



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

May 5, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 26

James J. Ostrom
President and Chief Executive Officer
Milk Source, LLC
3051 Progress Way, Suite 201
Kaukauna, Wisconsin 54130

Dear Mr. Ostrom:

On February 11 and 25, 2004, an investigator from the Food and Drug Administration (FDA) conducted an investigation into two illegal tissue residues in dairy cows sold for slaughter as human food by [REDACTED]. That investigation included a review of your firm's involvement with the aforementioned residues. The investigation revealed serious deviations from the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (21 C.F.R.), Part 530. These deviations caused animal drugs to be used in a manner that was unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. 360b(a)] and adulterated within the meaning of Section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)]. The investigation also revealed that an animal drug was misbranded within the meaning of Section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] in that its labeling fails to bear adequate directions for use.

On or about September 2, 2003 [REDACTED] sold a dairy cow identified with back tag number 35GM1823 for slaughter as human food. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow identified the presence of flunixin at 0.128 parts per million (ppm) in the liver. On or about September 14, 2003, [REDACTED] sold a dairy cow identified with back tag number 35HW7858 for slaughter as human food. USDA analysis of tissue samples collected from that cow identified the presence of flunixin at 0.7080 ppm in the liver. Flunixin is not approved for use in lactating or dry dairy cows (per 21 C.F.R. 522.970, copy enclosed). The presence of flunixin in the edible tissue of these

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dairy cows caused the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Extralabel use of approved veterinary or human drugs is permitted only if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that Dr. Joseph D. Gaines, a veterinarian employed by your firm, failed to comply with 21 C.F.R. Part 530 in that:

- Flunixin was prescribed for extralabel use, and that extralabel use caused an illegal drug residue in two dairy cows sold for slaughter as human food. 21 C.F.R. 530.11(d) prohibits any extralabel use that results in a residue exceeding an established safe level, safe concentration or tolerance.
- Flunixin was prescribed for extralabel use without establishing a substantially extended withdrawal period prior to marketing of milk or meat as required by 21 C.F.R. 530.20(a)(2)(ii). Dr. Gaines also failed to take appropriate measures to assure that assigned timeframes for withdrawal are met as required by 21 C.F.R. 530.20(a)(2)(iv).
- Flunixin was prescribed for extralabel use, and Dr. Gaines failed to provide labeling information adequate to assure the safe and proper use of the product as required by 21 C.F.R. 530.12. Labeling lacks frequency and duration of therapy and withdrawal/withholding time for meat and milk.
- Dr. Gaines prescribed sulfadimethoxine 12.5% oral solution for extralabel use (administration of the product intravenously) in lactating dairy cattle. The extralabel use of sulfonamide drugs in lactating dairy cattle is prohibited by 21 C.F.R. 530.41(a)(9). Approved uses of sulfadimethoxine 12.5% oral solution are listed in 21 C.F.R. 520.2220a (copy enclosed).

Because Dr. Gaines failed to comply with the requirements of 21 C.F.R. Part 530,  used flunixin and sulfadimethoxine in an unapproved manner without meeting the requirements for extralabel use set forth in Section 512(a)(4)(A) and 21 C.F.R. Part 530, thereby rendering the drugs unsafe under Section 512 of the Act and adulterated under Section 501(a)(5) of the Act. Flunixin was also misbranded under Section 502(f)(1) of the Act because it was prescribed for extralabel use without the labeling required by 21 C.F.R. 530.12.

The above is not intended to be an all-inclusive list of violations. You are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. You should take prompt action to correct the above violations and to establish procedures whereby such violations do

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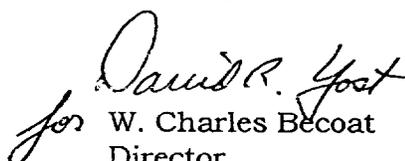
May 5, 2004

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 receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,


for W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosures: 21 C.F.R. 530, 522.970, 520.2220a

xc: Joseph D. Gaines, DVM
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