



3/16/97  
2/8  
HFI - 35

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell WA 98041-3012

April 4, 1997

VIA FEDERAL EXPRESS

Telephone: 206-486-8788  
Fax: 206-483-4996

In reply refer to Warning Letter SEA 97-15

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 March 17, 1997, confirmed that you offered an animal for sale for food in violation of Sections 402(a)(2)(D) 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 December 6, 1996, you sold a cow identified with back tag number 867 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of 0.34 ppm of penicillin in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(D).

Our investigation also found that you hold animals under conditions which allow medicated animals bearing 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) recording the individual who administers each medication; c) 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 tissues. Foods from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

You are adulterating the drug [REDACTED] brand of penicillin that your firm uses on cows within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug, at higher than labeled

Arie L. Slegers, President  
Slegers, Inc., Dayton, OR  
Warning Letter SEA 97-15  
Page 2

doses and exceeding the approved number of consecutive days of treatment, causes the drug to be unsafe to 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.

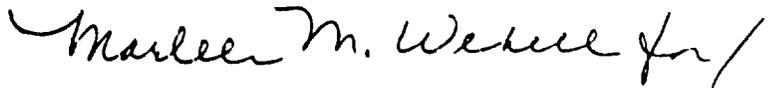
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

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 your 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,



Roger L. Lowell  
District Director