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# DIETARY SUPPLEMENTS

## FDA Should Take Further Actions to Improve Oversight and Consumer Understanding

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Highlights

Highlights of GAO-09-250, a report to congressional requesters

### Why GAO Did This Study

Dietary supplements and foods with added dietary ingredients, such as vitamins and herbs, constitute multibillion dollar industries. Past reports on the Food and Drug Administration's (FDA) regulation of these products raised concerns about product safety and the availability of reliable information. Since then, FDA published draft guidance on requirements for reporting adverse events—which are harmful effects or illnesses—and Current Good Manufacturing Practice regulations for dietary supplements. GAO was asked to examine FDA's (1) actions to respond to the new serious adverse event reporting requirements, (2) ability to identify and act on concerns about the safety of dietary supplements, (3) ability to identify and act on concerns about the safety of foods with added dietary ingredients, and (4) actions to ensure that consumers have useful information about the safety and efficacy of supplements.

### What GAO Recommends

GAO recommends that the Secretary of Health and Human Services direct the Commissioner of the FDA to request additional authority to oversee dietary supplements, issue guidance on new dietary ingredients and to clarify the boundary between dietary supplements and foods with added dietary ingredients, and take steps to improve consumer understanding of dietary supplements. In commenting on this report, FDA generally agreed with GAO's recommendations.

To view the full product, including the scope and methodology, click on GAO-09-250. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

### What GAO Found

FDA has made several changes in response to the new serious adverse event reporting requirements and has subsequently received an increased number of reports. For example, FDA has modified its data system, issued draft guidance, and conducted outreach to industry. Since mandatory reporting went into effect on December 22, 2007, FDA has seen a threefold increase in the number of all adverse event reports received by the agency compared with the previous year. For example, from January through October 2008, FDA received 948 adverse event reports—596 of which were mandatory reports submitted by industry—compared with 298 received over the same time period in 2007. Although FDA has received a greater number of reports since the requirements went into effect, underreporting remains a concern, and the agency has further actions planned to facilitate adverse event reporting.

FDA has taken some steps to identify and act upon safety concerns related to dietary supplements; however, several factors limit the agency's ability to detect concerns and remove products from the market. For example, FDA has limited information on the number and location of dietary supplement firms, the types of products currently available in the marketplace, and information about moderate and mild adverse events reported to industry. Additionally, FDA dedicates relatively few resources to oversight activities, such as providing guidance to industry regarding notification requirements for products containing new dietary ingredients. Also, once FDA has identified a safety concern, the agency's ability to remove a product from the market is hindered by a lack of mandatory recall authority and the difficult process of demonstrating significant or unreasonable risk for specific ingredients.

Although FDA has taken some actions when foods contain unsafe dietary ingredients, certain factors may allow potentially unsafe products to reach consumers. FDA may not know when a company has made an unsupported or incorrect determination about whether an added dietary ingredient in a product is generally recognized as safe until after the product becomes available to consumers because companies are not required to notify FDA of their self-determinations. In addition, the boundary between dietary supplements and conventional foods containing dietary ingredients is not always clear, and some food products could be marketed as dietary supplements to circumvent the safety standard required for food additives.

FDA has taken limited steps to educate consumers about dietary supplements, and studies and experts indicate that consumer understanding is lacking. While FDA has conducted some outreach, these initiatives have reached a relatively small proportion of dietary supplement consumers. Additionally, surveys and experts indicate that consumers are not well-informed about the safety and efficacy of dietary supplements and have difficulty interpreting labels on these products. Without a clear understanding of the safety, efficacy, and labeling of dietary supplements, consumers may be exposed to greater health risks associated with the uninformed use of these products.