

DEPARTMENT OF HEALTH & HUMAN SERVICES

From: NOV - from file
4-21-00

DER 141-084

Food and Drug Administration
Rockville MD 20857

MAR 15 2000

NADA 141-084

Sharon M. Redman, DVM
Regulatory Affairs Manager
Novartis Animal Health, US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

Dear Dr. Redman:

We refer to your Drug Experience Report dated February 14, 2000, and the subsequent submission dated February 17, 2000, for Sentinel (Milbemycin oxime and Lufenuron) Tablets, NADA 141-084.

The submission includes the Trade Ad titled "Do you want protection with questions? --- or unquestionable protection" (SFT200001A). You stated that due to an error in the internal process, this ad was released on January 14, 2000, but was not submitted to the FDA at the time of initial dissemination/publication. Please note that this action is in violation of 21 CFR 510.300(b)(3), although we appreciate your acknowledgment of the violation. We note that you are instituting further controls to assure compliance with regulations.

Furthermore, we find the promotional piece objectionable. The statements that "SENTINEL Flavor Tabs provide 100% heartworm protection that can't wash out or rub off and leaves no pesticide residue." are misleading and inappropriately compare this oral product with a topical product. A 100% effectiveness claim for SENTINEL as a heartworm preventive has not been demonstrated by substantial evidence or substantial clinical experience. Statements such as "Quarantine" "pesticide residues" and "misapplication" are inappropriate product description terms that suggest that your product is safer than others without substantial evidence or clinical experience. Thus, the promotional piece is in violation of 21CFR 202.1(e)(6)(i)&(ii).

We, therefore, ask that further dissemination of this promotional piece and other similar material being used or intended to be used in the future be stopped. We will appreciate your cooperation in this regard.

Please inform us of your intentions within 15 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Mukund Parkhie, DVM, Ph. D.
Acting Team Leader
Marketed Product Scientific and
Regulatory Review Team II, HFV-216
Division of Surveillance
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