



Highlights of [GAO-03-494](#), a report to the Chairman, Subcommittee on Wellness and Human Rights, Committee on Government Reform, House of Representatives

Why GAO Did This Study

Dietary supplements containing ephedra, such as Metabolife 356, have been associated with serious adverse health-related events. In a February 28, 2003, announcement, the Food and Drug Administration (FDA) proposed that dietary supplements containing ephedra include a statement on their label warning that “Heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids.”

GAO was asked to review health-related call records that Metabolife International—the manufacturer of Metabolife 356—collected from consumers from May 1997 through July 2002. Most of the records were from calls to a consumer phone line the company maintained. Metabolife International voluntarily provided the call records to GAO.

Specifically, GAO (1) examined the extent to which consumer information in the call records was comprehensive, interpretable, and consistently recorded, (2) counted the number of call records reporting types of adverse events that FDA had identified in 1997 as serious or potentially serious, and (3) compared GAO’s findings to those of six other reviews of the call records, including one by Metabolife International.

www.gao.gov/cgi-bin/getrpt?GAO-03-494.

To view the full report, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse (202) 512-7114.

DIETARY SUPPLEMENTS

Review of Health-Related Call Records for Users of Metabolife 356

What GAO Found

Adverse event reports generally are not sufficient on their own to establish that reported problems are caused by the use of a particular product, but can signal potential health problems that deserve investigation. The information in the Metabolife International call records was limited. Call records were sometimes difficult to understand, and consumer information was not consistently recorded. In some cases, the evidence for a report of an adverse event was limited to a single word on the record. Most call records also did not record complete information about potentially relevant items such as the consumer’s age, sex, weight, and height. Information about both the amount of product used and the duration of use was recorded for 60 percent of the call records. Handwritten call records were difficult to read and understand.

By GAO’s categorization, 14,684 of the call records contained reports of at least one adverse event. GAO found that there were 92 reports of the serious adverse events identified in FDA’s proposed label warning—18 reported heart attacks, 26 reported strokes, 43 reported seizures, and 5 reported deaths. Other types of adverse events identified as serious or potentially serious by FDA in 1997 that were reported in the call records included significant elevation in blood pressure, abnormal heart rhythm, loss of consciousness, and systemic rash. Because of the inherent limitations of adverse event reports and the incomplete nature of these call records, it can not be established from the information available to GAO that the adverse events reported were caused by Metabolife 356.

All of the reviews of Metabolife International call records—one by Metabolife International; three by consultants commissioned by Metabolife International; one by the minority staff of the Committee on Government Reform, House of Representatives; one by the RAND Corporation; and one by GAO—found reports of serious adverse events, although none reported identical results. For the set of adverse events counted by Metabolife International—heart attack, stroke, seizure, death, and cardiac arrest—GAO’s counts were similar to those of the other reviews. GAO counted 96 such reports and the counts of the other reviews ranged from 65 to 107.

In commenting on a draft of this report, FDA discussed the value of reports of adverse events in helping to understand the causes of such events.