

HENRY A. WAXMAN, CALIFORNIA  
EDWARD J. MARKEY, MASSACHUSETTS  
RICK BOUCHER, VIRGINIA  
EDOLPHUS TOWNS, NEW YORK  
FRANK PALLONE, Jr., NEW JERSEY  
BART GORDON, TENNESSEE  
BOBBY L. RUSH, ILLINOIS  
ANNA G. ESHOO, CALIFORNIA  
BART STUPAK, MICHIGAN  
ELIOT L. ENGEL, NEW YORK  
GENE GREEN, TEXAS  
DIANA DeGETTE, COLORADO  
VICE CHAIRMAN  
LOIS CAPPS, CALIFORNIA  
MIKE DOYLE, PENNSYLVANIA  
JANE HARMAN, CALIFORNIA  
TOM ALLEN, MAINE  
JAN SCHAKOWSKY, ILLINOIS  
HILDA L. SOLIS, CALIFORNIA  
CHARLES A. GONZALEZ, TEXAS  
JAY INSLEE, WASHINGTON  
TAMMY BALDWIN, WISCONSIN  
MIKE ROSS, ARKANSAS  
DARLENE HOOLEY, OREGON  
ANTHONY D. WEINER, NEW YORK  
JIM MATHESON, UTAH  
G.K. BUTTERFIELD, NORTH CAROLINA  
CHARLIE MELANCON, LOUISIANA  
JOHN BARROW, GEORGIA  
BARON P. HILL, INDIANA  
DORIS O. MATSUI, CALIFORNIA

ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN  
CHAIRMAN

JOE BARTON, TEXAS  
RANKING MEMBER  
RALPH M. HALL, TEXAS  
FRED UPTON, MICHIGAN  
CLIFF STEARNS, FLORIDA  
NATHAN DEAL, GEORGIA  
ED WHITFIELD, KENTUCKY  
BARBARA CUBIN, WYOMING  
JOHN SHIMKUS, ILLINOIS  
HEATHER WILSON, NEW MEXICO  
JOHN B. SHADEGG, ARIZONA  
CHARLES W. "CHIP" PICKERING, MISSISSIPPI  
VITO FOSSSELLA, NEW YORK  
ROY BLUNT, MISSOURI  
STEVE BUYER, INDIANA  
GEORGE RADANOVICH, CALIFORNIA  
JOSEPH R. PITTS, PENNSYLVANIA  
MARY BONO MACK, CALIFORNIA  
GREG WALDEN, OREGON  
LEE TERRY, NEBRASKA  
MIKE FERGUSON, NEW JERSEY  
MIKE ROGERS, MICHIGAN  
SUE WILKINS MYRICK, NORTH CAROLINA  
JOHN SULLIVAN, OKLAHOMA  
TIM MURPHY, PENNSYLVANIA  
MICHAEL C. BURGESS, TEXAS  
MARSHA BLACKBURN, TENNESSEE

June 25, 2008

DENNIS B. FITZGIBBONS, CHIEF OF STAFF  
GREGG A. ROTHSCILD, DEPUTY CHIEF OF STAFF  
AND CHIEF COUNSEL

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 FDA's ability to manage the approval of drugs prescribed to treat humans, but also those administered to America's pets.

Fort Dodge Animal Health (FDAH), a division of 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.

Accordingly, we request you provide responses to the Committee for the following issues:

1. At the 2005 VMAC meeting convened to address the safety of ProHeart 6, Dr. Sundlof, then Director of CVM, stated; "We [CVM] want to present our case in a public forum, which is this Veterinary Medicine Advisory Committee meeting. This is an important product obviously to veterinarians and to the company. We think it deserves a very thorough discussion, and we want to be sure that all the information gets thoroughly reviewed not only by CVM, but by independent specialists on the Veterinary Medicine Advisory Committee so we can get their opinions and benefit from their experience."
  - a. In light of Dr. Sundlof's stated commitment to a thorough, independent, and public review, why was a public VMAC meeting not convened to discuss the NADA for ProHeart 6 before the recent reintroduction of this product to the market?
  - b. Was a closed VMAC meeting convened to discuss reintroducing ProHeart 6 to the market? If so, please provide the attendees, the minutes, the briefing materials, and a transcript of the meeting.
  - c. Were comments solicited by CVM from consumer groups, the public, or independent specialists prior to the reintroduction of ProHeart 6? If so, please provide any and all records relating to such solicitations from CVM, or any division within FDA, including all comments or concerns received in response to such solicitations, between January 31, 2005, to the present, regarding ProHeart 6 or other ProHeart products (GUARDIAN SR, MOXIDEC SR, and ProHeart SR-12).
  - d. In the June 17, 2008, issue of *USA Today*, Dr. Bernadette Dunham, Director of CVM, stated, "FDA, Fort Dodge and veterinary health care professionals have explored virtually every aspect of problems associated with ProHeart 6. The FDA group that evaluated ProHeart 6 included toxicologists, epidemiologists, immunologists, pathologists, chemists, veterinary medical officers and statisticians." Who exactly were each of the participants of this "FDA group," and when did this evaluation occur? Did the "FDA group" include Wyeth/Fort Dodge participants? What data and/or studies were evaluated by the "FDA group" and when did these studies occur? Please provide any and all records reflecting notes, minutes, reports, or any other memorialization of the findings of the "FDA group," which reviewed ProHeart 6 according to Dr. Dunham's statement in *USA Today*.

The Honorable Andrew C. von Eschenbach, M.D.  
Page 3

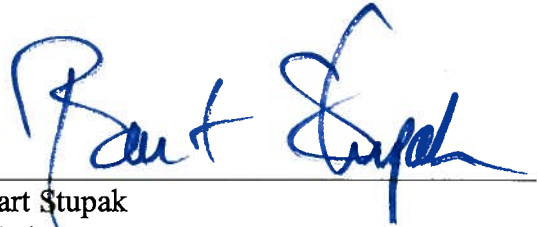
2. Committee staff have learned that FDAH requested multiple reviews from CVM—following the January 31, 2005, VMAC meeting—of data pertaining to ProHeart 6 efficacy and safety in the hopes of obtaining CVM’s approval to return ProHeart 6 to the market. Please provide all records and communications between CVM (and/or any other division of HHS including the Office of Chief Counsel) and FDAH relating to CVM reviews of data pertaining to ProHeart 6, submitted to CVM from January 21, 2005, to the present.

Please supply all requested answers and records in electronic form within two weeks of the date of this letter. For the purpose of responding to this request for information and documents, the terms “records” and “relating” should be interpreted in accordance with the attachment to this letter. Should you have any questions relating to this request, please have your staff contact Joanne Royce or Lisa Cody of 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

## ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.