



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 21 2000

NADA 011-789

Thomas R. Schriemer, Manager
Worldwide Animal Health Regulatory Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001
USA

Dear Mr. Schriemer:

We have become aware of promotional material used in the marketing of Predef 2x (isoflupredone acetate) NADA 011-789. The promotional pieces include a technical bulletin coded V-88195 "The Upham Fresh Cow Program (Modification to P&U Product Recommendations); Dialogue 1999 Vol. 8 No. 2, "The fresh-cow decision tree"; Dialogue 2000 Vol. 9 No. 1 "The value of a healthy fresh cow"; and "The 100 Day Contract-Dairy Wellness Plan", coded V-99279R, which are considered labeling under 21 CFR 202.1(1)(2).

With regard to Predef 2X, "The Upham Fresh Cow..." bulletin recommends "because of the product's anti-inflammatory abilities, it should also be included as a fever reducer and given one time to cows that have a fever and are off-feed (look sick)." Under recommendations in "The fresh-cow..." and "The 100 Day Contract", for fresh cows with fever (temperature greater than 103°F) after normal calving or abnormal calving, the materials suggest on "Day 1 of Fever... Predef 2x (10 ML)". The Dialogue 2000 article "The value..." recounts a study, using the 10-day postpartum monitoring program protocol, conducted by Roger Saltman, DVM. The study promotes the use of Predef 2X in cows with a rectal temperature above 103°F. Dr. Saltman, as a dairy technical services specialist with Pharmacia and UpJohn, is considered a representative of your company. As such, your company is responsible for any information he disseminates in the company's name concerning your products.


Predef 2X is approved for use in situations requiring glucocorticoid, anti-inflammatory and/or supportive effect. Non-judicious use of corticosteroids in an animal with a fever of unknown origin could have devastating results. The approved labeling allows for the use in animals **moribund** from overwhelmingly severe infections for which specific antibacterial therapy is available, to aid in correcting the circulatory defect by counteracting the responsible inflammatory changes to permit the antibiotic agent to exert its full effect. There is no approved NADA supplement allowing for use as an anti-pyretic in the approved labeling. Therefore, the above promotional materials are deemed false and misleading, and cause your product to be misbranded under §502(a) of the Act.

Incidentally, upon review of your labeling, we found that the package insert is lacking the prescription legend, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." We recommend this statement be included at the top of the insert above the description at the next printing.

We request that further distribution of this material be discontinued. In addition, we request that you review your company policies to ensure that your promotional materials comply with the requirements of the Federal Food, Drug, and Cosmetic Act and the attendant regulations.

Please inform us of your intentions within 30 days of the receipt date of this letter. Should you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,



Mohammad I. Sharar, DVM, MSc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
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