



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Food and Drug Administration
466 Fernandez Juncos Avenue
San Juan, Puerto Rico, 00901

Telephone: 787-474-9510
FAX: 787-729-6658

July 26, 2004

WARNING LETTER
SJN-04-12

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. José Gregorio Toledo
Owner
HC-04 Box 30580
Hatillo, Puerto Rico 00659

Dear: Mr. Toledo:

An investigation which included your dairy operation facilities located at HC-04 Box 30580 Hatillo, Puerto Rico 00659 and Road number 482, Sector Arca de Noe, Quebradillas, Puerto Rico 00678, listed under the name of Jose Gregorio Toledo (AKA Tary Toledo), conducted by a Food and Drug Administration (FDA) investigator between February 24, and March 16, 2004 confirmed that you caused animal drugs to be unsafe under Section 512(a) of the Federal Food, Drug, and Cosmetic Act (the Act), and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about October 14, 2003, you sold a dairy cow with retain tag number 44174525. This animal was sold for slaughter as human food at [REDACTED]. [REDACTED] United States Department of Agriculture (USDA) analysis of tissue samples revealed the presence of penicillin residues in this animal with a tag number 44174525 and found 0.41 ppm. in the kidney and 0.57 ppm. in the liver. Tolerance for residues of penicillin in the uncooked edible tissues of cattle has been established at 0.05 parts per million per Title 21 Code of Federal Regulations Part 556.510. By failing to adhere to the withdrawal time contained in this drug's labeled directions, you caused this drug to be unsafe within the meaning of Section 512(a)(1) of the Act, and adulterated within the meaning of Section 501(a)(5) of the Act.

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You also caused the adulteration of the drug Agri-Cillin Rx drug (Penicillin) when you used it to treat dairy cows contrary to the product's approved uses. The extralabel use of approved animal drugs is allowed if the use complies with Sections 512(a)(4) of the Act and 21 CFR Part 530. You administered Agri-Cillin, a Rx drug, to cow #17 without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a), and your extralabel use resulted in an illegal drug residue, in violation of 21 CFR 530.11(d). Because your extralabel use of penicillin was not in compliance with 21 CFR 530, the drug was unsafe under Section 512(a) of the Act and your use caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

The above mentioned violations are not intended to be an all-inclusive list of violations. As a producer of animals, you are responsible for assuring that your overall operation is 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 do so may result in regulatory action, such as seizure and/or injunction, without further notice. 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 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 the Food and Drug Administration, attention Carlos I. Medina, Compliance Officer. If you have any questions concerning this letter, you can contact Carlos I. Medina, Compliance Officer at telephone number 787-474-9539.

Sincerely yours,



Donald J. Voeller
District Director

Enclosure