United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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M E M O R A N D U M

TO: Reporters and Editors
RE: ProHeart 6 back on the market with FDA approval
DA: Thursday, June 5, 2008

Senator Chuck Grassley, Ranking Member of the Committee on Finance, today asked the Food and Drug Administration Commissioner to report on how the agency decided that ProHeart 6, a heartworm medication for dogs, is safe to put back on the market after the drug maker pulled it from the market in September 2004.

Senator Grassley said his inquiry is based on information he has received that some FDA safety officers were left out of internal agency discussions about the safety of ProHeart 6.

Today's request is a continuation of oversight by Senator Grassley of the FDA's actions with this drug. A February 6, 2008 Grassley letter
finance.senate.gov/press/Gpress/2008/prg020608.pdf
to the Commissioner detailed Senator Grassley's findings regarding the FDA's removal of the safety officer who raised questions about ProHeart 6 and that removal being tied to the drug maker hiring a private investigator to try to discredit the safety officer. The FDA hasn't yet replied to Senator Grassley's February letter. The text of today's letter follows here.

June 5, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

I recently learned that the canine heartworm drug, ProHeart 6 will be returning to the market. The drug, as you know, was withdrawn by Wyeth Pharmaceuticals in September 2004 due to safety concerns.

Based on documents we received, I learned that FDA has held over 18 meetings and 85 phone calls to discuss ProHeart 6 since it was withdrawn. I understand further that the first meeting to discuss bringing the drug back onto the market happened on or about January 31, 2005. However, I do not know if any of these numerous discussions involved FDA safety officials. I have also learned that FDA may be relying on safety studies for ProHeart 6 that were performed with guinea pigs.

In light of my interest in this matter, I am requesting that the Food and Drug Administration (FDA or Agency) provide me with an update on ProHeart 6.

In addition, I would like to remind you that FDA's response to my letter dated February 6, 2008, regarding ProHeart 6 and Dr. Victoria Hampshire is almost four months past the requested deadline. I expect to hear from you immediately on the status of the Agency's response.

Also, I would appreciate receiving responses to the following questions by no later than June 19, 2008:

1. Were any FDA safety officers involved in any of the 18 meetings and/or 85 telephone calls regarding the safety of ProHeart 6 and the potential return of the drug to the market? If so, please identify those safety officials, the dates of the meeting/telephone calls and describe the extent of the discussion. If not, please explain why the safety officers were not present for discussions.

2. Please also include copies of all agendas and minutes for meetings and teleconference calls between FDA and Wyeth/Fort Dodge regarding ProHeart 6 since the drug's removal in September 2004.

3. Since the Veterinary Medicine Advisory Committee meeting in January of 2005, what studies were conducted by and/or on behalf of Wyeth/Fort Dodge in support of the return of ProHeart 6 to the market?

What types of studies and how many studies were conducted? We understand that one of the primary studies involved guinea pigs not dogs. Therefore please identify all studies conducted with dogs in the newly reformulated heartworm medication.

What animals and how many animals were included in those studies?

What were the findings of the studies?

Were all of the proposed studies shared with and discussed by the ProHeart 6 working group before they began?

Did any individuals in the ProHeart 6 working group express any concerns and/or objections with regard to the design of the studies and/or the conclusions reached by Wyeth/Fort Dodge? If yes, please provide pertinent names, documents, and communications.

Were any immunology studies conducted? If so, which veterinary immunologists within and outside of FDA were consulted by CVM and when were they consulted? If yes, please provide pertinent names, documents, and communications. And if not, why not?

4. Please describe, in detail, any risk mitigation strategy for safety that FDA may have proposed for ProHeart 6. Did FDA present this strategy to a Veterinary Medicine Advisory Committee?

5. Please provide any documents or communications related to any Advisory Board meeting held to discuss among other things bringing ProHeart 6 back onto the market. If there was no Advisory Board meeting, please explain why one was not convened.

Thank you in advance for your assistance.

Sincerely,

Chuck Grassley
United States Senator
Ranking Member of the Committee on Finance