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Luke W. Weninger
July 29, 2003

- Under 21 CFR 530.11(a), extralabel use by a layperson is not permitted except under the supervision of a licensed veterinarian. You administered flunixin to the aforementioned dairy cow without the supervision of a licensed veterinarian, and you failed to follow a 10-day withhold time for meat that had been specified on the veterinarian's label.
- Your 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 was sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Our investigation also found that you failed to maintain drug treatment records. See observation number three on the form FDA-483. It is very important that you maintain complete drug treatment records to allow you to properly adhere to withdrawal times for milk and meat.

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.

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.

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Luke W. Weninger
July 29, 2003

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 556.286
21 CFR 522.970
21 CFR 530

xc: 