DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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ANADA 200-338 (L-0129)

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Regulatory Affairs Associate/Animal Testing
Heska Corporation
2538 SE 43rd Street
Des Moines, Iowa 50327

Nancy Thompson-Brown
Senior Regulatory Compliance Specialist
Schering-Plough Animal Health Corporation
1095 Morris Avenue
Union, NJ 07083-1982

RE: ANADA 200-338 Tri-Heart® Plus (ivermectin/pyrantel); promotional labeling piece: spah-thp-27R2

Dear Dr. Porter and Ms. Thompson-Brown:

The Center for Veterinary Medicine (CVM) has reviewed a mailer piece produced by the Heska Corporation's marketing partner, Schering Plough Animal Health, entitled "The most Comprehensive Guarantee in Heartworm Prevention" (spah-thp-27R2) for Tri-Heart® Plus (ivermectin/pyrantel). The piece was submitted to CVM in a special Drug Experience Report (DER) on August 30, 2006, and also sent directly by mail accompanied by a letter dated November 10, 2006, to veterinarians that practice in the United States. The promotional piece is misleading because it presents an unsubstantiated claim regarding Tri-Heart Plus, misbranding the drug under sections 502(n) and 201(n) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 352(n) and 321(n)] and FDA implementing regulations, 21 CFR 202.1(e)(6)(i).

Background

Tri-Heart® Plus is an oral antiparasitic medication for use in dogs indicated for prevention of heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of ascarids (*Toxocara canis, Toxocara leonina*) and hookworms (*Ancylostoma caninum, Uncinaria stenocephala, Ancylostoma braziliense*).

Unsubstantiated Claim of Effectiveness

In the section entitled "Our Guarantee Covers," this promotional piece states "Tri-Heart® Plus is not registered for removal and control of whipworms, but if you prescribe Tri-Heart® Plus to a whipworm negative dog and the animal is diagnosed with whipworms within the Tri-Heart® Plus use period, our guarantee will cover the cost of a remedial treatment." The piece later describes patient eligibility for the guarantee: "Dog must be whipworm negative prior to starting on monthly Tri-Heart® Plus prevention. If dog is diagnosed whipworm positive during the Tri-Heart® Plus use period, guarantee will be activated."

The above statements suggest that Tri-Heart® Plus is effective for the prevention, removal, and/or control of whipworm, indications that are not permitted under the product's approved labeling. Calling the coverage part of the "Tri-Heart® Plus Guarantee" implies that you are giving assurances about Tri-Heart® Plus. This is reinforced by the fact that the promotional materials do not mention that the product has not been shown to be effective for whipworms. The coverage guarantee includes the qualification that the product is not "registered" for removal and control of whipworms. New animal drugs, however, are approved, not registered, as being safe and effective for particular indications of use. The implication of not being registered seems to be that the product has not been listed as part of some formal index rather than that the product has not been shown to be safe and effective.

By suggesting that the product is effective for the prevention, removal, and/or control of whipworms, the above statements overstate the demonstrated effectiveness of Tri-Heart Plus. CVM is not aware of substantial evidence to support this claim. If you have supporting data, please submit it to FDA for review.

Conclusion and Requested Action

The promotional piece is misleading in that it overstates the effectiveness of Tri-Heart® Plus. Accordingly, the drug is misbranded under sections 502(n) and 201(n) of the Act and FDA implementing regulations at 21 CFR 202.1(e)(6)(i).

The Division of Surveillance requests that Schering Plough Animal Health immediately cease the dissemination of the Tri-Heart® Plus promotional piece described above. Please submit a written response within 30 days of receipt of this letter describing your intent to comply with this request. Please direct your response to me at the Food and Drug Administration, Division of Surveillance, HFV-216, 7519 Standish Place, Rockville, MD 20855. When responding to our request, please make reference to our letter by the date and file number shown at the top of this letter.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to see that your promotional materials for Tri-Heart® Plus, as well as for your other sponsored products, comply with the requirements of the Act and the FDA

implementing regulations. If you have any questions, you may contact us at (240) 276-9066.

Sincerely yours,

Arnel B. Peralta, DVM
Acting Team Leader, Post-Approval
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