

Food and Drug Administration
Rockville MD 20857

February 20, 1998

• **NADA 141-101**

Elizabeth D. Dunlap, Ph.D.
Regulatory Manager
Bioscience
Division of Milk Specialties
P.O. Box 278
Dundee, IL 60118

Re: PREEMPT

Dear Dr. Dunlap:

We have recently been made aware of information included in the January/February 1998 issue of *Poultry & Egg Marketing*, product information in the December 29, 1997, issue of *Poultry Times*, as well as materials that were made available at your booth at the International Poultry Exposition in Atlanta from January 21-23, 1998.

The materials in the two publications, which are U.S.-based publications, provide information referring to the efficacy of the above product:

PREEMPT is a defined competitive exclusion culture, specifically formulated to reduce both the incidence and severity of salmonella colonization in chickens. When sprayed on day-old chicks and ingested, its patented formula rapidly establishes healthy mature gut flora, preventing salmonella from colonizing the ceca."

This information appears in both publications.

The materials made available at the Poultry Expo appear to be labeling reproductions and include graphs, charts and other materials that refer to the efficacy of the product for control of salmonella in poultry.

Taken as a whole or in parts, this material constitutes pre-approval promotion of a product that does not have an approved New Animal Drug Application (NADA) at this time. This type of promotional activity is expressly prohibited in 21 Code of Federal Regulations, Part 511, New Animal Drugs for Investigational Use, Section 511.1(b)(8)(iv), which states that investigational animal drugs are exempt from the

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adulteration provisions of the Food, Drug and Cosmetic Act as long as the sponsor, among other actions, *"Shall not, nor shall any person acting for or on behalf of the sponsor, represent that the new animal drug is safe or effective for the purposes for which it is under investigation. This requirement is not intended to restrict the full exchange of scientific information."*

This situation does not, in our view, fall under the scientific information exchange provision of the above regulation.

You should cease any further pre-approval promotion of this product in U.S.-based publications and at U.S.-based meetings. Additional violations of these regulations could jeopardize the pending approval of the product.

Please inform us of your intentions as soon as possible. If you have any questions, feel free to call us at (301) 827-6642. Please note our new telephone number for our Division in your records.

Sincerely yours,



William C. Keller, DVM
Director, Division of Epidemiology
and Surveillance
Center for Veterinary Medicine