DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV - 6 2000

NADA 95-735

Katherine M. Ehrenfried
Regulatory Associate
Elanco Animal Health
2001 W. Main Street, DC GL21
Greenfield, IN 46140

Dear Ms. Ehrenfried:

We have received and reviewed a series of [ ] Marketing Research Surveys [ ] which were conducted for and distributed by Elanco Animal Heath. These surveys are directed at the dairy industry relating to the use of Rumensin (monensin) NADA 95-735, for use in lactating dairy cattle. We consider the surveys to be promotional labeling that make unapproved claims for use of Rumensin in lactating dairy cattle to increase milk production, reduce acidosis, improve body condition, increase feed efficiency, reduce ketosis, may reduce the incidence of Johne's disease, and reduces days open. The surveys provide a dose of 24 ppm to increase milk production and feed efficiency.

Rumensin (monensin) for animal use is a new animal drug as defined by Section 201(v) of the Federal Food, Drug, and Cosmetic Act (the Act). There is no approved New Animal Drug Application (NADA) on file for use of this product in lactating dairy cattle. Advertisement or promotion of this new animal drug for the unapproved uses noted above causes the drug to be misbranded under Section 502(f)(1) of the Act in that the product is intended for use in lactating dairy animals but fails to bear adequate directions for that use. Adequate directions for use cannot be written because no one knows what adequate directions might be since there is no approved NADA on file for this use.

[ ] you have violated the "Applicant's Commitment" as stipulated under Title 21, Code of Federal Regulations, Part 514.1(b)(11), and the commitment you made when you signed the New Animal Drug Application, Form FDA-356V, that you will promote your product only in accordance with the labeling provided for in the approved application.

We request that you immediately discontinue using these survey materials in promoting your product for conditions of use that are still under investigation. Please inform us of your intentions as soon as possible or in any event within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

[redacted]

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

cc:
Eric M. Nelson
Feed Program Manager
Bureau of Ag-Chem Management
Department of Agriculture
Trade and Consumer Protection
2811 Agriculture Drive
Madison, WI 53718-6777