ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

July 31, 2008

Mr. Bernard J. Poussot
Chairman, President, and CEO
Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Dear Mr. Poussot:

Pursuant to rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the controversial safety record and potentially premature return to the market of ProHeart 6, a heartworm preventative treatment containing moxidectin, manufactured by Fort Dodge Animal Health, a division of Wyeth. Accordingly, the Committee is interested in the possible safety concerns of alternative uses of moxidectin in humans and other animals.

Wyeth Pharmaceuticals is currently conducting, in collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR) (which is sponsored by the United Nations Children's Fund, United Nations Development Programme, World Bank, and World Health Organization), a phase II clinical trial in Ghana involving 192 subjects infected with the microfilaria parasite, the organism known to cause river blindness (onchocerciasis) in humans. This clinical trial is designed to test whether Wyeth's moxidectin can inhibit microfilaria production more effectively than Merck's ivermectin, a drug currently used extensively to prevent and treat river blindness.

According to a *TDR News* report published in December 2007, "The planned 2004 commencement of the trial [phase II clinical trial for moxidectin in Ghana] was then delayed for nearly two years after a public controversy erupted in the USA over an animal drug containing moxidectin [ProHeart 6] and used to prevent heartworm in dogs, which resulted in Wyeth withdrawing the drug from the US market, pending a United States Food and Drug Administration [FDA] Center for Veterinary Medicine [CVM] review still ongoing – although the drug continues to be sold in Canada, Europe and Australia." Further, *TDR News* reports that an informal meeting with independent experts, including scientists from France, Nigeria, and Sudan, representatives from regulatory authorities in Ghana, and the national ethics review

committee, was convened in Ghana in 2005, to review summaries of safety data for moxidectin. The expert panel concluded that a phase II clinical trial for moxidectin should begin as soon as possible and thus, in September 2006, the trial was initiated in Ghana.

Given that a 2005 FDA Veterinary Medicine Advisory Committee meeting composed of independent experts determined that ProHeart 6, containing moxidectin, is not safe for use in dogs, the Committee is interested in examining the process by which the expert panel mentioned in *TDR News*, which met in Ghana in 2005, determined it was safe to proceed with the phase II clinical safety trial for moxidectin in humans with onchocerciasis.

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

1. Please provide a list of attendees, minutes, meeting summaries for, and all records of, data reviews, summaries, or studies examined by the expert panel at the informal meeting convened in Ghana in 2005 to review the safety of moxidectin;

2. Please provide all records pertaining to the determination by that expert panel in 2005 that it was safe to proceed with a moxidectin phase II human clinical trial in Ghana, despite CVM's reports of dangerously high numbers of adverse drug events in dogs receiving ProHeart 6, the recall of that product in 2004, and the 2005 VMAC determination that ProHeart 6 is not safe for use in dogs; and

3. Please provide all records relating to the market potential and market size for ProHeart 6 and ProHeart SR-12 in dogs, and moxidectin use in food animals, companion animals, and humans, including all documents, communications, and market potential and market-sizing analyses performed.

Please supply all requested answers and records in searchable 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 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