DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 1 2001

NADA 108-901 (L0336 and L0337)

Thomas R. Schriemer
Manager
Worldwide Animal Health Regulatory Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Schriemer:

We refer to your Drug Experience Report submissions dated December 14, 2000 and January 29, 2001 for LUTALYSE (dinoprost tromethamine) NADA 108-901. The submissions included Veterinary Scope, Volume 4 no. 1 and Dialogue 2000, Volume 9 No. 1, coded V99138.

We have noticed a continuing trend in your company's promotion of extralabel use of products in conjuction with the "100 Day Contract" and associated protocols. In the Dialogue 2000 newsletter distributed by Pharmacia & Upjohn (P&U), Dr. Rodger Saltman, a P&U dairy technical services specialist, conducted a study to test the 10-day postpartum monitoring program. According to the article, this program is a part of the "100 Day Contract". The protocol recommends in cows with "abnormal calvings- twins, dead calves, assisted calvings, milk fever and/or retained placenta – were treated with a combination of ECP® and Lutalyse® Sterile Solution to stimulate uterine cleaning." The Veterinary Scope recommends, on pages 2 and 5, the use of Lutalyse® in cows that have had problem calving, a fever or are off-feed in a two injection treatment regimen.

Lutalyse® has no approved supplemental New Animal Drug Application allowing for the indications enumerated in the above cited promotional materials. The advertising and/or promotion of extralabel uses in animals of approved new animal drugs is a violation of 21 CFR §530.4. These materials cause your product to be adulterated under §501(a)(5) and misbranded under §502(a) of the Act. [Also refer to our letter dated November 21, 2000, addressing similar issue concerning Predef 2x, NADA 11-789]

Pharmacia & Upjohn must immediately discontinue using these and any other similar promotional materials. You are again reminded of the commitment you made when you signed the New Drug Application Form, FDA-356-V, that you will promote your product only in accord with the labeling provided for in the approved application. You are obligated to ensure that your company's promotional practices and the resulting materials comply with the requirements of FDA regulations.

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

Sincerely yours,

/S/

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