DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 13 2000

Food and Drug Administration
Rockville MD 20857

NADA 055-028

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

Dear Mr. Schriemer:

We refer to your special DER submission dated August 2, 2000, for Quartermaster® (Dihydrostreptomycin-Penicillin) Suspension, NADA 055-028. The submission included a promotional item "The Milk Memo" Vol. 5, No. 2 which is considered labeling under 21 CFR 202.1(l)(2).

The promotional item contained a statement "Pharmacia & Upjohn offers two products that play a key role in mastitis management to control environmental **strep** outbreaks during the dry period" which is deemed an unapproved claim for Quartermaster® Suspension. The Quartermaster Suspension is approved for intramammary use to reduce the frequency of existing infection and to prevent new infections with **Staphylococcus aureus** in dry cows. The Milk Memo, therefore causes your product to be adulterated under section 501(a)(5) and misbranded under 502(f)(1) of the Act.

We remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356 V, that you will promote your product only in accord with the labeling provided for in the approved application. We request that you discontinue using this promotional item immediately. In addition, we suggest that you give due consideration and attention to your company's promotional practices and ensure that your promotional materials comply with the requirements of FDA Act and the attendant regulations.

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

Sincerely yours,

Mohammad I. Sharar, DVM., M.Sc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine