

FDA to Revisit ProHeart6 for Dogs

Committee will discuss heartworm preventive that was recalled in 2004 for safety concerns.

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The next meeting of the U.S. Food and Drug Administration's Veterinary Medicine Advisory Committee will discuss the current Risk Minimization Act Plan for ProHeart 6. The discussion, which takes place March 24, 2010 at the Rockville Hilton in Rockville, Md., will be based on data gathered during the first 18 months of marketing the heartworm preventive under a RiskMAP.

The goal of this RiskMAP strategy is to manage the re-introduction of ProHeart 6 to ensure safe, appropriate use to achieve the maximum benefits of heartworm protection, while minimizing risk to dogs. Fort Dodge Animal Health voluntarily recalled ProHeart 6 in September 2004 to address the FDA's Center for Veterinary Medicine's safety concerns about the product.

CVM will present the results of the FDA's analysis of 18 months of information collected under the RiskMAP, and also will seek feedback from a panel of experts. The meeting is open to the public and interested persons may present oral or written data, information or views on the issues pending before the committee.

Written statements may be sent to Aleta Sindelar, CVM, (HFV-3), FDA, 7519 Standish Place, Rockville, MD 20855 by March 17. Oral presentations from the public are set from 1 to 2 p.m. on March 24. Interested persons must notify Sindelar by March 9.

Time allotted for each oral report may be limited. Individuals are required to submit a brief statement of the general nature of the evidence or arguments they would like to make, the names and addresses of proposed participants, as well as an indication of an estimated time requested to present their case.

Notifications regarding requests to speak will be made by the contact person March 10. The meeting has been scheduled from 8:30 a.m. to 5 p.m.