



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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PB 12/18/00
Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905
Telephone: (913) 752-2100

December 7, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER
KAN #2001-010

Mr. Dale E. Senestraro
Managing Partner
Coolidge Dairy Farm L.L.C.
Box 199
Coolidge, KS 67836

Dear Mr. Senestraro:

On November 7, 2000 an investigation performed at your dairy operation located at Coolidge, Kansas confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act [the Act]. In addition you caused an animal drug to be adulterated within the meaning of Section 501(a)(5) of the Act.

On or about September 11, 2000 you sold a cow identified with USDA laboratory report number 347358, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 3.9 ppm of sulfadimthoxine in the liver and 1.4 ppm of sulfadimethoxine in the muscle of the subject beefed cow. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle per Title 21, Code of Federal Regulations Section 556.640 [21 CFR 556.640]. The presence of this drug in edible tissue from this cow causes the food to be adulterated.

You adulterated the drug Albon® bolus brand of sulfadimethoxine within the meaning of Section 501(a)(5) when you failed to use the drug in conformance with its approved labeling. Your use of this drug without following labeled withdrawal periods causes the drug to be unsafe to use.

As evidenced by your repeat violative residues and our investigation you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter into the food supply. Your firm does not maintain adequate records of treatment of animals offered for slaughter. For example you do not identify: a) the treated

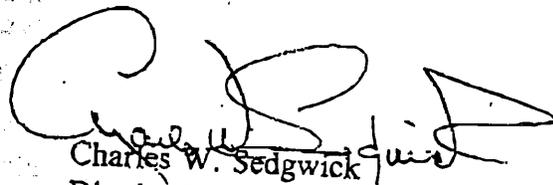
Mr. Dale E. Senestraro, Managing Partner
Coolidge Dairy Farm L.L.C.
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animal; b) the date of treatment; c) the drug; d) the dosage; and e) the period of time the culled animal is held to meet the prescribed withdrawal time of the drug in your records. Furthermore your firm does not maintain an adequate inventory record of drugs maintained in the medication room or the medication cart. Food from animals held under such conditions is adulterated under the Act.

You should take prompt action to establish procedures to prevent their recurrence. Failure to promptly established and follow a system to prevent a recurrence of these violations may result in regulatory actions without further notice including but not limited to seizure and/or injunction.

Please provide the requested information and any further response you want to submit within fifteen (15) working days. Your reply should be directed to Ralph J. Gray, Compliance Officer at the above address.

Sincerely,



Charles W. Sedgwick
District Director
Kansas City District