



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53223

April 21, 1997

Philip J. Nyberg, D.V.M.
Misty Meadow Farms
105 North Main Street
Fortuna, California 95540

WARNING LETTER

Dear Dr. Nyberg:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 27, 1997, by Food and Drug Administration (FDA) Investigator John A. Gonzalez 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 January 7, 1997, you sold a bull calf (identified by USDA laboratory report number 391963) for slaughter as human food. This calf 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 calf revealed gentamicin in the kidney at 3.10 parts per million (ppm) and in the liver at 3.70 ppm. No tolerance level for gentamicin has 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 that 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 system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The *Legacy* brand of Gentamicin sulfate that your establishment uses on calves 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 approved labeling. A preslaughter withdrawal time for *Legacy* has not been established to deplete potentially harmful residues of the drug from animals used for human food. Our investigation found that not applying an adequate withdrawal time is likely the cause of the gentamicin residues in the calf you sold for slaughter.

The use of new animal drugs in food-producing animals in any manner other than in accordance with approved labeling constitutes extra-label use and causes the drugs to be adulterated under the Act. Nevertheless, extra-label use may be considered by a veterinarian when the health of the animals is immediately threatened and suffering or death would result from failure to treat the affected animals. In such situations, extra-label use of approved new animal drugs requires all of the following criteria to be met and precautions observed:

1. A careful medical diagnosis is made by a veterinarian within the context of a valid veterinarian-client-patient relationship.
2. A determination is made that there is no marketed drug specifically labeled to treat the condition diagnosed, or drug therapy at the dosage recommended by the labeling has been found clinically ineffective in the animal to be treated;

3. Procedures are instituted to assure that identity of the treated animal(s) is carefully maintained: and,
4. A significantly extended time period is assigned for drug withdrawal period to marketing meat, milk, or eggs: steps are taken to assure that the assigned time frames are met and no illegal residues occur.

When in the course of your professional practice, you prescribe new animal drugs under extra-label use to medicate food-producing animals, you assume the responsibility to assure that the identities of the animals are properly maintained, that withdrawal times are sufficient and observed, and that no illegal residues occur.

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.

Your firm has established a history of offering cull calves for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of March 4, 1996, through June 25, 1996, your firm offered two calves which contained violative levels of gentamicin. During the same period, you offered one other calf which was found by USDA to be CAST positive because of the possible presence of antibiotics. An inspection of your dairy was conducted on August 21, 1996, and you were warned that it is illegal to market calves containing violative levels of antibiotics in their edible tissues. As a result of the inspection, a Warning Letter, dated September 13, 1996, was sent to you for the violations found during that inspection. Also, the United States Department of Agriculture (USDA) sent you a letter for each instance in which USDA analysis found violative levels of drug residues. According to USDA analytical reports, during the period of December 3, 1996, through January 30, 1997, your firm sold another six calves which contained violative levels of gentamicin. A second inspection of your dairy was conducted on February 27, 1997. Again, you were warned that it is illegal to market calves containing violative levels of antibiotics in their edible tissues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure

Misty Meadows Farms
Fortuna, California

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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 current inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, Investigator, 2202 Monterey Avenue, Suite 104 E, Fresno, California 93721.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District