



DEPARTMENT OF HEALTH & HUMAN SERVICES

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: 29-52562

September 3, 1997

Willem F. De Boer
14799 Avenue 168
Tulare, California 93274-9518

WARNING LETTER

Dear Mr. De Boer:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on August 8 and 13, 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. On June 2, 1997, you sold a cow (identified by USDA laboratory report number 385974) to be slaughtered for 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 cow revealed tetracycline in the kidney at 1.6 parts per million (ppm). A tolerance level for tetracycline in the edible tissues of lactating dairy cows has not been established.

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 drug Polyotic brand of tetracycline hydrochloride soluble powder that your establishment uses to medicate lactating dairy 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) of the Act since it is not being used in conformance with its approved labeling. Product labeling states it is to be administered orally for calves and does not allow its use in lactating dairy cows. Using Polyotic to prepare a uterine infusion for use in your cattle 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.

Our investigation also revealed that you treated the cow (identified by USDA laboratory report number 385974) on June 1, 1997, with the drug Albacillin brand of penicillin G procaine and novobiocin sodium, and delivered the cow to be slaughtered for food for human consumption on June 2, 1997. Your use of Albacillin is not in conformance with its approved labeling directions. The directions specify that animals intended for human consumption must not be treated within fifteen days of being slaughtered. Withholding treated cows for less than fifteen days creates the likely possibility that illegal residues will occur.

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

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.

Willem F. De Boer
Tulare, California

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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 dairy cow in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated dairy cow 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 are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen 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, CSO, Post Office Box 169, Fresno, California, 93707.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc:

