

FDA recalls popular heartworm drug for dogs

Medicine linked to thousands of injuries, deaths

Advertise

Jump to discuss comments below

Below: Discuss Related

AP Associated Press

updated 9/15/2004 10:51:17 AM ET

Print | Font: + -

WASHINGTON — ProHeart 6, a twice-a-year time-released heartworm medication used to treat millions of dogs, was recalled Friday at the request of the Food and Drug Administration after thousands of animals suffered adverse reactions.

ProHeart 6 was the first, and only, product approved by the FDA to be administered once every six months to treat heartworm disease in dogs. Its active ingredient, moxidectin, has been administered without problem to horses and cattle.

The time-released version caused few problems when given to dogs at higher doses in clinical trials. Health and safety problems quickly cropped up, however, when ProHeart 6 was used to treat dogs after receiving FDA approval.

Reports of injuries, deaths

As of Aug. 4, the drug agency received 5,552 reports of adverse reactions after dogs received heartworm shots. About 500 dogs died, though the agency said many deaths were not directly attributable to the product, manufactured by Fort Dodge Animal Health, based in Overland Park, Kan., a subsidiary of the pharmaceutical company Wyeth.

Some dog deaths were linked convincingly to the heartworm medication, which prompted the recall, said Stephen F. Sundlof, director of the FDA's Center for Veterinary Medicine.

Dog owners were urged to consult veterinarians about other medications to prevent heartworm.

The agency had already asked Fort Dodge to revise the drug's label and to issue notices to veterinarians and dog owners pointing out safety questions associated with the product.

"Despite all of the things that have been done, we continue to see these adverse events at approximately the same rate,"

Don't miss these Health stories

More women opting for preventive mastectomy - but should they be?



Splash News

Rates of women who are opting for preventive mastectomies, such as Angeline Jolie, have increased by an estimated 50 percent in recent years, experts say. But many doctors are puzzled because the operation doesn't carry a 100 percent guarantee, it's major surgery -- and women have other options, from a once-a-day pill to careful monitoring.

[Larry Page's damaged vocal cords: Treatment comes with trade-offs](#)

[Report questioning salt guidelines riles heart experts](#)

[CDC: 2012 was deadliest year for West Nile in US](#)

[What stresses moms most? Themselves, survey says](#)

Advertise

Sundlof told reporters late Friday.

The problems suffered by dogs include sudden lethargy, uncontrolled bleeding, vomiting, diarrhea, heart and liver problems and such nervous system abnormalities as seizures.

Problems affect dogs of all sizes, ages

“We don’t really understand why this product is causing these problems,” Sundlof said. “It affects dogs of all sizes and, apparently, dogs of all ages.”

Fort Dodge Animal Health is cooperating with FDA’s request for a recall but has “concerns about how the agency interpreted these complex data,” the animal health product manufacturer said in a prepared statement. “Based on a thorough evaluation of FDA’s data and consultation with independent experts in veterinary medicine and epidemiology, Fort Dodge Animal Health stands behind ProHeart 6.”

The FDA will convene an independent scientific advisory committee to review the matter.

Heartworm disease is caused by a parasite transmitted to dogs via mosquito bite. Roughly 250,000 dogs develop the potentially fatal ailment per year. Fort Dodge Animal Health said it has sold 18 million doses of ProHeart 6 to veterinarians since FDA approval in June 2001.