

March 18, 1998

NADA 141-084

John Paige III, Ph.D.
Regulatory Affairs Manager
Novartis Animal Health, U.S., Inc.
1500 Pinecroft Road, Suite 400
Greensboro, NC 27407

Dear Dr. Paige:

This is in reference to your submission dated February 20, 1998, concerning your approved product, Sentinel (milbemycin and lufenuron), NADA 141-084. The submission includes Video Tape on Direct To Consumer (DTC) TV ad titled "Dog Fears."

We have reviewed the tape and find it to be violative of the prescription drug advertising regulations, 21 CFR part 202.1(e)(1) in that the ad fails to include the required information relating to the major side effects of the drug product provided in the approved labeling. This information is required to be included in the audio or audio and visual portion of the ad.

We wish to remind you of the commitment you made when you signed the new animal drug application, Form 356-V, that you will promote and advertise your product only in accord with the approved labeling and that it would be neither false nor misleading in any particular.

We ask that you IMMEDIATELY discontinue distribution of this violative video tape and also pull all future scheduled broadcasting of this ad from TV. Your cooperation in this matter will be highly appreciated.

Sincerely yours,



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