



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

June 22, 2004

WARNING LETTER
SJN-04-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Juan Manuel Barreto
Owner
J.M. Dairy Corporation
HC-05 Box 916535
Bo. Hato Bajo
Arecibo, Puerto Rico 00612

Dear Mr. Barreto,

On February 18 to March 18, 2004, an investigator from the Food and Drug Administration conducted an inspection at your dairy facility located at road number 635, km. 3.3; sector Hato Bajo, Arecibo, Puerto Rico 00612. This inspection confirmed that you caused the adulteration of new animal drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act). By not using these drugs in conformance with their approved uses, you caused the animal drugs 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.

On February 18, 2004, a middleman offered for slaughter a dairy cow purchased from your dairy farm on February 17, 2004. The cow was identified with retain tag number [REDACTED], United States Department of Agriculture (USDA), Case number [REDACTED], at [REDACTED] [REDACTED] located at road number [REDACTED], intersection with road number [REDACTED] [REDACTED] USDA analysis of tissue samples collected from this animal confirmed the presence of 0.11 parts per million (ppm) of penicillin. The tolerance for residues of penicillin in the uncooked edible tissues of cattle has been established at 0.05 parts per million in Title 21, Code of Federal Regulations (CFR), Section 556.510. By failing to adhere to the withdrawal time contained in this drugs' 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.

In addition, you caused the adulteration of the drug oxytetracycline hydrochloride injection when you used it to treat lactating dairy cows contrary to the product's approved uses (see 21 CFR § 1662a). This use caused the animal 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.

Furthermore, a prior notice from the USDA Food Safety and Inspection Service was sent to you regarding a dairy cow offered for sale for slaughter on [redacted] by a middleman who purchased the animal from your dairy farm on the same day. The cow was identified with retain tag number [redacted] USDA, Case number [redacted], at [redacted]. Slaughterhouse located at road number [redacted] intersection with road number [redacted] [redacted] USDA analysis of tissue samples collected from this animal confirmed the presence of penicillin and sulfadimethoxine as follows:

- In Kidney, penicillin 00.49 parts per million.
- In Liver, penicillin 00.33 parts per million.
- In Liver, sulfadimethoxine 00.60 parts per million.
- In Muscle, sulfadimethoxine 00.73 parts per million.

Tolerance for residues of sulfadimethoxine in uncooked edible tissues of cattle has been established at 0.1 part per million (see 21 CFR § 556.640), and as mentioned earlier, the tolerance for residues of penicillin in the uncooked edible tissues of cattle has been established at 0.05 parts per million (see 21 CFR § 556.510). By failing to adhere to the withdrawal times contained in these drugs' labeled directions, you caused these drugs 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.

The abovementioned 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 operations 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.

You should 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.

Mr. Barreto
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Your reply should be directed to the Food and Drug Administration, Attention: Carlos A. Medina, Compliance Officer at the above address. If you have any questions concerning this letter, you may contact Mr. Medina at 787-474-9538.

Sincerely,

for Elizabeth Kaye
Donald J. Voeller
District Director
San Juan District

Enclosure