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

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October 14, 2008

Mr. Gary S. Balkema
President
Bayer HealthCare LLC
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962–1910

Dear Mr. Balkema:

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 are investigating direct-to-consumer (DTC) advertising for pharmaceutical products. The Committee is examining the DTC advertising for your product, Bayer Aspirin with Heart Advantage, which is a combination product that includes both an over-the-counter medication as well as a dietary supplement.

In a May 30, 2000, letter concerning the regulatory status of products that combine an over-the-counter drug with a dietary supplement, the U.S. Food and Drug Administration (FDA) stated that the addition of a new ingredient could affect the safety and efficacy of a drug component, and consumers may believe that both drug and food components have been scrutinized for safety and effectiveness, when in fact only the approved drug component has been subject to such regulation. The letter also states, "FDA strongly recommends that firms refrain from marketing products that combine or co-package drug and dietary supplement ingredients."

It appears that Bayer Aspirin with Heart Advantage is such a combination product, and DTC advertising of it may mislead the public. The Committee is concerned that your company engaged in DTC advertising of this product, particularly in light of FDA's recommendation to refrain from marketing combination products.

Therefore, we ask that you answer the following question in writing:

1. Has Bayer submitted, or does Bayer plan to submit, a New Drug Application, Abbreviated New Drug Application, or new or amended monograph to FDA for Bayer Aspirin with Heart Advantage?

In addition, we ask that you please provide the following:

1. All documentation relating to claims made about the phytosterol component of Bayer Aspirin with Heart Advantage as well as claims about the combination product, including the claim that its natural ingredient is clinically proven to lower low-density lipoprotein (bad) cholesterol;

2. All records relating to studies, both positive and negative, that demonstrate the effect of Bayer Aspirin with Heart Advantage on cholesterol and heart disease;

3. All records relating to communications with FDA officials relating to Bayer Aspirin with Heart Advantage, or any other over-the-counter drug and dietary supplement combination product;

4. All records relating to internal deliberations regarding the development and marketing of the combination product from the date of the discontinuation of Baycol (cerivastatin) to the date of launch of Bayer Aspirin with Heart Advantage; and

5. Copies of all DTC advertisements for Bayer Aspirin with Heart Advantage, including storyboards and scripts for television and radio advertisements.

Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records or staff interviews with company officials.

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact us or have your staff contact Paul Jung or David Nelson 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

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.