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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M36907

Refer to: FEI 3002834134

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

April 12, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Mervin E. Roderick, President
Avon Hill Farms Inc.
Route 2, Box 64
Charlestown, West Virginia 25414

Dear Mr. Roderick:

An inspection was conducted of your dairy cow operation located in Charlestown, West Virginia by a Food and Drug Administration (FDA) investigator on February 15-25 and March 14-17, 2000. The inspection confirmed that you offered animals for sale for slaughter as human food that contained illegal drug residues. This causes such food to be adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On or about April 12, 1999, you sold a dairy cow identified with back tag #6527 for slaughter as human food at [REDACTED] subsequently slaughtered the cow for use as human food. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 4.50 ppm penicillin in the kidneys. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of dairy cows (Title 21, Code of Federal Regulations, Part 556.510). The presence of these drugs in edible tissue from this animal causes the food to be adulterated.

This is not the first time USDA has detected an illegal drug residue in an animal identified as originating from your dairy farm. On or about August 18, 1999, you sold a dairy cow identified with back tag #8617 for slaughter as human food at [REDACTED] subsequently slaughtered the cow for use as human food. USDA analysis of tissue samples collected from that animal identified the presence of 0.15 ppm penicillin in the liver tissue and 0.10 ppm penicillin in the

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kidney tissue of this animal. You should have received a letter from USDA dated May 10, 1999 regarding the residue violations.

Our investigation found that you hold animals under conditions that permit potentially harmful drug residues to enter the food supply. For example:

- You fail to maintain medication and/or treatment records that identify the animal, the date of medication, the drug and dosage administered, and pre-slaughter withdrawal times for each animal.
- You have failed to establish a system for the review of treatment records prior to offering dairy cows for slaughter as human food, which assures that drugs have been used only as directed and that appropriate withdrawal times have been observed.
- In addition, you fail to notify buyers that animals from your farm have been medicated.

Foods from animals held under such conditions are adulterated within the meaning of the FD&C Act. An FDA-483, Inspectional Observations, was issued to you at the conclusion of the FDA inspection. You are adulterating the drug penicillin within the meaning of Section 501(a)(5) of the FD&C Act when you fail to use the drug in conformance with its approved labeling.

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

The above violations are not meant to be an all-inclusive list of violations. As a producer of animals offered for use as human 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.

Within 15 working days of receipt of this letter, you should notify this office in writing of the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and to

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prevent their recurrence. If corrective action cannot be completed within 15 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 the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of William Bargo, Acting Compliance Officer. Mr. Bargo can be reached at (410) 962-3461, Ext. 115.

Sincerely,



Lee Bowers

Director, Baltimore District

cc: West Virginia Department of Agriculture
Meat and Poultry Division
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305-0170

USDA/FSIS/FO
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