



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JAN 02 2002

NADA 140-971  
NADA 141-078

Rosalind S. Dunn  
Director, Regulatory Affairs  
Merial Ltd.  
2100 Ronson Rd  
Iselin, NJ 08830

Dear Ms. Dunn:

We refer to several of your promotional pieces for Heartgard Plus for Dogs, NADA 140-971, and Heartgard for Cats, NADA 141-078 that have come to our attention. Specifically, the two promotional pieces in question for Heartgard Plus are: "Protect Your DOG from HEARTWORM DISEASE" a brochure coded "HGD-9-1992-DBK" and an animal print Surgical Scrub top. These items are allegedly being distributed to Veterinarians and deemed to be promotional labeling as defined under 21 CFR 202.1(l)(2). We note the following deficiencies in both the pieces:

- Both pieces fail to display the generic name of the product in letters that are at least half as large as the letters comprising the trade name (21 CFR 201.10(g)(2)).
- The backside of the brochure contains product claims for Heartgard for Cats but does not include full disclosure information, i.e., the product insert information for cats. The brochure also fails to provide the risk/benefit information in the text of the promotional piece in the same language and emphasis as provided for in the approved labeling (21 CFR 201.105(d)(1)).
- The surgical scrub top is considered to be promotional labeling due to the "100% protected from heartworm disease with Heartgard Plus" efficacy claim. Therefore, full disclosure information should have been provided with the material (21 CFR 201.105(d)(1)).

We request that you stop using these violative promotional pieces immediately and in the future promote your products in a manner that is consistent with the promotion and advertising regulations. Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM., M.Sc.  
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and Regulatory Review Team II, HFV-216  
Division of Surveillance  
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