



NOV 30 2001

Food and Drug Administration  
Rockville MD 20857

NADA 141-189

Dr. Andrew Palmeter, DVM  
Associate Director, Regulatory Affairs  
Fort Dodge Animal Health  
P.O. Box 5366  
Princeton, NJ 08543-5366

Dear Dr. Palmeter:

We refer to the promotional piece for your product - Proheart 6 (NADA 141-189), entitled "THE HEARTWORM PREVENTION YOU CONTROL" produced by [redacted] CVM has reviewed the promotional piece as part of its routine monitoring and surveillance program. The detailer piece is distributed to veterinarians by your distributor - Midwest Veterinary Supply, Inc. The promotional piece is deemed labeling under 21 CFR 202.1(l)(2).

We note that the promotional piece includes product claims and dosing information but fails to provide full prescribing information as required by 21 CFR 201.105(d).

We request that you have [redacted] cease distribution of the violative promotional labeling piece immediately and destroy all the remaining copies. Please respond 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)827-4462.

Sincerely yours,

[redacted]  
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