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DIETARY SUPPLEMENTS

FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products

GAO Accountability * Integrity * Reliability

Highlights

Highlights of GAO-13-244, a report to congressional requesters

Why GAO Did This Study

Dietary supplements, such as vitamins and botanical products, are a multibillion dollar industry; national data show that over half of all U.S. adults consume them. FDA regulates dietary supplements and generally relies on postmarket surveillance, such as monitoring AERs, to identify potential concerns. Since December 2007, firms receiving a serious AER have had to report on it to FDA within 15 days. In January 2009, GAO reported that FDA had taken several steps to implement AER requirements and had recommended actions to help FDA identify and act on safety concerns for dietary supplements. GAO was asked to examine FDA's use of AERs in overseeing dietary supplements. This report examines the (1) number of AERs FDA has received since 2008, their source, and types of products identified; (2) actions FDA has taken to ensure that firms are complying with AER requirements; (3) extent to which FDA is using AERs to initiate and support its consumer protection efforts; and (4) extent to which FDA has implemented GAO's 2009 recommendations. GAO analyzed FDA data, reviewed FDA guidance, and interviewed FDA officials.

What GAO Recommends

GAO recommends, among other things, that FDA explore options to obtain poison center data, if determined to be useful; collect information on how it uses AERs; provide more information to the public about AERs; and establish a time frame to finalize guidance related to GAO's 2009 recommendations. FDA generally concurred with each of GAO's recommendations.

View GAO-13-244. For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

What GAO Found

From 2008 through 2011, the Department of Health and Human Services' Food and Drug Administration (FDA) received 6,307 reports of health problems—adverse event reports (AER)—for dietary supplements; 71 percent came from industry as serious adverse events as required by law, and most of these AERs were linked with supplements containing a combination of ingredients, such as vitamins and minerals or were otherwise not classified within FDA's product categories. However, FDA may not be receiving information on all adverse events because consumers and others may not be voluntarily reporting these events to FDA, although they may be contacting poison centers about some of these events. From 2008 to 2010, these centers received over 1,000 more reports of adverse events linked to dietary supplements than did FDA for the same period. FDA officials said that they are interested in determining whether the poison center data could be useful for their analysis and have held discussions with American Association of Poison Control Centers representatives, but cost is a factor.

To help ensure firms are complying with AER requirements (i.e., submitting serious AERs, maintaining AER records, and including firms' contact information on product labels), FDA increased its inspections of supplement firms and took some actions against noncompliant firms. Specifically, FDA increased firm inspections from 120 in 2008 to 410 from January 1 to September 30, 2012. Over this period, FDA took the following actions: 3 warning letters, 1 injunction, and 15 import refusals related to AER violations, such as not including contact information on the product label or submitting a serious AER.

FDA has used AERs for some consumer protection actions (e.g., inspections and warning letters) but may be able to expand their use. FDA officials said that most AERs do not initiate or support such actions because it is difficult to establish causality between the product and the health problem based on the limited information in an AER. However, FDA does not systematically collect information on how it uses AERs for consumer protection actions; by collecting this information, it may be able to assess whether AERs are being used to their fullest extent. In addition, FDA is not required to provide information to the public about potential safety concerns from supplement AERs as it does for drugs. Making such information public, if consistent with disclosure provisions in existing law, could expand FDA's use of AERs and improve consumer awareness and understanding of potential health events associated with dietary supplements.

FDA has partially implemented all of GAO's 2009 recommendations, such as issuing guidance for new dietary ingredients, clarifying the boundary between dietary supplements and conventional foods, and expanding partnerships to improve consumer understanding. Specifically, FDA developed draft guidance in 2009, 2011, and 2012 to address three GAO recommendations about dietary supplement oversight and formed new partnerships to conduct consumer outreach. However, FDA has not issued final guidance in two cases. FDA officials said that they plan to complete implementation, but they have provided no time frame to do so. With final guidance in place, firms may be able to make more informed product development and marketing decisions, which could ultimately reduce FDA's enforcement burden in these areas.