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J. Sopko

J. Royce

January 10, 2008

Congressional Requesters

Subject: Regulation of Dietary Supplements and Functional Foods

Concerning your request to the Comptroller General for a GAO study of FDA's regulation of dietary supplements and functional foods, we met with your staff on January 3, 2008, to gain a further understanding of your needs. We also met with staff from the other relevant Committees. Please see enclosure I for the list of requesters with whom we will be coordinating this assignment.

Due to the complexity of the issue, we need to proceed with a separate design phase. The purpose of this letter is to set forth the study objectives and provide you with a completion date for the design phase. We agreed that the overall objectives of our work will be to examine FDA's actions to implement a mandatory adverse event reporting system for dietary supplements, the extent to which FDA has the ability to identify and act on safety concerns of dietary supplements, the extent to which FDA monitors potential safety issues raised by the increasing presence of dietary supplement ingredients in conventional food products, and FDA's actions to ensure that consumers understand label claims and have adequate information about the safety and efficacy of a product.

The design phase will be completed by April 11, 2008. We will remain in contact with your staff, and at the end of the design phase, we will provide you with a projected completion date for the total study. If you should have questions, you may contact me on (202) 512-3841 or my Assistant Director, Alfredo Gomez, on (202) 512-4101.

Sincerely yours,

Lisa Shames  
Director, Natural Resources  
and Environment

Enclosure

Enclosure I

Chairman, Committee on Energy and Commerce  
United States House of Representatives  
(Staff Member: Joanne Royce)

Chairman, Committee on Oversight and Government Reform  
United States House of Representatives  
(Staff Member: Sarah Despres)

Chairman, Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
United States House of Representatives

Chairman, Subcommittee on Agriculture, Rural Development, Food and Drug  
Administration, and Related Agencies  
Committee on Appropriations  
United States Senate  
(Staff Member: Brian Hickey)