



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC - 3 1999

NADA 140-890
NADA 141-077

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

Dear Mr. Schriemer:

We have become aware of two advertisements, which appeared in the October 1999 issue of *Beef Magazine*. Specifically, they are: 1) Excenel™, NADA 140-890 entitled "Hospital Pen;" and 3) Adspec™, NADA 141-077 entitled "Beef Quality Is Everyone's Business. We have reviewed the advertisements and find them to be in violation of the prescription drug advertising regulations [21 CFR §202].

The advertisements are deemed violative because they are not fairly balanced. The advertisements make effectiveness claims about treating bovine respiratory disease in the body of the advertisements, yet fail to provide any balance with the risks associated with use of the drugs. [21 CFR §202.1(e)(5)(ii)]. The approved professional labeling includes important risk information associated with use of the drugs, yet none of the important risk information appears in the body. Fair balance is not achieved merely by including a brief summary or approved professional labeling. Additionally, our records do not indicate that the Pharmacia & Upjohn Company submitted the advertisement entitled "Hospital Pen" advertisement on Form FDA 2301 at the time of initial publication, as required [21 CFR §510.300(b)(3)].

We ask that these advertisements and similar promotional material being used or intended to be used in the future be immediately stopped. Please inform us of your intentions within 15 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6639.

Sincerely yours,

Vitolis Vengris, D.V.M., Ph.D.
Marketed Product Scientific and
Regulatory Review, Team 1, HFV-214
Division of Surveillance
Center for Veterinary Medicine