



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 10 2002

NADA 141-099

Ann Hokinson
Assistant Manager
Pharmaceutical Regulatory Affairs
Fort Dodge Animal Health Division of American Home Products
P.O. Box 518
Fort Dodge, IA 50501

Dear Ms. Hokinson:

We refer to the promotional piece, FDP #2128, entitled "STOP: The Direction of Parasite Control Has Changed Forever. GUARANTEED" for Cydectin Pour-On for Cattle (moxidectin), NADA 141-099. The piece in question was distributed at the Bovine Practitioners Meeting in Frederick, Maryland, on April 4 and April 5, 2002, and is deemed to be labeling. 21 CFR 202.1 (1)(2). We have the following concerns with the material:

- * The use of the word "New" throughout the piece in statements such as: "New Cydectin Pour-On Has The New Chemistry That Changes Everything" and "The New Cydectin Rainfast Formulation Puts You In Charge" is potentially false and misleading under 502 (a) of the Federal Food, Drug, and Cosmetic Act. We are unaware of any changes to the original formulation that was approved in 1998 to support such claims.
- * We consider the 100 day guarantee for protection against disease caused by gastrointestinal roundworms or lungworms and the 180 day guarantee for control of 4 species of biting and sucking lice to be above and beyond the scope of the currently approved label. According to the label, the activity of Cydectin has not been demonstrated longer than 42 days for lungworms and 28 days for roundworms. Persistent activity for control of lice beyond the initial treatment is unsubstantiated as well.

As you may recall, we have previously addressed the guarantee issue in our teleconference on October 19, 1999. It is disappointing that your firm continues to promote this product guarantee in a false and misleading manner. We again wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA 356V, that you will promote your product only in accord with the labeling provided in the currently approved application. We request that you immediately cease distribution of the piece in question and destroy any and all materials purporting such unsubstantiated guarantee claims.

Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt date of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours

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