DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 11 2001

NADA 065-140

Ms. Stacy Scheidle
Regulatory Affairs Associate
Alpharma Animal Health
One Executive Drive
Fort Lee, NJ 07024
USA

Dear Ms. Scheidle,

This is in reference to your submission for Annual Drug Experience Report dated August 17, 2000, concerning Tetracycline, NADA 065-140.

The submission includes a promotional labeling piece from [redacted] for [redacted]. Our files indicate that we do not have a distributor statement on file for [redacted]. Please submit this distributor statement immediately.

In addition, the promotional item referenced above includes "hexamitiasis" among the indications for use. According to the approved labeling Hexamitiasis is not an approved indication for your product.

Unapproved claims, recommendations, or suggestions in labeling causes your product to be misbranded and /or adulterated under the Federal Food, Drug, and Cosmetic Act. We request you to cease distribution of the promotional item immediately. We remind you of the commitment you made when you signed the new animal drug application (NADA) Form FDA-356 stating that labeling and advertising would prescribe, recommend, or suggest product usage only under the conditions stated in the labeling which is part of the application.

We expect to receive your response within 15 days of receipt of this letter. If you have any questions, you may contact Dr. Thomas Moskal at (301) 827-2722.

Sincerely yours,

/S/

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