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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

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

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 continuing to investigate direct-to-consumer (DTC) advertising of pharmaceutical products. As part of its investigation, the Committee is examining Bayer Aspirin with Heart Advantage, a combination product that includes both an over-the-counter medication as well as a dietary supplement.

We understand that the Food and Drug Administration (FDA) discourages the marketing of combination products that include an over-the-counter medicine and a dietary supplement. In a letter dated May 30, 2000, FDA warned that the addition of a new ingredient could affect the safety and efficacy of a drug component, and consumers may believe that both the 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 plainly states, "FDA strongly recommends that firms refrain from marketing products that combine or co-package drug and dietary supplement ingredients."

Bayer Aspirin with Heart Advantage is such a combination product, but the company appears to have ignored FDA's recommendation to refrain from marketing such combination products. The Committee would like to know whether FDA, its Office of Chief Counsel (OCC), or its Office of General Counsel (OGC) were apprised of this product prior to its marketing, whether they are aware of other combination products being marketed, and whether these Offices have made any recent decisions related to the regulation of marketing such combination products.

Therefore, we ask that you please provide the following:

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

2. All records relating to internal deliberations regarding Bayer Aspirin with Heart Advantage, or any other over-the-counter drug and dietary supplement combination product; and

3. All records specifically relating to internal deliberations within the OCC and the OGC regarding Bayer Aspirin with Heart Advantage or any other over-the-counter drug and dietary supplement combination product, as well as all records relating to communications on such issues with any FDA office.

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 agency 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 John F. Sopko 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.