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DIETARY SUPPLEMENTS CONTAINING EPHEDRA

Health Risks and FDA's Oversight

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Highlights

Highlights of GAO-03-1042T, testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Dietary supplements containing ephedra have been associated with serious health-related adverse events, including heart attacks, strokes, seizures, and deaths. The Food and Drug Administration (FDA) regulates dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA). Reports of adverse events have been received by FDA and others, including Metabolife International, the manufacturer of a dietary supplement containing ephedra, Metabolife 356.

Because of concerns surrounding the safety of dietary supplements containing ephedra, GAO was asked to discuss and update some of the findings from its prior work on ephedra, including its examination of Metabolife International's records of health-related calls from consumers of Metabolife 356. Specifically, GAO examined (1) FDA's analysis of the adverse event reports it received for dietary supplements containing ephedra, (2) how the adverse events reported in the health-related call records collected by Metabolife International illustrate the health risks of dietary supplements containing ephedra, and (3) FDA's actions in the oversight of dietary supplements containing ephedra.

www.gao.gov/cgi-bin/getrpt?GAO-03-1042T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse, (202) 512-7119.

What GAO Found

FDA has used the adverse event reports it has received to conclude that dietary supplements containing ephedra pose a significant public health hazard. Since February 1993, FDA has received 2,277 reports of adverse events associated with dietary supplements containing ephedra, 15 times more reports than it has received for the next most commonly reported herbal dietary supplement.

The types of adverse events that GAO identified in the health-related call records from Metabolife International were consistent with the types of adverse events reported to FDA and with the documented physiological effects of ephedra. Although call records contained limited information for most of the reports, GAO identified 14,684 call records that had reports of at least one adverse event among consumers of Metabolife 356. GAO's count of 92 serious events—heart attacks, strokes, seizures, and deaths—was similar to that of other reviews of the call records, including counts by Metabolife International and its consultants. Many of the serious events were reported among relatively young consumers—more than one-third concerned consumers who reported an age under 30. In addition, for call records containing information on the amount of product consumed or length of product use, GAO found that most of the reported serious adverse events occurred among consumers who followed the usage guidelines on the Metabolife 356 label.

As part of its oversight of dietary supplements, FDA has taken some actions specifically focused on dietary supplements containing ephedra. FDA has issued warnings that focus on improper labeling, issued warnings to consumers, and issued a proposed rule in 1997 that, among other things, would require a health warning on the label of dietary supplements containing ephedra and prohibit a dietary supplement from containing both ephedra and a stimulant. FDA subsequently banned the sale of certain classes of over-the-counter drugs containing ephedrine and related alkaloids—the active ingredient in ephedra—in combination with an analgesic or stimulant. As the 1997 proposed rule has not been finalized, there is no rule prohibiting the marketing of dietary supplements with similar ingredients, and many dietary supplements with ephedra, such as Metabolife 356, also include caffeine or other stimulants. To receive comments on new evidence, FDA recently reopened the comment period for the proposed rule, and FDA reported to GAO that the agency is in the process of reviewing comments it has received and has not reached a decision regarding further action.