy cows and calves which contained violative levels of gentamicin, oxytetracycline, penicillin, streptomycin, sulfadimethoxine, sulfamethazine, sulfamethoxazole, and tetracycline. An inspection was conducted of your dairy on January 21 and 22, 1993. During the inspection you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Warning Letter, dated May 21, 1993, was sent to your firm as a result of the violations found during the inspection. Also, the U.S. Department of Agriculture has sent you

Petrissans Dairy
Bakersfield, California

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letters for each of the cull cows and calves in which USDA analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act 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 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 Thomas W. Gordon, Investigator, Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc:

A large black rectangular redaction box covering several lines of text in the carbon copy list.