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Christopher J. Elbe  
November 7, 2003

530.11(a), extralabel use by a layperson is not permitted except under the supervision of a licensed veterinarian.

- The extralabel use of flunixin resulted in an illegal drug residue. 21 CFR 530.11(d) prohibits any extralabel use that results in a residue above an established tolerance level.

Because your extralabel use of flunixin was not in compliance with 21 CFR Part 530, the drug is unsafe under Section 512(a) of the Act. As a result, your use of this drug caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

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

We have enclosed a copy of 21 CFR Part 530 for your reference. We strongly suggest that you review 21 CFR Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

Our investigation found other deficiencies in your operations as cited on the Form FDA-483 that was issued to you on September 17, 2003. For example, you failed to maintain complete and accurate drug treatment records, failed to review treatment records prior to offering an animal for slaughter, and failed to maintain records to correlate the backtag number applied by a trucker to your own animal identification number. You must correct these deficiencies in your dairy operation in order to assure that animals are medicated properly and withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

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

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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,



W. Charles Becoat  
Director  
Minneapolis District

TGP/ccl

Enclosures: 21 CFR 530  
21 CFR 556.286  
21 CFR 522.970

xc:   
