



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

VIA FEDERAL EXPRESS

Our Reference: 29-53352

February 3, 1999

Robert Wilbur  
Wilbur Brothers  
20298 Road 52  
Tulare, California 93274

**WARNING LETTER**

Dear Mr. Wilbur:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 11 and 12, 1999, by Food and Drug Administration (FDA) Investigator Christopher J. Lee have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

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. On November 13, 1998, you consigned a dairy cow (identified by USDA laboratory report number 273741) to be slaughtered as human food. This cow, 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 sulfadimethoxine in the liver at 1.20 parts per million (ppm), and in the muscle at 1.00 ppm. The tolerance level for sulfadimethoxine in the edible tissues of cows has been established at 0.10 ppm.

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 species or class.
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 medicated your cows and calves.

The RXVeterinary Sulfadimethoxine Injection-40% brand of sulfadimethoxine that your establishment uses to treat lactating 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 approved labeling. Labeling for Sulfadimethoxine Injection-40% requires a five day withdrawal period prior to slaughter for food use. Failure to adhere to the withdrawal time is likely the cause of the sulfadimethoxine residues in the cow you sold for slaughter. Failure to comply with the label instructions on the drug you use to treat your cows presents the likely possibility that illegal residues will occur and makes the drugs unsafe to 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.

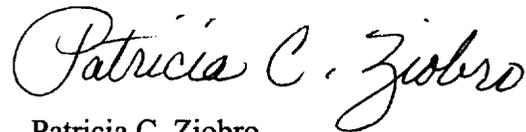
Wilbur Brothers  
Tulare, California

3

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 met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, please 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 Christopher J. Lee, Investigator, P.O. Box 169, Fresno, California 93707.

Sincerely yours,



Patricia C. Ziobro  
District Director  
San Francisco District

cc:

