



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

g1498d

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert J. Sturm
Vice President and Co-Owner
J-Rob Farms, Inc.
1488 Federal Rd.
Caledonia, NY 14423

July 2, 2001

File No. NYK 2001-90

Dear Mr. Sturm:

On May 24, 25, and 30, 2001, a U.S. Food and Drug Administration investigator conducted an inspection at your dairy operation located in Caledonia, New York. This inspection confirmed that in October 2000 and January 2001 you offered two 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). The inspection also revealed that you caused an animal drug to become adulterated within the meaning of Section 501(a)(5).

On or about October 18, 2000, you offered a cow identified with ear tag 21ZDA2474 for slaughter as human food. The cow was slaughtered at [REDACTED]
USDA analysis of tissue samples collected from that animal identified the presence of 1.30 parts per million (ppm) and 1.00 ppm sulfadimethoxine in liver and muscle tissues, respectively.

On or about January 10, 2001, you offered a cow identified with ear tag 21ZDA2609 for slaughter as human food. The cow was slaughtered at [REDACTED]
USDA analysis of tissue samples collected from that animal identified the presence of 7.52 ppm and 3.47 ppm sulfadimethoxine in liver and muscle tissues, respectively.

A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in edible tissues of cattle (Title 21 Code of Federal Regulations 556.640). The presence of this drug in the liver and muscle tissues of these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

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Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You also caused the drug Albon, containing sulfadimethoxine, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the labeling. Labeling directions specifically indicate the dosage amounts to be administered based on the body weight of the animal. Your administration of three boluses to the cow you offered for slaughter on or about January 10, 2001 exceeded the manufacturers labeled dosage rate for administration of the product.

You should not consider this to be an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include 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 Federal Food, Drug and Cosmetic Act. The fact you caused the adulteration of an animal that was sold and offered for sale to a slaughterhouse which subsequently sold the meat to a processor that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

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Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Richard T. Trainor, Compliance Officer, at the following address: FDA, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely,

A handwritten signature in black ink that reads "Timothy E. Hansen". The signature is written in a cursive style with a large, stylized initial 'T'.

Timothy E. Hansen
Acting District Director

cc: Jerrold L. Sturm, President and Co-Owner
(address, as above)