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Mark A. Daley  
April 23, 2004

entering the food supply. For example, you lack an adequate system for assuring that drugs are not used in a manner contrary to the labeled directions and 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. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

You adulterated flunixin meglumine within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the approved conditions of use or the extralabel use regulations at 21 CFR Part 530. Flunixin meglumine is not approved for use in dairy cows. This use of flunixin meglumine is contrary to the approved conditions of use. Such an extralabel use is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in conformance with other criteria set forth in 21 CFR 530, including that there may be no residue that may present a risk to the public health. A veterinarian prescribed "1 cc per 100# BW given IV or IM" flunixin meglumine for extralabel use to treat your dairy cows, and indicated on the label to "withhold from slaughter for 4 days after last treatment." Because your use of flunixin meglumine was outside of this prescribed use and, therefore, was not on the order of a licensed veterinarian, your use of the drug was not in compliance with extralabel use regulations, in particular 21 CFR 530.10 and 530.11(a). As a result, your use of this drug caused it to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

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 operations 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 occur. Failure to do so may result in regulatory action (such as seizure or injunction) without further notice to you.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be held responsible for a violation of the Act. The fact that you offered an animal for sale 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 receipt of this letter of the steps you have taken to bring your dairy operation 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 that corrections have been made.

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Your reply should be directed to Compliance Officer Brian D. Garthwaite, Ph.D. at the address indicated on the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Charles Becoat". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

W. Charles Becoat  
Director  
Minneapolis District