

NOV - 6 2000

.NADA 108-901

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

Dear Mr. Schriemer,

We refer to your DER submission dated October 5, 2000, for Lutalyse (dinoprost tromethamine), NADA 108-901. A print advertisement, "The birds. The bees. And LUTALYSE.", was included in the submission. We have reviewed the advertisement and found it to be in violation of the prescription drug advertising regulations [21 CFR 202.1].

The advertisement fails to present a fair balance of information relating to the side effects and contraindications with a prominence, depth, and detail reasonably comparable to the presentation of the information relating to the effectiveness of the drug in the body of the advertisement [21 CFR 202.1(e)(5)(ii)]. The approved official labeling details important risk information associated with the use of Lutalyse, however little of the important risk information appears in the body of the advertisement.

We request that you discontinue the use of this advertisement immediately and in the future devise your promotional materials in accordance with FDA's promotion and advertising regulations.

Please inform us of your intentions within 30 days of the receipt of this letter. If 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
Center for Veterinary Medicine