

MAR 14 2001

Food and Drug Administration
Rockville MD 20857

NADA 141-101

Ms. Lori A. Spatola
Regulatory Associate
MS Bioscience
3698 Kinsman Blvd.
Madison, WI 53704

Dear Ms. Spatola:

We refer to your November 7, 2000 submission of a promotional letter for the competitive exclusion product PREEMPT™, NADA 141-101. In your cover letter you state that the promotional letter was sent to customers on or about November 1, 2000. The promotional letter sent is classified as promotional labeling for the product. You were previously notified by our letter dated May 26, 1998, written in response to your April 7, 1998 submission of promotional materials, of our objections to your use of unapproved claims for promotion of this product.

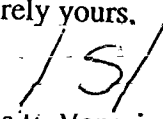
Your current promotional piece contains a number of objectionable claims, for example:

- "PREEMPT rapidly colonizes and establishes a healthy gut flora."
- "A healthy gut flora has been shown to exclude salmonella and other pathogenic bacteria..."
- "In addition to providing your poultry flocks with natural disease resistance against salmonella..."
- "...improve the growth and production characteristics of your flock."

The approved claim for your product is "**for the early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization**", and only this benefit is acceptable for use in promotional and advertising materials.

Unapproved and misleading statements must not be used in promotional materials. We request you to cease distribution of the promotional letter 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 be neither false nor misleading in any particular. 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,


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