



DEC 17 1999

NADA 121-473

John J. Lauber, PhD
Manager, Product Registration
Hoechst Roussel Vet
Independence Blvd.
P.O. Box 4915
Warren, NJ 07059

Dear Dr. Lauber,

We have become aware of an advertisement which appeared in the August 1999 issue of *Veterinary Technician Magazine* (page 420) for Panacur, fenbendazole (NADA 121-473).

The advertisement fails to present a fair balance of information relating to side effects and contraindications with a prominence, depth, and detail reasonably comparable with the presentation of information relating to the effectiveness of the drug in the body of the advertisements [21 CFR §202.1(e)(5)(ii)]. The ad leaves the impression that only Panacur is 100% effective, economical and specific for whips, hooks and ascarids. The brief summary is located 44 pages away from the advertisement on page 464. The brief summary should appear on the same page as the advertisement or at the most within one turn of a page either preceding or following the advertisement.

We request that you review your company policies to give due consideration and attention to promotional practices and ensure that your promotional materials comply with the requirements of FDA regulations.

Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6639.

Sincerely yours,

Mohammad I. Sharar, DVM, MSc.
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine