

May 21, 1998

Ms. Rosalind S. Dunn
Director, Regulatory Affairs
Merial Ltd.
2100 Ronson Road
Iselin, NJ 08830-3077

Dear Ms. Dunn:

We refer to your promotional material for Zimecterin Paste (Ivermectin), NADA 134-314. The advertisements from Horseplay Magazine are titled "Powerful. Dependable," " Exceptional. Irreplaceable" and those which appeared in Horseman Magazine are captioned "Protect your horse from encysted cyathostomes. Kill them before they encyst."

The first promotional material makes claims that " It (Zimecterin) kills encysted larvae as they exist from the intestinal mucosa," while the latter advertisement claims that "Zimecterin kills small strongyle (cyathostome) larvae before they encyst, before they have a chance to damage the horse."

The promoted therapies against encysted cyathostomes are false or misleading. Therefore, the advertisement causes your product to be misbranded under 502(a) of the Federal Food, drug, and cosmetic Act as amended.

We request that you immediately discontinue using these advertisements and in the future promote your product only in accord with the approved labeling. We remind you of the commitment you made when you signed the new animal drug application(NADA) Form FDA-356 that the labeling and advertising would neither be false nor misleading in any particular.

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

Sincerely yours,



Mohammad I. Sharar, DVM, M. Sc.
Team Leader, Division of Epidemiology
& Surveillance.