Congress of the United States

House of Representatives

Washington, D.C. 20515

May 14, 2007

The Honorable David M. Walker
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

In 2000, the Government Accountability Office (GAO) issued an important report entitled "Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods." In that report, GAO concluded that there were weaknesses in consumer safeguards for functional foods and dietary supplements. GAO pointed out three areas of particular concern: (1) lack of a clearly defined safety standard for new dietary ingredients; (2) lack of regulations or guidance on safety information required on labels; and (3) the failure of the Food and Drug Administration (FDA) to investigate most reports of adverse health events associated with dietary supplements.

Since GAO issued this report, there have been numerous significant developments in the regulation of dietary supplements that may help FDA better ensure dietary supplement safety. Some of these developments include FDA's successful ban of ephedra-containing supplements in 2004; the Bioterror Act of 2002, which imposed new registration requirements for dietary supplement manufacturers; and the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006, which required dietary supplement companies to report adverse events to FDA. However, while FDA was able to ban ephedra-containing supplements, it took many years and a significant commitment of resources. Moreover, it is probable that some people were seriously injured or died from ephedra while FDA gathered the necessary data.[1] If another dangerous product is discovered

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[1] *See, e.g.,* Christine Haller, M.D. and Neal L. Benowitz, M.D., *Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids*, New England Journal of Medicine (Dec. 21, 2000). The authors reviewed 140 reports of adverse events associated with ephedra-containing supplements and concluded that 62 percent of the reports were definitely, probably, or possibly related to these products, including reports of stroke, seizures and death. Ephedra remained on the market for over three years after the publication of this study.

on the market, we want to avoid the several very high-profile deaths and years of required data collection before FDA takes action.

As to products that may not pose a safety issue, we have concerns about whether consumers understand dietary supplement labels and FDA's role in regulating labels and label claims. For example, some consumers may erroneously believe that dietary supplement manufacturers have to demonstrate the efficacy of their products before they are marketed. Consumer confusion has increased as the number of dietary supplement claims have proliferated.

In order to understand what challenges remain, we ask GAO to update its work in this area. Specifically, we would like GAO to examine the following:

1. In 2006, Congress gave FDA the authority to establish a mandatory adverse event reporting system for dietary supplements. What has FDA done to implement this system? Has this system helped FDA identify safety concerns? Is the FDA's authority sufficient to identify and act on safety concerns? What is the ability of FDA, under current authority, to take action against dietary supplements the agency has identified as potentially dangerous? What gaps remain in FDA's ability to monitor emerging safety concerns, including concerns regarding individual ingredients and combinations of ingredients?

2. How effectively does FDA monitor potential safety issues raised by the increasing presence of dietary supplement ingredients in conventional food products, including ingredients that are not generally recognized as safe (GRAS) or which may exceed GRAS levels for particular substances?

3. What has FDA done to ensure that consumers understand label claims and have adequate information about the safety and efficacy of these products in order to make informed decisions about whether or not to take a particular product?

If you have any questions regarding this request, please contact us, or have your staff contact Joanne Royce with the Committee on Energy and Commerce staff at (202) 226-2424, or Sarah Despres with the Oversight and Government Reform Committee staff at (202) 225-5056.

Sincerely,

John D. Dingell
Chairman
Committee on Energy and Commerce

Henry A. Waxman
Chairman
Committee on Oversight and Government Reform

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Tom Davis, Ranking Member
Committee on Oversight and Government Reform

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations