



DEPARTMENT OF HEALTH & HUMAN SERVICES

HF1-35
95023d
Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

September 29, 2004

Ref: 2004-DAL-WL-32

WARNING LETTER

Certified Mail
Return Receipt Requested

John H. Newman, DVM
101 CR 438
Dublin, Texas 76446

Dear Dr. Newman:

An investigator from the US Food and Drug Administration (FDA) conducted an inspection at your veterinary practice on April 9, May 13, and June 4, 2004. The investigation confirmed that you prescribed on two occasions Flunixin Meglumine injection 50 mg/mL in an extralabel manner for dairy cattle owned by [REDACTED]

Our investigation revealed that on May 12, 2003 and December 2, 2003, you signed a prescription form which allowed the dispensing of, among other drugs, flunixin meglumine 50 mg/mL 250 ml bottles to [REDACTED] for his use at [REDACTED]. The prescription dated May 12, 2003, does not indicate a quantity and the December 2, 2003 prescription indicates "PRN," or as needed. Both prescriptions were renewable for 180 days. The prescriptions ordered the dispensing of Flunixin Meglumine for use as an anti-endotoxin, anti-inflammatory administered either intramuscularly (IM) or intravenously (IV), 1 mL per 100 pounds of body weight twice a day for not more than 3 days. The prescription further ordered a milk withhold of 96 hours and a meat withdrawal of 4 days.

On September 17, 2003, [REDACTED] dba [REDACTED] offered a cow, back tag number [REDACTED] for slaughter as human food at [REDACTED]. USDA analysis (Laboratory Report #436141) of tissue samples collected from that animal identified the presence of flunixin at 0.777 ppm in the liver.

In addition, on February 20, 2004, [REDACTED] offered a cow, back tag number [REDACTED] for slaughter as human food at [REDACTED].

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valid veterinarian-client-patient relationship (VCPR). A copy of 21 CFR 530, which includes the definition of a valid VCPR, is enclosed.

The above is not intended to be an all-inclusive list of violations. You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include injunction. You should notify this office, in writing, within fifteen (15) working days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to Sherrie L. Krolczyk, Recall and Emergency Coordinator, at the above letterhead address.

Sincerely,


Michael A. Chappell
Dallas District Director

MAC:slk

Enclosure