



1/27/98

January 22, 1998

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

Ref: 98-DAL-WL-14

**WARNING LETTER****VIA FEDERAL EXPRESS**

Mr. Kars Tamminga, President  
Fri-Tex Dairy, Inc.  
700 Hoyt Road #A  
Waxahachie, Texas 75168

Dear Mr. Tamminga:

A Food & Drug Administration (FDA) investigation of your dairy operation on August 7/8 and September 9, 12 and 18, 1997, confirmed that you offered dairy animals for sale for slaughter as food in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Additionally, you have adulterated food for animals in violation of 402(a)(1). Section 201(f) of the Act defines "food" as "\*\*\*\* articles used for food or drink for man or other animals, \*\*\*."

On August 4, 1997, you directed the delivery of seven (7) high producer dairy cows for slaughter at [REDACTED]. Five (5) of the animals were dead-on-arrival at [REDACTED]. Two (2) animals identified with ear tags #503 and #628 were accepted and processed for slaughter as human food at [REDACTED].

You delivered the dairy animals for slaughter for food, although numerous animals in your high producer herd had become sick, resulting in death of many animals beginning on August 2, 1997. Your high producer animals were being treated/medicated by local veterinarians, and milk from the herd was being dumped on the farm. Additionally, dead animals were offered as rendering stock where they are used in production of meat and bone meal for sale as animal feed ingredients for food producing animals.

On August 7, 1997, FDA investigators sampled the remaining Total Mix Ration used as feed for high producer dairy cattle on August 2, 1997. This ration exhibited a strong pesticide odor at the time of sampling. FDA laboratory analysis of the ration confirmed the presence of the pesticide chemical "Terbufos" at the levels of 29.8ppm (original) and 26.2ppm (check). There is no established tolerance for Terbufos in animal feed, therefore, the feed is adulterated because it contains an added poisonous or deleterious substance, which may render the feed injurious to health [Section 402(a)(1) of the Act].

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Our investigation found that you hold animals under conditions which are so inadequate that diseased or sick animals bearing potentially harmful pesticide and drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that dairy ration, for your milk producing dairy herd, contains only those feed ingredients identified on ration formula sheets. You sent to slaughter for human food, seven animals with obvious symptoms of poisoning, and which had likely been treated with an antidote without withdrawal. Additionally, a system was not in place for identification of animals treated/medicated with methylene blue during the time period of August 2/5, 1997, when approximately [REDACTED] high producer dairy animals died on the farm. Foods from animals held under such conditions are adulterated [Section 402(a)(4) of the Act].

During the investigation, you advised the investigators that a partial brown paper bag labeled in part "\*\*\*\* Cyanamid Company \*\*\* Chemical \*\*\*\*" was removed from the remaining dairy ration produced on August 2, 1997. Additionally, two (2)/50lb. bags (in a state of deterioration) of "\*\*\*\* Cyanamid \*\*\* Counter 15 G \*\*\*" were retrieved from the bulk and bagged dairy feed ingredient storage area on August 8, 1997.

As the producer/grower of milk and milk producing animals, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. As producer/grower you are the individual who introduced or offered for slaughter into interstate commerce animals that may contain potentially hazardous tissue residues; as such you are responsible for violations of the Act. To avoid future violations, you should take precautions such as:

- 1) Implementing a system to identify treated/medicated animals to establish that milk and meat products are not marketed which may contain potentially violative drug residues of public health significance. This includes requesting withdrawal times from your veterinarian and adhering to these times.
- 2) Implementing a system of storing animal feed ingredients away from potentially hazardous chemicals which may serve to contaminate feed ingredients and result in adulteration of animal feeds.
- 3) Implementing a system of controlling batch production of dairy rations, designed to provide the assurance that only approved feed ingredients are incorporated into feed production batches.

A review of FDA files for your firm finds documentation of previous violative drug residues in edible tissues of dairy cattle offered for slaughter. An August 5, 1996, letter (referencing Case No. 3-0113-96) addressed to your firm from the United States Department of Agriculture (USDA) cited violative drug residues of Oxytetracycline and Sulfadimethoxine

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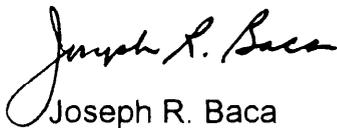
in an animal offered for slaughter at [REDACTED] on July 2, 1996. A follow-up inspection by the Texas Department of Health (TDH) on November 21, 1996, determined your firm failed to follow drug labeling directions, including preslaughter withdrawal time. The TDH also determined drug treatment records were not maintained. Additional documentation of drug residues in animals offered for slaughter by your firm includes Penicillin residues in dairy animals on June 20, 1994, and March 1, 1993.

The above is not intended to be an all-inclusive list of violations. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also, include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely yours,

  
Joseph R. Baca  
Dallas District Director

JRB:JRL:jab

cc: Dr. Mike McNalley, DVM  
P.O. Box 247 HC-1  
Sulphur Springs, Texas 75482

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1705 W. 287 Business  
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