



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) 758-7114
FAX: (612) 334-4134

March 15, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 18

Donald Statz
Co-Owner
Statz Farms and Sons
Also known as Statz Brothers, Inc.
6075 Skala Road
Sun Prairie, Wisconsin 53590-9547

Dear Mr. Statz:

Two tissue residue reports received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in cows that originated from Statz Farms and Sons. As a follow-up to USDA's finding, an investigator from the Food and Drug Administration (FDA) conducted an inspection on November 21, 2003, at your dairy farm located in Sun Prairie, Wisconsin. This inspection revealed serious violations of Section 512 of the Federal Food, Drug, and Cosmetic Act (the Act).

On August 19, 2003, you sold a cull dairy cow, identified with back tag number 6741, last four digits, for slaughter as human food. During our inspection, you identified this cow as #860. USDA analysis of tissue samples (USDA's Lab Report 443092) collected from that animal identified the presence of the drug flunixin in the liver at 2.848 parts per million (ppm). Flunixin is not approved for use in lactating dairy cows [Title 21, Code of Federal Regulations, section 522.970(e)(2)(iii) (21 CFR 522.970(e)(2)(iii))].

You are adulterating the drug brand (Flunixin Meglumine Injection), within the meaning of Section 501(a)(5) of the Act, in that it does not conform to the approved labeling. The extra-label use of drugs may only be done in compliance with 21 CFR Part 530, Extralabel Drug Use in Animals. These regulations require, among other conditions, that the extra-label use not result in residues above the established safe level or tolerance. See 21 CFR

Page Two

Donald Statz
March 15, 2004

§ 530.11(d). The manufacturer's labeling directs Flunixin's use for non-lactating dairy cattle only. Your practice of administering this product to your dairy cows is not in conformance with 21 CFR Part 530 and has resulted in a residue that renders the new animal drug unsafe and adulterated.

On August 21, 2003, you sold a cull dairy cow, identified with back tag number 6479, last four digits, for slaughter as human food. During our inspection, you were unable to further identify this cow. USDA analysis of tissue samples (USDA's Lab Report 443098) collected from that animal identified the presence of the drug sulfadimethoxine in the liver at 0.19 parts per million (ppm), and in the muscle at 0.25 ppm. No tolerance level has been established for sulfadimethoxine in the edible tissues of dairy cows (21 CFR 556.640).

You are also adulterating the drug  brand  (sulfadimethoxine 12.5% Oral Solution), within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act. The manufacturer's labeling directs its use as an oral solution only. Your practice of administering this product to your dairy cows as an intravenous solution is not in conformance with the labeled uses. The extra-label use of drugs may only be done in compliance with 21 CFR Part 530, Extralabel Drug Use in Animals. See 21 CFR 530.41(a)(9). Your failure to use the drug, sulfadimethoxine, in conformance with the approved labeling causes it to be adulterated.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute 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.

Please notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step 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.

In addition, you lack an adequate system for determining the medication status of animals, and assuring that animals to which you administer medication, such as a dairy cow, have been withheld from slaughter for the appropriate period of time to deplete potentially hazardous residues of drug. For example, our investigators noted the following:

Page Three

Donald Statz
March 15, 2004

- You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the dosages administered, the identity of the individual administering the drug, or the pre-slaughter withdrawal times.
- You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
- You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in the product's or your veterinarian's labeling.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated on the letterhead.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TSW/ccl



Enclosures: 21 C.F.R. 530
21 C.F.R. 522.970(e)(2)(iii)
21 C.F.R. 556.640