



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 22, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-29

WARNING LETTER

Arie L. Slegers, President
Slegers, Inc.
18345 Nichols Road
Dayton, Oregon 97114

Dear Mr. Slegers:

An investigation at your dairy operation located at Dayton, Oregon, conducted on June 6 and 17, 1999, confirmed that you offered animals for sale for food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On April 22, 1999, you sold a cow identified with back tag number 592 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of 1.10 ppm of sulfadimethoxine in the liver and 0.58 ppm sulfadimethoxine in the muscle. On May 6, 1999, you sold a cow identified with back tag number 070 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of 1.40 ppm of sulfadimethoxine in the liver and 0.69 ppm of sulfadimethoxine in the muscle. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in edible tissues of cattle. The presence of this drug in edible tissue from these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions which allow medicated animals with potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for: a) assuring that drugs are used in a manner not contrary to the directions contained in the labeling; b) and assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time (to permit depletion of potentially hazardous residues of drugs from edible tissue). Foods from animals held under such conditions are adulterated with the meaning of section 402(a)(4) of the Act.

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Slegers, Inc.
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Your failure to use the drugs Albon® and DI-METHOX™, brands of sulfadimethoxine in conformance with their approved labeling caused the drugs to become adulterated within the meaning of 501(a)(5). Your use of these drugs, at higher than labeled doses, causes these drugs to become unsafe for use.

The above is not intended to be an all inclusive list of violations. As a producer of animals offered for food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring you dairy into compliance with the law. Your response should include each step being taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed, Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,

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Richard S. Andros

for Roger L. Lowell
District Director