



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94961d

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

Via Federal Express

Our Reference: 1000221388

August 10, 2004

John M Troost and Jeff J. Troost, Partners
J Troost Dairy
24868 Road 9
Chowchilla, CA 93610

WARNING LETTER

Dear Messrs. Troost:

Tissue residue reports received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residue in two cows that originated from your dairy located at 24686 Road 9, Chowchilla, CA. As a follow-up to USDA's findings, our investigators performed an inspection of your dairy operation April 8 through 19, 2004. This inspection confirmed that you offered two animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On February 27, 2004, you consigned three dairy cows, one of which was subsequently identified with [REDACTED] back tag number [REDACTED] (last three digits) and USDA retain tag # 8013 (last four digits), for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 394844) collected from that animal identified the presence of the drug penicillin in the kidney at 0.48 parts per million (ppm).

On October 27, 2003, you consigned four dairy cows, one of which was subsequently identified with [REDACTED] back tag number [REDACTED] (last three digits) and USDA retain tag # 3769 (last four digits), for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 366573) collected from that animal identified the presence of the drug penicillin in the kidney at 0.38 ppm and in the liver at 0.21 ppm.

The tolerance level for penicillin in kidney and/or liver of cattle is 0.05 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.510.) Your use of penicillin in this animal resulted in the illegal drug residues found in the kidney and liver.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is also 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 investigators noted the following:

1. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling or your veterinarian's prescription labeling. For example, your veterinary label for [REDACTED] prescribes a withdrawal time of 18 days, however, for cow with ear tag # [REDACTED] you only observed an eleven (11) day withdrawal time. Your veterinarian's prescription label for [REDACTED] requires a withdrawal time of 14 days, however for cow with ear tag # [REDACTED] you only observed a ten (10) day withdrawal period.
2. You lack an adequate inventory/accountability system for determining the quantities of drugs used to medicate your cows.
3. You fail to systematically review treatment records prior to offering an animal for slaughter for human food, to assure that drugs have been used only as directed and that appropriate withdrawal times have been observed.
4. You fail to maintain complete permanent medication treatment records on the dairy cows. For example, your treatment records fail to include the dosage administered, the route of administration, withholding times, and the person administering the drug.

You are adulterating the following drugs within the meaning of Section 501(a)(5) of the Act, in that they are new animal drugs within Section 201(v) of the Act, and are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with their approved labeling or valid veterinary prescription.

1. [REDACTED] injectable suspension: Your veterinarian prescribed a dosage of 4cc per 100 lbs, BID per cow with a withdrawal time of 18 days. The drug's labeling prescribes no more than 10 ml administered at one site for a maximum of four (4) consecutive days. You are administering the drug for seven (7) consecutive days with up to 25cc administered at one site and observing an eleven (11) day withdrawal time.
2. [REDACTED]: The veterinary label prescribes a meat withdrawal of 14 days. You have sent animals for slaughter as human food after only 10 days.
3. [REDACTED]: The labeling states that the drug is intended for oral administration to beef and non-lactating dairy cattle. You administer [REDACTED] to your mature lactating dairy cows and you failed to obtain a veterinary prescription for this use.

4. [REDACTED]: The manufacturer's label prescribes a treatment of up to five (5) consecutive days. You are administering this drug up to six (6) consecutive days.
5. [REDACTED]: The veterinary label for [REDACTED] prescribes a dosage of 2 cc administered intramuscularly, to be repeated after seven (7) days with a meat withdrawal time of seven (7) days. You are administering 3 cc intramuscularly for up to two (2) consecutive days and are not following any withdrawal time for ECP.
6. [REDACTED]: You are using a solution of [REDACTED] to treat foot wart in you cows, however, the manufacturer's labeling prescribes the drug for oral use in swine and broiler chickens only.

Failure to comply with the label instructions and/or veterinarian's prescription on drugs you use to treat your animals 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. 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 are being met.

You should take prompt action to correct the violations observed during FDA's inspection. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

We are extremely concerned about your firm's history of illegal drug residue in cows your dairy offers for sale or consignment for slaughter as human food. The USDA has reported eight (8) illegal tissue residues originating from your dairy since February, 2001. Some of the same significant insanitary conditions found during the most recent inspection were previously cited in a May 9, 1996 Warning Letter. In addition, that Warning Letter also cited the adulteration of drugs for failure to use the drugs in conformance with approved labeling. You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, 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 Russell A. Campbell, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Barbara J. Cassens".

Barbara J. Cassens
District Director
San Francisco District