



DEPARTMENT OF HEALTH & HUMAN SERVICES

11/29/99

Food and Drug Administration  
Denver District Office  
Building 20 – Denver Federal Center  
P.O. Box 25087  
Denver, Colorado 80225-0087  
TELEPHONE: 303-236-3000

September 10, 1999

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Randall D. Vander Meulen  
Partner/Owner  
Woodcrest Dairy  
3793 E. Brasher Rd.  
Roswell, NM 88201

Ref. # : DEN-99-21

PURGED

Dear Mr. Vander Meulen:

An investigation at your dairy operation located in Roswell, New Mexico, was conducted by Consumer Safety Officer Barbara J. White. The inspection confirmed that you offered animals 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).

Specifically, you sold cows on [x] separate occasions to [x x x x x x x x] [x x x x x] and one cow to [x x x x x x x x x x x x] which were found to contain illegal levels of drug residues by USDA testing. Further, at least one of these cows was offered for sale after you were informed by certified letter dated May 12, 1999, from Dr. Manzoor Chaudry, USDA/Food Safety and Inspection Service, that a drug residue was found in a cow originating from your premises.

These [x] incidents were recorded under USDA case No. 99-0381-NM and include:

**April 5, 1999:** USDA analysis of tissue samples collected from your animal (USDA Sample No. 327462) identified the presence of Gentamicin sulfate residue of [x] ppm in the kidney. No tolerance has been established for residues of Gentamicin sulfate in the edible tissues of dairy cattle in Title 21 Code of Federal Regulations Part 556.300 (21 CFR 556.300).

**April 27, 1999:** USDA analysis of tissue samples collected from your animal (USDA Sample No. 327496) identified the presence of Gentamicin sulfate residue of [x] ppm in the kidney.

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**May 4, 1999:** USDA analysis of tissue samples collected from your animal (USDA Sample No. 327461) identified the presence of Gentamicin sulfate residue of 2.7 ppm in the kidney.

**May 5, 1999:** USDA analysis of tissue samples collected from your animal (USDA Sample No. 371788) identified the presence of Gentamicin sulfate residue of 2.7 ppm in the kidney.

**May 17, 1999:** USDA analysis of tissue samples collected from your animal (USDA Sample No. 327472) identified the presence of Gentamicin sulfate residue of 2.7 ppm in the kidney.

**June 11, 1999:** USDA analysis of tissue samples collected from your animal (USDA Sample No. 327422) identified the presence of Gentamicin sulfate residue of 2.7 ppm in the kidney.

Our investigation revealed the use of 2.7 (Gentamicin sulfate, Dexamethazone, Neomycin). The presence of Gentamicin drug at the level found in the edible tissue from these animals cause the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues may 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 potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 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 response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

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Sincerely,  
  
Gary C. Dean  
District Director