ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

June 25, 2008

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

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the American public from the unnecessary risks associated with prescription drugs. We are concerned not only about the risks of drugs prescribed to treat humans, but also those administered to America's pets.

Wyeth Pharmaceuticals recalled ProHeart 6, a canine heartworm treatment, from the market in September 2004 following FDA revelations of dangerously high numbers of adverse drug event reports. In fact, serious safety problems arose in connection with ProHeart within months of its approval in June 2001. By June 2002, the label for ProHeart was amended to warn of anaphylaxix/anaphylactoid reactions, depression, lethargy, hives, and head and facial edema. In November of the same year, the label was amended again to include cardiopulmonary issues associated with heartworm-positive dogs. "Rare reports of death" was added to the label in July 2003. The FDA Veterinary Medicine Advisory Committee (VMAC), comprised of veterinary experts, also voted in 2005 that the drug was unsafe and that further studies were necessary.

Given the controversial safety record of ProHeart 6, the Committee is concerned that its return to market may be premature. Further, the public materials released in connection with FDA's announcement of ProHeart's reapproval do not adequately explain the basis of that approval. The Committee is therefore interested in learning the nature of the meetings, expertise, studies, and science that contributed ultimately to FDA's decision to reintroduce ProHeart 6 to the market.

As a preliminary matter, the Committee seeks to find out what meetings were held to discuss ProHeart's approval, who attended the meetings, when the meetings occurred, and ultimately, the nature of the meetings.

Accordingly, we request you provide the Committee with the following documents:

1. Copies of each and every calendar day, including all entries and attachments, contained in the Microsoft Outlook calendar of Daniel G. McChesney, Ph.D.; Director of the Office of Surveillance of Compliance, the Center for Veterinary Medicine from November 1, 2004, to the date of this letter.

2. Copies of each and every calendar day, including all entries and attachments, contained in the Microsoft Outlook calendar of Aleta Sindelar, R.N., Executive Secretary of the Veterinary Medical Advisory Committee, from November 1, 2004, to the date of this letter.

3. Copies of each and every calendar day, including all entries and attachments, contained in the Microsoft Outlook calendar of Stephen Sundlof, D.V.M., Ph.D., (Former Director of the Center for Veterinary Medicine), current Director of the Center for Food Safety and Applied Nutrition, Food and Drug Administration, from November 1, 2004, to the date of this letter.

4. Copies of minutes from each and every meeting held by FDA officials and/or held between FDA officials and any third party including Wyeth representatives and/or outside experts, to evaluate ProHeart 6 beginning in September 2004, to the date of this letter.

Please supply all requested answers in electronic form within two weeks of the date of this letter. Should you have any questions relating to this request, please have your staff contact Joanne Royce or Lisa Cody with the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations