



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

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December 30, 2002

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. James P. Reynolds, Co-owner
Reyncrest Farms, Inc.
9660 Allegheny Road
Corfu, NY 14036

File No.: NYK 2003-10

Dear Mr. Reynolds:

On October 21 and 22, 2002, a U.S. Food and Drug Administration (FDA) Investigator conducted an inspection at your dairy farm located in Corfu, New York. This inspection confirmed that in April 2002 you offered two animals for sale for food that were adulterated within the meaning 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 serious deviations from the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530). These deviations caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about April 16, 2002, you sold a cow identified with barn tag 1071 to [REDACTED] for slaughter as human food. The cow was subsequently delivered to and slaughtered at [REDACTED] on or about April 17, 2002. USDA analysis of tissue samples collected from that animal identified the presence of 1.45 parts per million (ppm) of flunixin in the liver tissue. A tolerance of 0.125 ppm has been established for residues of flunixin meglumine in the liver tissue of cattle (Title 21 Code of Federal Regulations 556.286). The presence of this drug in excess of the tolerance in the liver tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about April 22, 2002 you sold a cow identified with barn tag 781 to [REDACTED] for slaughter as human food. The cow was subsequently delivered to and slaughtered at [REDACTED] on or about April 23, 2002. USDA analysis of tissue samples collected from that animal identified the presence of 0.10 parts per million (ppm) of penicillin in the liver tissue. A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). The presence of this drug in excess of the tolerance in the liver tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Reyncrest Farms, Inc.
Corfu, NY 14036

On or about November 21, 2001, you provided [REDACTED] a signed Livestock Owner's Certificate. This certificate certified that none of the livestock are adulterated within the meaning of the Act and that none of the livestock have an illegal level of drug residues. On or about April 16, 2002 and April 22, 2002 you sold these cows, adulterated with these residues, to [REDACTED].

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. You failed to review your cattle treatment record prior to offering cows 1071 and 781 for slaughter as human food and you failed to have a drug inventory system. Foods from animals held under such conditions are adulterated under Section 402(a)(4).

You also caused the drug [REDACTED] containing flunixin meglumine, 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. Your use of this drug at levels that exceeded the recommended dosage limits and failure to follow labeled withdrawal periods as prescribed by your veterinarian causes the drug to be unsafe for use.

You also caused the drug Penicillin G Procaine under the trade name [REDACTED] 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 this drug exceeded the manufacturer's labeled dosage rate for this product. [REDACTED] is for intramuscular use only. During the initial treatment of this cow, you administered this drug subcutaneously without the benefit of a veterinarian's oversight.

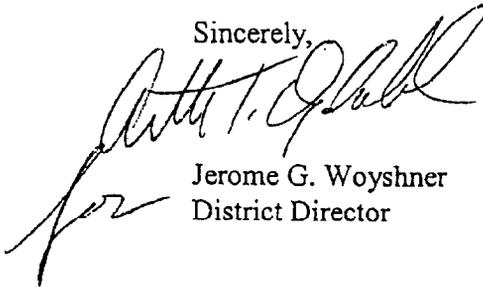
You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law. It is not necessary for you to personally 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 that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

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 FDA seeking regulatory action, without further notice. This may include seizure and/or injunction.

Reyncrest Farms, Inc.
Corfu, NY 14036

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, appearing to read "Jerome G. Woysner". The signature is written in a cursive style with a large, sweeping initial "J".

Jerome G. Woysner
District Director

cc: Mr. John P. Reynolds, Co-owner
(same address)