Drs. Foster & Smith Educational Staff

September 2004 News
Fort Dodge Animal Health, of Overland Park, Kansas, at the Food and Drug Administration's (FDA) request, has agreed to immediately cease production and recall its heartworm medication ProHeart® 6 from the market until the FDA's concerns about adverse reaction reports associated with the product can be resolved. FDA is requesting that the firm continue to conduct research to determine the cause of related adverse reactions and develop a strategy to help prevent such problems in the future before the product is marketed again. The FDA will convene an independent scientific advisory committee to thoroughly evaluate all available data.

ProHeart® 6 is an approved injectable sustained-release heartworm prevention product for dogs. Heartworm disease is a serious and potentially fatal condition of dogs, cats, and other species of mammals. The parasite that causes heartworm disease is transmitted through the bite of a mosquito.

FDA is also advising veterinarians to avoid administering this product to dogs until further notice. Pet owners should consult their veterinarians regarding their pet's health care needs.

Since the product was approved in June 2001, Fort Dodge Animal Health has cooperated with FDA to investigate numerous adverse event reports. As a result, Fort Dodge has voluntarily changed the label to include post approval safety information including rare reports of death and a caution to practitioners that dogs should have a negative test for heartworm before administration.

Despite these label changes, FDA is still receiving unexplained adverse event reports, some of them severe. 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 (which contains the drug moxidectin) as well as the mandatory reporting of adverse events by Fort Dodge Animal Health.

Fort Dodge Animal Health has agreed to recall any product that has already been distributed to veterinarians.

As of August 4, 2004, FDA's Center for Veterinary Medicine (CVM) had received 5,552 adverse event reports for ProHeart® 6. The actual number of adverse events is likely even higher because studies show that only a fraction of actual ADEs are reported.

The Agency has observed an increase in the number of cases associated with liver and bleeding abnormalities followed in some cases by death.

While Fort Dodge Animal Health is cooperating with FDA's request for a recall, the company has concerns about how the FDA interpreted the complex data. As such, Fort Dodge supports the review process, and has indicated it will work closely with FDA to provide any necessary information for the panel. Spokespeople for Fort Dodge say the company remains confident in the safety and efficacy of ProHeart® 6 based on an evaluation of FDA's data and consultation with independent experts in veterinary medicine and epidemiology.

Fort Dodge wants to point out to consumers that potential adverse events reported to the FDA are "unfiltered," meaning all reported potential events are submitted without regard to cause, and cases subsequently determined not to be related to the product are still included in the overall reporting numbers. Fort Dodge says an evaluation of the data indicates that the incidence of disease and death seen with the use of ProHeart® 6 is at or below the baseline (the normal number that would be expected) for the U.S. canine population. Specifically:

- The overall incidence of adverse events represent less than one half of one percent of the more than 18 million doses that have been sold to veterinarians.
- For hematologic and autoimmune signs, the incidence rate is one in 31,000 doses, well below the baseline for the U.S. canine population.
- The average age for liver signs in ProHeart® 6 reports is within the range reported in the general canine population.