

GAO Highlights

Highlights of [GAO-17-416](#), a report to congressional requesters

Why GAO Did This Study

Memory supplements—dietary supplements claiming to improve memory—are a growing market, with sales estimated at \$643 million in 2015, almost double 2006 sales. FDA and FTC share oversight of memory supplement marketing—labeling and advertising claims—but generally do not approve claims before products are marketed.

GAO was asked to review memory supplement marketing and oversight. This report examines (1) how memory supplements are marketed and the extent marketing targets older adults and may violate federal requirements; (2) related enforcement and outreach actions taken by FDA and FTC; and (3) challenges to agency oversight.

GAO reviewed five types of media (Internet, television, among others) to identify examples of memory supplement marketing practices and potential violations of federal requirements. GAO selected these channels using demographic and survey data relevant to older adults. GAO analyzed FDA and FTC data on enforcement actions for fiscal years 2006 through 2015—the most recent data available. GAO also reviewed relevant agency oversight policies, interviewed agency officials, and interviewed selected consumer and industry groups.

What GAO Recommends

GAO recommends that FDA and FTC provide additional guidance to consumers clarifying the agencies' differing roles in their shared oversight of memory supplement and other dietary supplement marketing on the Internet. The two agencies concurred with GAO's recommendation.

View [GAO-17-416](#). For more information, contact Seto Bagdoyan at (202) 512-6722 or bagdoyans@gao.gov or Steve Morris at (202) 512-3841 or morriss@gao.gov.

May 2017

MEMORY SUPPLEMENTS

Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness

What GAO Found

GAO's market review during a 2-month period found most examples of memory supplement marketing on the Internet. About 96 percent of marketing identified appeared on the Internet, and a total of 490 memory supplement products were identified by the market review. GAO found 28 examples of advertisements that linked supplement use to treatment or prevention of memory-related diseases, which is generally prohibited by federal law. Food and Drug Administration (FDA) officials subsequently determined that 27 of these examples appeared to violate federal requirements. Officials reported that they had issued two advisory letters to two firms and would continue monitoring all of the examples that were identified.

Oversight of memory supplements falls under FDA's general authority to regulate dietary supplements and their labeling, and the Federal Trade Commission's (FTC) general authority to enforce the prohibitions against deceptive advertising. Between 2006 and 2015, FDA and FTC have taken similar types of enforcement actions for memory supplements as for other dietary supplements—with most FDA actions being warning letters and FTC actions being a mix of administrative and federal court actions. Nineteen of 551 enforcement actions involved memory supplements. The agencies coordinate enforcement actions in the same way for all dietary supplements. FDA and FTC have done some outreach to industry and consumers on dietary supplement use by older adults as well as some specific outreach related to memory supplement enforcement actions. In prioritizing enforcement and outreach efforts, the agencies focus on safety, egregiousness of deception, and impact of marketing.

FDA faces challenges related to limited information about the dietary supplement market, including memory supplements, to inform its oversight efforts. FDA officials said the agency is exploring ways to obtain additional market information to improve its oversight. FTC officials believe their existing tools and information are sufficient to inform its oversight efforts. While Internet marketing of dietary supplements was a concern for agencies, consumers, and industry groups, GAO found that consumer groups were unclear about FDA's and FTC's roles for overseeing supplement marketing found on the Internet. FDA and FTC share oversight of marketing on the Internet, with FTC exercising primary jurisdiction over advertising on the Internet and FDA exercising primary jurisdiction over aspects considered to fall under labeling, including information provided at the point of sale. However, few documents explicitly delineate their differing roles and coordination in oversight, or communicate the roles to industry and consumers. Federal internal control standards state that agencies should communicate quality information with external parties to achieve objectives, and GAO has also previously reported that delineating roles and responsibilities are issues agencies should consider when collaborating. Absent clarification of FDA and FTC roles, consumers may not understand which agency to report concerns to involving Internet marketing, and there is a risk that agencies may not receive consumer complaints directly, which may delay agencies taking action to address a problem. Consumer complaints are an important tool for both agencies to learn about potential dietary supplement issues, according to agency officials.