DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 13, 2004

Important Drug Information about ProHeart® 6

Dear Doctor:

FDA has requested that Fort Dodge Animal Health, Inc., recall **ProHeart® 6** (moxidectin) Sustained Release Injectable for Dogs to the veterinarian. Since the product was approved in June 2001, the FDA Center for Veterinary Medicine (CVM) has received over 5,000 reports of adverse reactions suspected of being associated with ProHeart® 6. Many of the reports received have involved serious, life-threatening adverse events, such as anaphylaxis, convulsions, hematopoetic disorders, and hepatopathies, followed in some cases by death. FDA has also evaluated a number of adverse drug reports associated with ProHeart® 6 that include neurologic problems and unusual cardiac signs.

Due to the seriousness of these reports, we advise you to discontinue administration of ProHeart® 6 until further notice. Pet owners should be advised on appropriate alternative heartworm preventatives for their dogs.

At FDA's request, the product sponsor has also made three label revisions, added a Client Information Sheet, and issued two "Dear Doctor" letters since approval to advise veterinarians and pet owners of the risks associated with use of the product. Despite these label changes and educational efforts, FDA is still receiving an unacceptable number of unexplained adverse event reports. FDA's concern is based on voluntary self-reporting to FDA by veterinarians and owners whose dogs have suffered adverse drug experiences (ADEs) to ProHeart®6 as well as the mandatory reporting of adverse events by Fort Dodge Animal Health. The actual incidence of adverse events is likely to be even higher than reported, because studies show that only a fraction of actual adverse reactions are reported. FDA is requesting that Fort Dodge Animal Health conduct research to determine the cause of the adverse reactions and develop a strategy to help prevent such problems before the product is marketed again.

We consistently encourage veterinarians to report adverse events through the product sponsor. Sponsors are then obligated to submit their reports to CVM. Adverse events may also be reported directly to CVM by submission of Form 1932a (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-1932a.pdf) or by use of our hotline: 1-888-FDA-VETS. Adverse events for veterinary patients submitted to the FDA are routinely updated on the CVM web site (http://www.fda.gov/cvm/index/ade/ADEReport.htm).

We will continue to serve veterinarians and their clients by providing updated, accurate, and unbiased information with respect to the safe and effective use of veterinary pharmaceuticals.

Sincerely,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine