

## Dog Heartworm Drug to Relaunch With Conditions

**The FDA encourages vets and dog owners to report any possible adverse reactions to ProHeart 6.**

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Fort Dodge Animal Health will be reintroducing its heartworm preventive ProHeart 6 (moxidectin) Sustained Release Injectable for Dogs to the U.S. market under a post-marketing surveillance, restricted distribution and risk minimization program patterned after similar programs for human medications — a first for a veterinary medication.

Under the program, veterinarians wishing to purchase ProHeart 6 must participate in an online training program with Fort Dodge and communicate the product's risks and benefits with pet owners, as well as provide pet owners with a Client Information Sheet and obtain a signed "informed consent" form, before administering the product.

In addition, the product's label has been revised to warn against administering the drug within one month of vaccinations and to use the product with caution in dogs with pre-existing allergies or allergic diseases, including food allergies, allergic hypersensitivity, and flea allergy dermatitis. It also warns against administering the drug to dogs who are sick, debilitated, underweight, or who have a history of weight loss.

"This is the first veterinary drug to be marketed under a risk minimization and restricted distribution program," said Bernadette Dunham, DVM, Ph.D., director of the FDA's Center for Veterinary Medicine, noting numerous human medications had been marketed under similar programs. "While we concur with the limited return of ProHeart 6 to the U.S. market, we strongly encourage veterinarians and pet owners to report any possible adverse reactions."

The program's requirements will allow Fort Dodge to gather additional product data and better communicate any issues with the FDA and veterinarians. Fort Dodge voluntarily withdrew the product from the U.S. market in 2004, in response to FDA concerns regarding adverse reactions, including loss of appetite, lethargy, vomiting, seizures, difficulty walking, convulsions, jaundice, allergies, and some deaths, reported with, but not necessarily caused by, the use of the product.

The product is the longest-lasting (six months) preventive on the market, and Fort Dodge believes it is a valuable tool to ensure compliance with veterinary recommendations for year-round heartworm prevention. Other products include monthly and daily medications, which can be missed, thereby leaving a dog vulnerable to heartworm infection.

The American Heartworm Society reported that 250,000 pets were infected with heartworm in 2004, up 5 percent from 2001 figures, according to Fort Dodge. Heartworm is a potentially fatal disease for dogs that is transmitted through the bite of an infected mosquito.

Fort Dodge reformulated the product in 2002 to decrease "residues of the solvents used in the manufacture of ProHeart 6." Those residues were suspected of possibly causing allergic reactions.

"Few adverse events have been reported with this reformulated product," the FDA reported, noting that it has been available in international markets.

ProHeart 6 holds a 51 percent market share in Australia and a 42 percent market share in Italy, according to Rami Cobb, BVSc (Hons), MACVSc, Fort Dodge's senior vice president of pharmaceutical research and development. Cobb said the number of adverse events reported, and not necessarily associated, with ProHeart 6 dropped from "rare" (two-three dogs per 10,000 doses) to "very rare" (one dog per 10,000 doses) after the reformulation.