



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
FAX: (612) 334-4134

April 21, 2003

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 03 - 18

Randy R. Stewart  
Owner  
Cottonwood Cattle Company  
5700 East Tomar Road  
Sioux Falls, South Dakota 57108

Dear Mr. Stewart:

On December 16, 2002, an investigator from the Food and Drug Administration (FDA) conducted an investigation of your cattle operation in Sioux Falls, SD. That investigation confirmed that several animals sold by you, for slaughter for human food, were in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

USDA/FSIS analysis of tissues collected from cattle sold by you and slaughtered at  disclosed the presence of the following drugs:

<u>Retain Tag No.</u>	<u>Date</u>	<u>Drug</u>	<u>Tissue</u>	<u>Level</u>	<u>Tolerance</u>
					<u>(ppm)</u>
31207049	12/11/01	Gentamicin	Kidney	09.87	0.
	12/11/01	Gentamicin	Liver	02.97	0.
	12/11/01	Sulfadimethoxine	Liver	01.71	.1
	12/11/01	Sulfadimethoxine	Muscle	02.17	.1
40716263	12/13/01	Oxytetracycline	Kidney	154.70	12.
	12/13/01	Oxytetracycline	Liver	48.17	6.
	12/13/01	Oxytetracycline	Muscle	39.03	2.
31207586	12/20/01	Penicillin	Kidney	00.14	.05
	12/20/01	Sulfamethazine	Muscle	12.74	.1
	12/20/01	Tilmicosin	Muscle	13.19	0.
	12/20/01	Tilmicosin	Kidney	17.56	0.

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Retain Tag No.	Date	Drug	Tissue	Level	Tolerance
				(ppm)	
31203464	02/21/02	Sulfamethazine	Muscle	01.35	.1
	02/21/02	Tilmicosin	Muscle	10.50	0.
	02/21/02	Tilmicosin	Kidney	05.23	0.
31203445	03/06/02	Sulfamethazine	Liver	19.71	.1
	03/06/02	Sulfamethazine	Muscle	13.67	.1
31225719	04/22/02	Sulfamethazine	Muscle	11.79	.1
	04/22/02	Kidney	Tilmicosin	02.20	0.
42532651	10/16/02	Tilmicosin	Liver	01.44	1.2
	10/16/02	Tilmicosin	Muscle	06.68	0.
	10/16/02	Tilmicosin	Kidney	11.85	0.

Tolerance levels for residues of animal drugs in foods are found in Title 21, Code of Federal Regulations, Part 556 (21 CFR 556). The presence of these drugs, at levels above the tolerances, in edible tissue from these animals causes the food to be adulterated.

Our investigation found that you hold animals 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. As noted on the form FDA-483 issued to you on December 16, 2002, you do not have adequate controls in place to prevent medicated animals from being purchased and sold for human food, and you do not keep records to permit traceability to the source of the animals. Foods from animals held under such conditions are adulterated.

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.

The violations discussed above are not intended to be an all-inclusive list. It is your responsibility to ensure that your operations are in compliance with the law. To avoid future residue violations you should take precautions such as:

1. Implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;
2. Implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and
3. If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially

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hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

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, that has been 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 Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,



W. Charles Becoat  
Director  
Minneapolis District

TGP/ccl