



May 2017

MEMORY SUPPLEMENTS

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

Accessible Version

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 morris@gao.gov.

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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.

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Abbreviations

CFSAN	Center for Food Safety and Applied Nutrition
DSHEA	Dietary Supplement Health and Education Act of 1994
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HHS	Department of Health and Human Services
NDI	new dietary ingredient
SARS	Severe Acute Respiratory Syndrome

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May 16, 2017
The Honorable Claire McCaskill
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Robert P. Casey, Jr.
Ranking Member
Special Committee on Aging
United States Senate

Approximately 5.4 million Americans were living with Alzheimer’s disease in 2016, a number that is projected to more than double by 2050 as baby boomers age into their later years, according to the U.S. Department of Health and Human Services’ (HHS) National Institutes of Health. Alzheimer’s disease, considered the most common form of dementia, is a progressive disease that begins with mild memory loss and has no known cure. Consumers searching to prevent or treat age-related memory loss, including Alzheimer’s disease, have increasingly turned to dietary supplements¹ for help. Scientific evidence shows that some dietary supplements are beneficial for overall health and for managing some health conditions; however, in some instances, dietary supplements have caused serious adverse health effects. Specialty dietary supplements that claim to address specific health issues, including those that claim to improve or in other ways positively affect memory (referred to in this report as memory supplements), have emerged in the market. The memory supplements market reportedly almost doubled from 2006 to 2015, with total estimated sales increasing from \$353 million to \$643 million.² Older adults are especially vulnerable to claims that promise to

¹The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines a dietary supplement in part as a product (other than tobacco) that, among other requirements, is intended to supplement the diet; contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents; is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is labeled on the front panel as being a dietary supplement. DSHEA places dietary supplements in a special category under the umbrella of foods.

²Nutrition Business Journal, *Mental Acuity Health Condition Specific Supplement, Pharmaceutical Sales* (Boulder, Colo.: Penton Media, Inc., 2016), chart 116.

prevent or reverse declines in cognitive function, according to the Federal Bureau of Investigation.

HHS's Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) share responsibility for overseeing the marketing of dietary supplements, including the claims made on dietary supplement product labels and in dietary supplement product advertising, respectively. FDA regulates dietary supplements, including labeling, under the Federal Food, Drug, and Cosmetic Act,³ including amendments made by the Dietary Supplement Health and Education Act of 1994 (DSHEA).⁴ As part of its authorities over dietary supplements, FDA exercises primary jurisdiction over dietary supplement labeling, which includes marketing information accompanying the product. FTC is responsible for preventing false advertising—advertising is defined broadly to include traditional print and broadcast advertisements, infomercials, Internet marketing, social media, press releases, and other promotional materials—for dietary supplements and most other products sold to consumers under the Federal Trade Commission Act.⁵ FDA and FTC authorities are generally limited to after dietary supplements go to market, and in most cases neither agency has premarket authority that allows for approvals of labeling or advertising claims before dietary supplements may be sold to consumers.

There is no federal law specifically regulating the subset of dietary supplements we refer to in this report as memory supplements, and there is no definition of a memory supplement in federal law. As a result, the oversight of memory supplements falls under FDA's general authority to regulate dietary supplements and labeling of dietary supplements, and under FTC's general authority to enforce the prohibitions against unfair or deceptive acts and practices, including false advertising.

³21 U.S.C. §§ 301-399.

⁴Under DSHEA, Pub. L. No. 103-417, FDA regulates dietary supplements, including vitamins, minerals, herbals and other botanicals, amino acids, certain other dietary substances, and derivatives of these items.

⁵Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, prohibits unfair or deceptive acts or practices in or affecting commerce, and Section 12, 15 U.S.C. § 52, prohibits the false advertisement of food (which includes dietary supplements), drugs, devices, services, or cosmetics. Although FDA authorities distinguish between drugs and foods and provide distinct regulatory frameworks for health claims and structure-function claims, FTC's authorities generally make no such distinctions.

Given the growth of memory supplements and older adults' vulnerability to exploitation, especially those adults experiencing age-related memory loss, you asked us to review how memory supplement companies market their products and how FDA and FTC oversee memory supplements and memory supplement marketing. This report examines: (1) how memory supplements are marketed, and the extent to which the marketing targets older adults and is potentially deceptive or inconsistent with federal requirements; (2) what enforcement and outreach actions FDA and FTC have undertaken in overseeing memory supplements and their marketing; and (3) what challenges FDA and FTC face in overseeing memory supplements.

To conduct our work, we reviewed relevant laws and regulations related to each agency's oversight of dietary supplements. We worked with officials from FDA and FTC, as well as representatives from the HHS National Institutes of Health, to develop and obtain concurrence on a single definition of memory supplements for the purposes of this review. To determine how memory supplements are marketed, and the extent to which the marketing targets older adults and is potentially deceptive or inconsistent with federal requirements, we conducted a market review in which we monitored five media channels (the Internet, retail stores, television, magazines, and newspapers) in 2 months of 2016, targeting media most likely used by older adults, to identify, catalogue, and review memory supplement advertisements for marketing claims.⁶ We also conducted a targeted review of the Internet search results from the market review to identify (1) examples of Internet marketing containing memory supplement advertisements in the form of text and visuals targeting older adults, and (2) visuals that may positively affect a consumer's view of the product, such as pictures of medical professionals or testimonials made by older adults. Although our review of the memory supplement market is not generalizable and cannot be projected to the entire memory supplement market, we believe that our sampling methodology provides us with the ability to obtain important insights into

⁶We did not find a consistent definition among federal agencies as to what age constitutes "older," with some federal laws and agencies using 60 or 65 years as the threshold and other sources using 50 years. For the purposes of this review, we define the term older adults to include persons age 50 years and older to be consistent with relevant FDA educational material aimed at older consumers of dietary supplements, which use 50 years of age as the threshold for defining older. This definition was also consistent with AARP representation (an advocacy group for older adults). By using this lower threshold, we are also able to capture consumers of dietary supplements aiming to prevent memory loss before it begins.

memory supplement marketing practices. In addition, we identified and reviewed marketing claims for examples that may be potentially deceptive or in violation of federal requirements—specifically, disease-related claims that a product can treat, cure, or prevent a memory-related disease. We shared the examples with staff from FDA and FTC for their review.

To determine what enforcement and outreach actions FDA and FTC have undertaken in overseeing memory supplements and their marketing, we collected and analyzed agency oversight policies. We also conducted semistructured interviews with FDA and FTC officials to review their activities and guidance related to dietary supplement enforcement and outreach efforts. We also interviewed agency officials about strategic plans and program priorities related to dietary supplements as well as reviewed documents showing how each agency prioritizes dietary supplement work in their enforcement or outreach efforts. Additionally, we conducted semistructured interviews with consumer groups and industry associations regarding FDA and FTC oversight efforts of dietary supplements, including memory supplements and efforts specific to older adults.⁷ Finally, we obtained and analyzed data from FDA and FTC on their enforcement actions⁸ involving dietary supplements and memory supplements for fiscal year 2006 through fiscal year 2015—the most recent years for which such data were available at the time of our review.⁹ As part of this analysis, we interviewed FDA and FTC staff about these memory supplement actions. Based on our analysis of the data provided

⁷We identified the consumer groups actively working on dietary supplement issues as well as the dietary supplement industry groups through a review of past GAO reports on dietary supplements, Internet searches for groups actively engaged in dietary supplement issues, referrals from agency officials, and interviews with other consumer groups and industry associations.

⁸For the purpose of this report, we use the term “enforcement” to refer to actions an agency takes against a dietary supplement firm or product after a violation has been identified—this includes advisory communications and regulatory actions (administrative and judicial court actions) taken by FDA as well as administrative court and judicial court actions taken by FTC.

⁹At the time we undertook our review in 2016, FDA and FTC were able to provide information on actions taken through 2015; complete data for 2016 were not available at the time we concluded our audit work. According to FTC staff, the agency took no actions involving memory supplements in 2016. We subsequently received information about two memory supplement-related actions taken by FTC in 2017, shortly before the issuance of this report; we included information related to these actions, as appropriate. Also, in February 2017, FTC issued a consumer alert about scams involving deceptive “brain booster” supplement advertisements that mimic news websites and rely on fake endorsements from public figures to promote their products.

on memory supplement enforcement actions as well as the responses from FDA and FTC officials to our questions about these data, we determined these data to be sufficiently reliable for the purposes of providing the number of enforcement actions taken by each agency that involved dietary supplements as well as the number of enforcement actions taken by each agency that involved memory supplements.

To identify what challenges FDA and FTC face in overseeing memory supplements, we interviewed agency officials, consumer groups, and industry groups, and reviewed relevant documentation. We analyzed top-marketed memory supplements to identify potential new dietary ingredients (NDI), and asked FDA officials to confirm whether the supplements contained an NDI and whether a notification was filed with FDA for the product, to the extent possible. Where applicable, we also assessed FDA and FTC oversight issues and challenges against federal internal control standards for communicating quality information with external parties to achieve objectives. For more detailed information on our methodology, see appendix I.

We conducted this performance audit from February 2016 to May 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Memory Supplements

For the purpose of this review, we define a memory supplement as a dietary supplement that is intended to improve or in other ways positively affect memory, as exhibited by the claims on its label or advertising. Claims may involve proxies for memory loss such as cognitive function, brain power, and absentmindedness. There is no federal law specifically regulating or defining the subset of dietary supplements we refer to in this report as memory supplements.

There is no definitive source of data regarding dietary supplements, including memory supplements, on the market, since federal law does not require that dietary supplements be listed with FDA or another federal

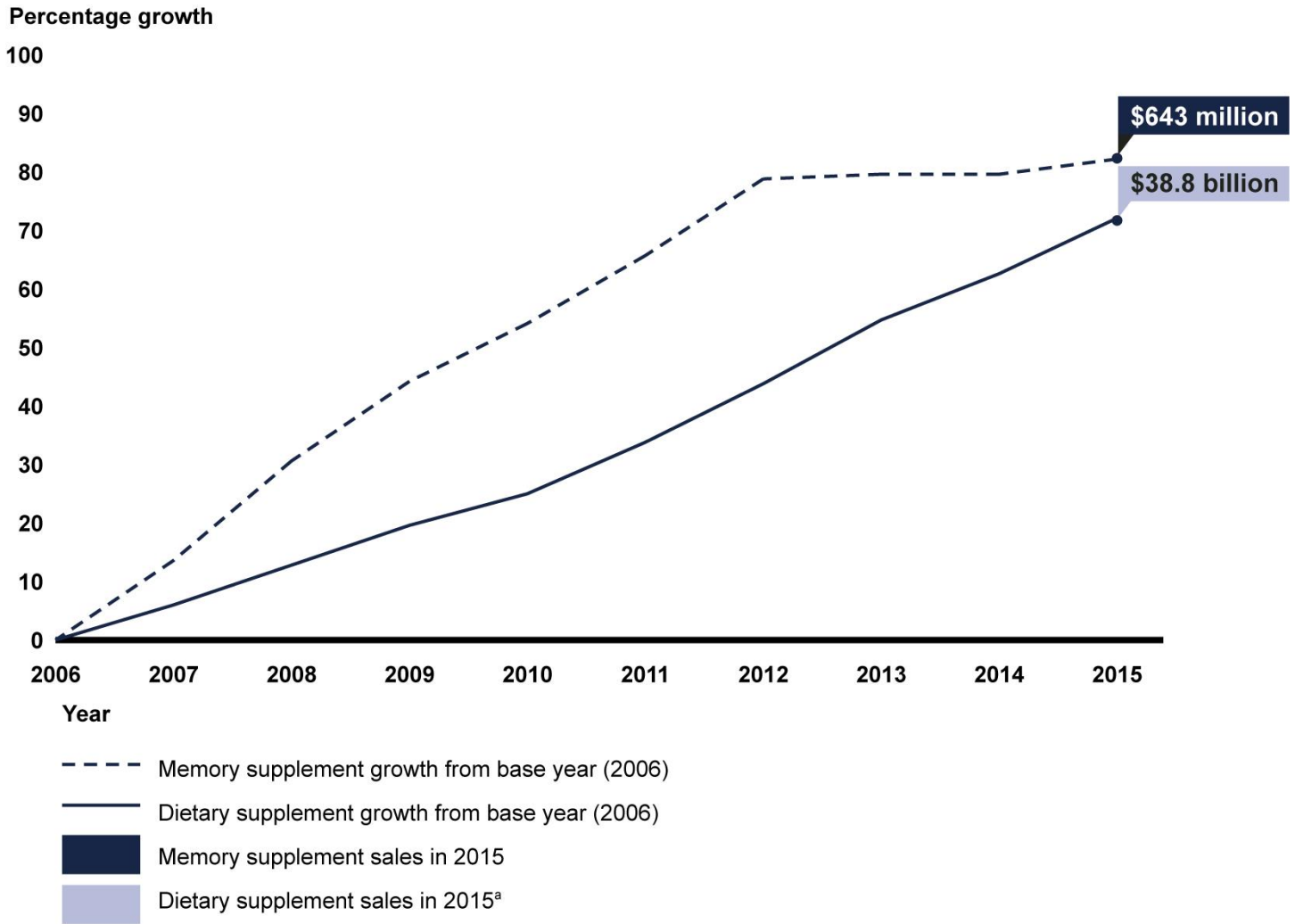
agency.¹⁰ However, available data indicate that memory supplements comprise a small segment of the overall dietary supplement market, but their number has grown substantially over the recent decade and they are valued in the hundreds of millions of dollars. Specifically, in 2015 memory supplement sales were estimated at \$643 million,¹¹ and accounted for nearly 2 percent of total dietary supplement sales in that year, approximated at \$39 billion.¹² As shown in figure 1, memory supplement sales nearly doubled in value from 2006 to 2015—a larger increase than for dietary supplements overall.

¹⁰While food facilities, including manufacturers and distributors of dietary supplements, are required to register with FDA, federal law does not require that dietary supplements be listed with FDA or another federal agency.

¹¹Nutrition Business Journal, *Mental Acuity Health Condition Specific Supplement, Pharmaceutical Sales* (Boulder, Colo.: Penton Media, Inc., 2016), chart 116.

¹²Nutrition Business Journal, *Supplement Category Sales by Channel* (Boulder, Colo.: Penton Media, Inc., 2016), chart 64.

Figure 1: Growth in Sales of Memory Supplements and Dietary Supplements, 2006 through 2015



Source: GAO analysis of National Business Journal consumer sales data. | GAO-17-416

^aDietary supplement sales includes all sales, including memory supplements.

The number of dietary supplements on the market has grown exponentially, from an estimated 4,000 products in 1994¹³ to an estimated

¹³According to the Dietary Supplement Health and Education Act of 1994, the estimated 600 dietary supplement manufacturers in the United States produced approximately 4,000 products, with total annual sales of such products alone reaching at least \$4 billion at that time.

80,000 in 2016,¹⁴ according to FDA officials. Dietary supplement data from the National Institutes of Health estimate the number of memory supplement products at almost 500 in 2016, though officials believe this is likely a low estimate.¹⁵

Memory supplement firms¹⁶ may market their products in numerous ways, including through advertisements on television, in print, and on the Internet, as well as placement of products and displays in stores. Consistent with general definitions, in this report the term “marketing” includes all general promotional practices such as those listed above, whereas “advertising” is a subset of marketing that refers to promotional materials, such as Internet product reviews, television commercials, print advertisements, or in-store visual displays.

Oversight Agencies and Federal Requirements for Dietary Supplement Safety, Labeling, and Claims

FDA and FTC share oversight¹⁷ responsibility for the marketing of dietary supplements and their claims—with FDA generally taking responsibility for labeling¹⁸ claims and FTC generally taking responsibility for claims made in product advertising. FDA and FTC authorities related to dietary

¹⁴The total number of dietary supplements on the market is estimated to be over 90,000, according to the Natural Medicines Comprehensive Database. Natural Medicines Comprehensive Database, *About Natural Medicines Comprehensive Database*, accessed March 30, 2017, <http://naturaldatabase.therapeuticresearch.com>. According to the Centers for Disease Control and Prevention, over one-half of U.S. adults consumed dietary supplements between 2003 and 2006. Centers for Disease Control and Prevention, “Dietary Supplement Use Among U.S. Adults Has Increased Since NHANES III (1988-1994),” *NCHS Data Brief*, April 2011, accessed March 30, 2017 at <https://www.cdc.gov/nchs/data/databriefs/db61.pdf>.

¹⁵Estimate of memory supplements based on search of the Dietary Supplement Label Database.

¹⁶For the purposes of this report, dietary supplement firms are companies that manufacture, distribute, package, or store dietary supplement products. Similarly, memory supplement firms are companies that manufacture, distribute, package, or store memory supplement products.

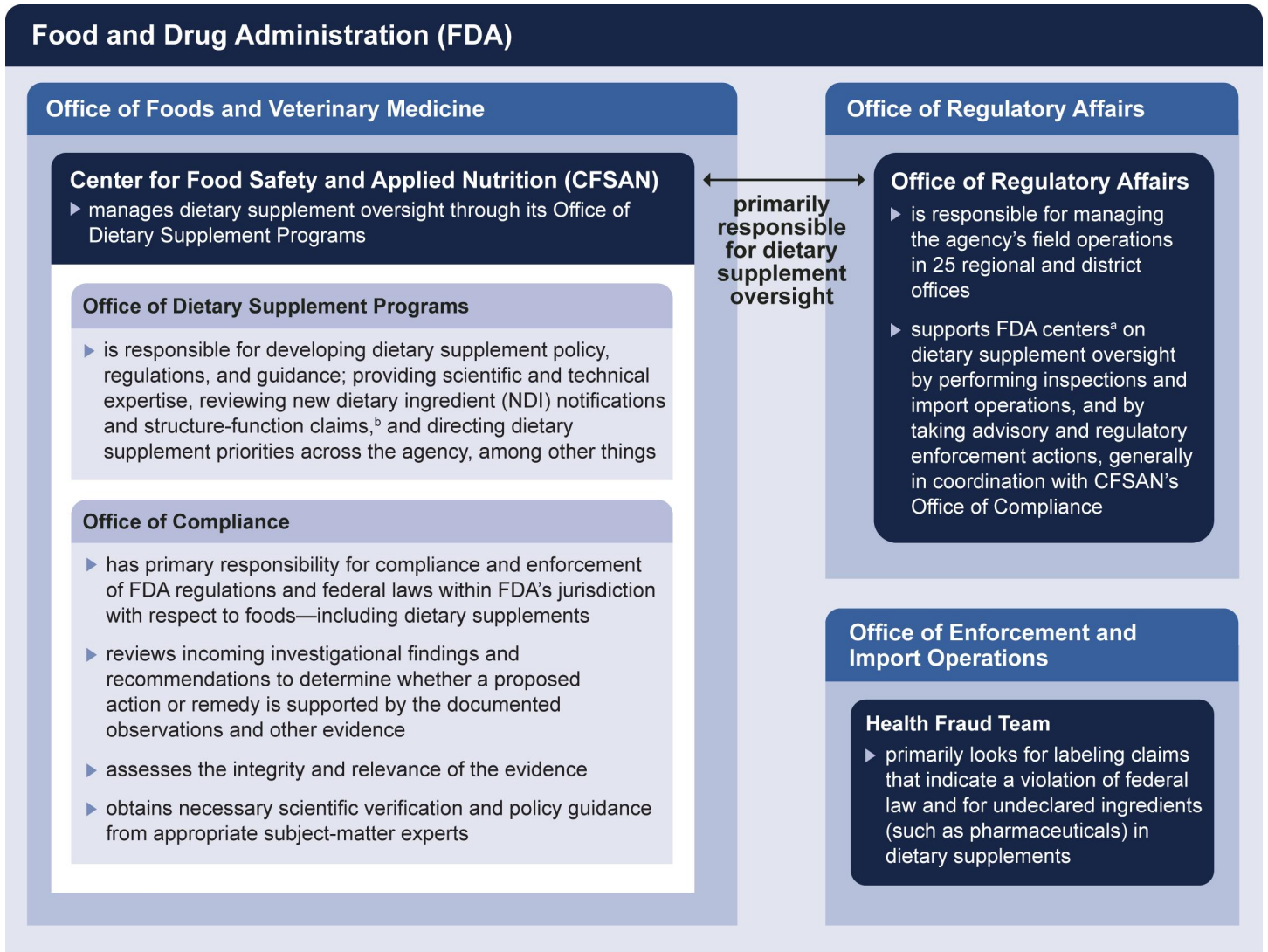
¹⁷For purposes of this report, we define oversight to include surveillance (monitoring), enforcement, and outreach.

¹⁸The term “labeling” means all labels and other written, printed, or graphic matter (1) on a dietary supplement product or any of its containers or wrappers, or (2) accompanying the product. 21 U.S.C. § 321(m).

supplements are generally limited to after dietary supplements go to market (postmarket). In general, neither agency has premarket authority that allows for approvals of labeling or advertising claims before dietary supplements may be sold to consumers, although as explained below, under relevant provisions of FDA regulations, firms may not make health claims that FDA has not authorized.¹⁹ Under DSHEA, FDA does not have the authority to require dietary supplements to be approved for safety or effectiveness before they are sold to consumers, as it does for drugs. Additional details about FDA oversight of supplements can be found in figure 2.

¹⁹Although FDA authorities distinguish between drugs and foods, FTC's authorities generally make no such distinctions. In 1999 a federal appeals court held that the First Amendment does not permit FDA to prohibit a potentially misleading health claim on the label of a dietary substance unless FDA first considers whether a disclaimer on the product's label could negate the potentially misleading nature of the claim. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). In response, FDA established procedures for exercising its enforcement discretion to not pursue health claim on labels under certain conditions. Petitions for these qualified health claims would be evaluated using an evidence-based ranking system that would rate the strength of the publicly available scientific evidence in support of the claim. A claim would be denied if there was no credible evidence to support it. Otherwise, based on the competent and reliable scientific evidence in support, a claim would be assigned by FDA to one of four ranked levels—the first level being “significant scientific agreement among qualified experts” and the remaining three levels being for claims supported by some lower level of credible evidence. Each of these lower three categories would require specific qualifying language. FDA would send a letter to the petitioner describing conditions for the use of the health claim and indicating that the agency would pursue the claim as a violation of the health claims provisions of Federal Food Drug and Cosmetic Act. For more details see GAO, *Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims*, [GAO-11-102](#) (Washington, D.C.: Jan. 14, 2011).

Figure 2: FDA Oversight Roles and Responsibilities



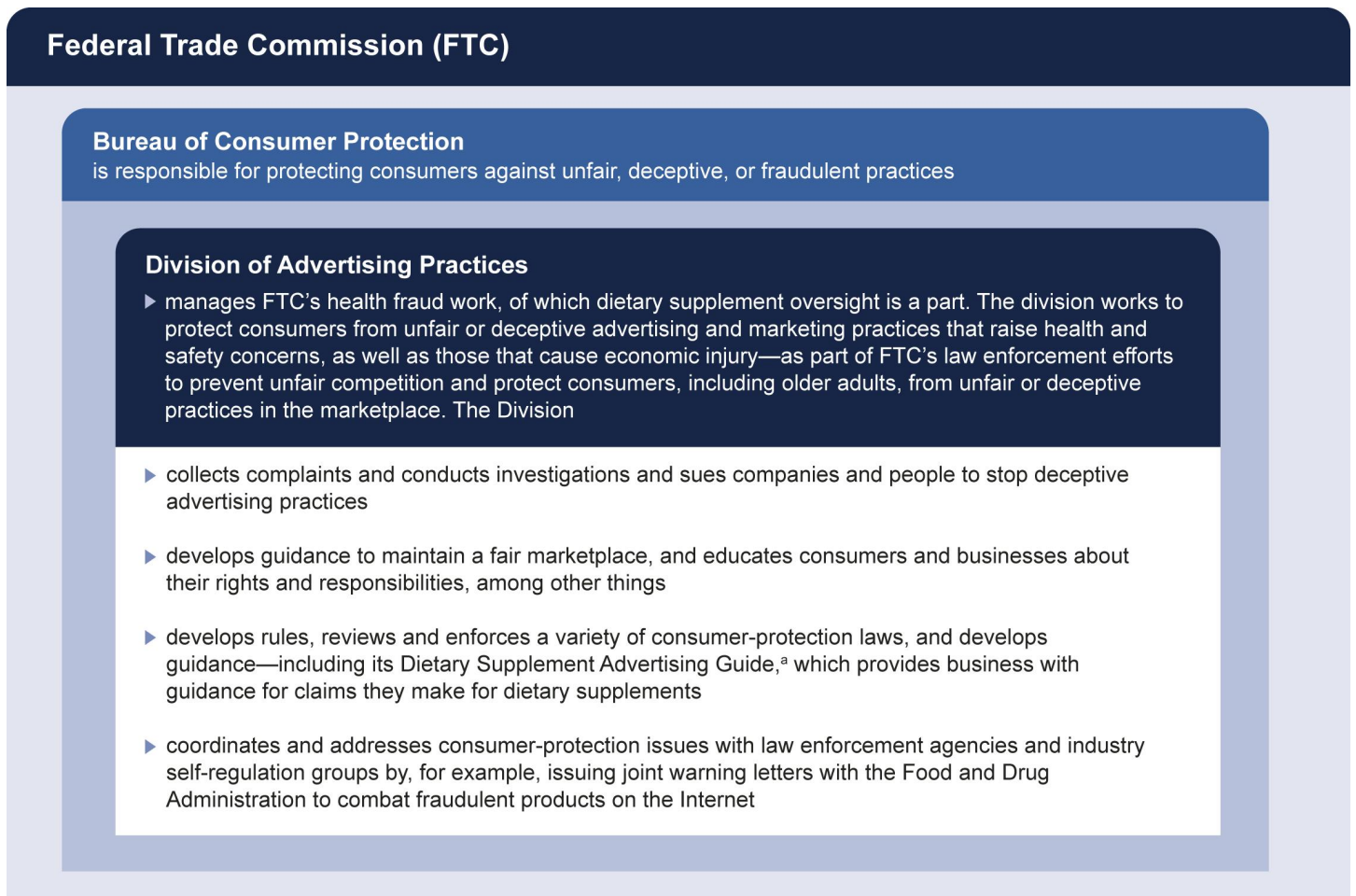
Source: GAO analysis of FDA information. | GAO-17-416

^aOther FDA centers include the Center for Drug Evaluation and Research, which is responsible for oversight of over-the-counter and prescription drugs. Center for Drug Evaluation and Research officials work with other FDA offices to identify products that are marketed as dietary supplements but are not because, for example, they do not contain any "dietary ingredients" or contain active ingredients in FDA-approved drugs.

^bStructure-function claims describe the role of substances intended to affect the normal structure or function in humans, for example, "calcium builds strong bones."

Additional details about FTC oversight of supplements can be found in figure 3.

Figure 3: FTC Oversight Roles and Responsibilities



Source: GAO analysis of FTC information. | GAO-17-416

^aAll companies—including marketers of dietary supplements—must comply with truth-in-advertising requirements. One guide, FTC's *Dietary Supplements: An Advertising Guide for Industry*, explains how to make sure such claims have appropriate scientific support.

Dietary supplement firms must meet federal requirements for dietary supplements related to safety, quality, and labeling elements, including the following:

Quality Requirements. FDA established current good manufacturing practice regulations for dietary substances describing the conditions

under which supplements must be manufactured, packed, labeled, and held. These requirements were implemented in phases, according to company size, and became fully effective in 2010.

Required Labeling Elements. FDA regulations implementing DSHEA require that dietary supplement labels include, among other things, a statement of identity that identifies the product as a supplement, a list of ingredients present in significant amounts and the quantity of such ingredients in the product.²⁰ Since December 2007, the Federal Food, Drug, and Cosmetic Act, as amended by the 2006 Dietary Supplement and Non-prescription Drug Consumer Protection Act, has required dietary supplement manufacturers, distributors, or packers (dietary supplement firms) to include on the dietary supplement product label several elements, including the firm's name and a domestic phone number or domestic address for individuals to submit an adverse event report to the manufacturer, packer, or distributor whose name appears on the product label as a way, according to FDA officials, to enhance FDA's ability to identify and act on public health issues associated with the use of dietary supplements.²¹

FDA Labeling Claim Requirements. Under federal law, firms can make certain labeling claims about dietary supplements but are generally prohibited from claiming that a supplement can treat, cure, or prevent a disease (such claims are referred to as disease claims). Allowable claims for foods are generally either: structure-function and related types of claims, health claims, or nutrient content claims. The Federal Food, Drug, and Cosmetic Act stipulates that the firm submit structure-function and related types of label claims to FDA for review within 30 days of the

²⁰Products may include "proprietary blends," which must list all ingredients but do not need to list the amount of each ingredient.

²¹The act requires that dietary supplement firms with their names appearing on the supplement label report information about any serious adverse event report they receive to FDA within 15 business days of receipt. As defined in the act, serious adverse events include any health-related events that result in, for example, a death, life-threatening experience, inpatient hospitalization, or birth defect, or that require, based on reasonable medical judgment, a medical or surgical intervention to prevent these serious outcomes. The act does not require firms to report moderate or mild adverse events, such as gastrointestinal distress or headaches, but firms may do so voluntarily. Under the act, firms are also required to maintain records on each report of an adverse event (whether serious or not) for 6 years and allow HHS officials access to these records during an inspection or other limited circumstances. The act also requires dietary supplement firms to provide FDA follow-up medical information received within 1 year after the initial serious adverse event report.

dietary supplement's first being marketed with the claim. FDA reviews the claims that firms make about dietary supplements, including the following:

- **Structure-function and related types of claims:** Structure-function claims describe the role of substances intended to affect the normal structure or function in humans.²² An example of a structure-function claim would be “calcium builds strong bones.” Related types of claims include those related to a classical nutrient deficiency disease for which the prevalence of such disease in the United States is disclosed with the claim, and general well-being claims from the consumption of a dietary ingredient. DSHEA requires that the manufacturer have substantiation that structure-function claims in labeling are truthful and not misleading. This requirement is consistent with FTC’s requirement that advertising claims be truthful, not misleading, and substantiated.
- **Health claims:** Health claims characterize the relationship between a substance (food or food component) to a disease or health-related condition.²³ To make a health claim, the firm must first present FDA with a petition or notification that contains scientific evidence supporting the proposed claim, and FDA must authorize the claim before it can be made. Health claims are limited to express or implied claims about disease risk reduction and cannot be claims about the cure, mitigation, treatment, or prevention of disease. For example, “Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber,” characterizes the reduced risk of the disease and has been authorized by FDA. In addition, in response to a federal appeals court ruling, FDA allows “qualified health claims.” Qualified health claims are health claims not authorized as health claims but for which the agency has stated its intention to exercise enforcement discretion (i.e., to refrain from taking enforcement action) under certain circumstances. Qualified health claims must include qualifying language that characterizes the level of evidence supporting the health claim, as well as any other information necessary to prevent the claim from being misleading. FDA reviews a qualified health claim petition and responds with a letter of enforcement discretion that outlines the level of evidence the agency found and the conditions

²²21 C.F.R. § 101.93.

²³21 C.F.R. § 101.14(a)(1).

under which the claim may be used, or a letter of denial if the claim is not supported by credible evidence. For example, FDA has issued a letter stating it intends to consider exercising enforcement discretion for, among other claims, “consumption of phosphatidylserine may reduce the risk of dementia in the elderly.”

- **Nutrient content claims:** Nutrient content claims describe the level of a nutrient in a food using terms such as “free,” “high,” or “low,” or they compare the level of a nutrient in a food to that of another food, using terms such as “more,” “reduced,” or “light.”²⁴ For example, a statement such as “only 200 mg of sodium” characterizes the level of sodium as being low and would have to conform to the criteria of an appropriate nutrient content claim or carry a disclosure statement. The Nutrition Labeling and Education Act of 1990²⁵ permits the use of nutrient content claims if they have been authorized by FDA and are made in accordance with FDA’s authorizing regulations.

FTC Requirements for Advertising Claims. In regulating advertising, according to FTC guidance, all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims. To this end, FTC may take actions against supplement manufacturers as well as advertising agencies, distributors, retailers, catalog companies, infomercial producers, and others involved in promotions it deems as deceptive. In addition, while FDA’s laws and regulations governing structure-function claims, health claims, and nutrient content claims do not apply to the FTC and its authority over advertising, structure-function claims must be truthful and not misleading, and they must be substantiated by competent and reliable scientific evidence. Further, according to FTC guidance, the agency generally defers to FDA authorizations of health claims and generally applies FDA’s definitions for nutrient content claims to advertising.

New Dietary Ingredients. Under DSHEA,²⁶ dietary supplement firms with an NDI—an ingredient that was not marketed in the United States before

²⁴21 C.F.R. § 101.13.

²⁵Pub. L. No. 101-535, 104 Stat. 2353.

²⁶Under section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b(a)(2)), as added by DSHEA, the manufacturer or distributor of a new dietary ingredient (NDI) that has not been present in the food supply as an article used for food, or a dietary supplement containing such an NDI, must submit a premarket safety notification to FDA at least 75 days before introducing the product into interstate commerce.

October 15, 1994—may be required to notify FDA at least 75 days before marketing the product, depending on whether this ingredient has been present in the food supply. The NDI notification should include information showing that the product containing the ingredient is reasonably expected to be safe. The NDI notification process is not a premarket approval process, and, as with other dietary supplements, to find that an NDI is adulterated, FDA must demonstrate that there is inadequate information to ensure a supplement containing an NDI does not present a significant or unreasonable risk of illness or injury. There has been a long-standing effort by FDA to issue guidance to industry on the NDI notification process. We recommended in previous reports issued in 2009 and 2013 that FDA issue NDI guidance.²⁷ FDA issued draft guidance in 2011 and revised draft guidance in August 2016, but this guidance has not yet been finalized and FDA is in the process of reviewing public comments on it.

Over the years, GAO has issued multiple reports and testimonies related to dietary supplement safety, labeling, and claims. For example, in 2010, we found potentially deceptive marketing about dietary supplements, including potential disease claims.²⁸ Similarly in 2011, we reported that consumers find it difficult to understand the differences among claims and that consumers are just as likely to purchase a product with a structure-function claim (which FDA does not verify) as they are to purchase a product with a health claim supported by significant scientific agreement (which FDA does verify).²⁹ Based on our findings in 2011, we recommended that FDA provide guidance to industry on the level of scientific evidence to substantiate structure-function claims, and also recommended that FDA pursue legal authorities to allow the agency to obtain evidence for claims from food companies (including dietary supplement firms). Lastly, we also recommended that FDA provide additional guidance to inspectors for identifying potentially false or

²⁷GAO, *Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products*, [GAO-13-244](#) (Washington, D.C.: Mar. 18, 2013). The 2009 report including a recommendation on issuing NDI guidance is GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, [GAO-09-250](#) (Washington, D.C.: Jan. 29, 2009).

²⁸GAO, *Herbal Dietary Supplements: Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice*, [GAO-10-662T](#) (Washington, D.C.: May 26, 2010).

²⁹[GAO-11-102](#).

deceptive structure-function claims on labels. FDA did not implement these recommendations, citing competing priorities.³⁰

Oversight Activities

As described above, FDA and FTC share responsibility for oversight of dietary supplements and related marketing, with FDA generally responsible for safety, quality, and labeling, and FTC generally responsible for advertising. The coordination of FDA and FTC oversight authorities is delineated in a 1971 memorandum of understanding designed to afford maximum protection to the consumer.³¹ Under the memorandum of understanding, FDA and FTC each designate a liaison to serve as the primary contact to coordinate activity as needed, such as when similar claims are found in both labeling and advertising, or when marketing material may be construed as either advertising or labeling, or both. The memorandum of understanding specifies that FDA has primary responsibility for preventing the misbranding of foods, among other items, shipped in interstate commerce and will exercise primary jurisdiction over all matters regulating the labeling of foods (which includes dietary supplements); and that FTC has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods (including dietary supplements), among other things,³² and will exercise primary jurisdiction over all matters regulating the truth or falsity of advertising of foods. Dietary supplement labeling under FDA's primary jurisdiction includes, among other things, packaging, inserts, and information at the point of sale.

In overseeing dietary supplements and related marketing, FDA and FTC conduct a variety of activities—including surveillance, enforcement, and outreach to industry and the public—related to the safety and quality of

³⁰The 2011 report covered labeling of foods, including dietary supplements, but the scope was not exclusive to dietary supplement labeling issues. FDA has issued guidance, published in 2008, on dietary supplements and the level of evidence to substantiate claims, including structure-function claims, made under section 403(r)(6) of the Federal Food, Drug and Cosmetics Act.

³¹This memorandum of understanding, which covers an indefinite period of time and may be modified by mutual consent, has not been updated or modified since it was signed in 1971.

³²These other things include drugs (with the exception of prescription drugs), devices, and cosmetics, according to the memorandum of understanding between the agencies.

dietary supplements as well as the validity of labeling claims and the truthfulness of dietary supplement advertising.

- Surveillance.** To identify potential safety or quality concerns related to dietary supplements, both agencies conduct surveillance activities to monitor dietary supplement firms and markets. These surveillance activities may result in enforcement actions and related outreach. FDA primarily relies on postmarket surveillance efforts, such as monitoring reports of health problems or adverse event reports it receives from industry, health-care practitioners, and individuals; reviewing consumer and industry complaints; and conducting inspections of dietary supplement firms. Similarly, FTC relies on postmarket surveillance efforts, such as its Consumer Sentinel Network that collects reports from consumers about potentially deceptive or untruthful advertising, according to agency officials; and conducting routine Internet monitoring for a range of potential advertising violations. Examples of FDA and FTC surveillance actions are listed in table 1.

Table 1: Examples of Food and Drug Administration (FDA) and Federal Trade Commission (FTC) Surveillance Actions

Type of action	Description
Complaints	<p>Consumers or other parties can contact FDA to submit complaints about FDA-regulated products by phone. Complaints may address any aspect of a product including, but not limited to, an adverse event. In one instance, a complaint indicated that the dropper dispenser in a liquid dietary supplement broke during use. In another instance, a complaint indicated that a fish oil dietary supplement had a rotten fish smell.</p> <p>FTC receives complaints about specific products from consumer health advocates, industry self-regulatory groups, industry competitors, law enforcement organizations, federal agencies, and state attorneys general, among others. Individual consumers may also contact FTC directly. FTC manages the Consumer Sentinel Network, an online database of consumer complaints available only to law enforcement organizations, from which complaints may also be identified.</p>
Inspections ^a	<p>FDA inspects firms that manufacture, pack, or hold dietary supplements for compliance with current good manufacturing practice regulations, among other things. There are four general types of inspections: (1) routine surveillance, (2) consumer complaint investigations, (3) for-cause compliance inspections, and (4) follow-up to a regulatory action. According to FDA officials, an inspection may include product examinations, sampling, and testing, as well as the inspection of the firm and facility involved with dietary supplements.</p> <p>FTC does not conduct inspections of firms.</p>
Internet monitoring	<p>FDA monitors the Internet for dietary supplement labeling violations, for new dietary ingredient initiatives, and to identify products marketed as dietary supplements that are fraudulently promoted as drugs for treating disease.</p> <p>FTC routinely monitors digital and viral marketing, including the Internet, to identify advertising campaigns likely to have the most substantial consumer impact. FTC also partners with law enforcement agencies and FDA to identify specific health problems, such as Zika virus, that may be the subject of particularly widespread fraud by online marketers—based on this, FTC identifies specific targets for coordinated Internet reviews.</p>

Market survey	<p>FDA staff conduct proactive market surveys when there is concern with an ingredient or type of product and focus on particular target areas in the market, including the Internet. These surveys are initiated to help the agency understand how widespread an ingredient is and how many products have the ingredient, or based on “hot topics” that are generating new or more products in the marketplace, such as Severe Acute Respiratory Syndrome (SARS) or Zika virus. These surveys include Internet market scans to provide product label information, according to FDA officials.</p> <p>FTC routinely monitors major television and print media to identify national advertising campaigns that are likely to have the most substantial consumer impact. It also watches for emerging trends in trade press and at industry conferences and meetings.</p>
Reports	<p>Firms must notify FDA of structure-function and related types of claims within 30 days after marketing, submit health claims and nutrient content claims for pre-authorization, submit notifications with safety information for certain NDIs, and report serious adverse events.^b</p> <p>Consumers may submit complaints about potentially fraudulent claims and products directly to FTC through FTC’s website.</p>

Source: GAO analysis of FDA and FTC information. | GAO-17-416

^aFDA uses a risk-based approach to inspect firms that manufacture foods, including dietary supplements. According to FDA officials, and consistent with the FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 201(a), 124 Stat. 3885, 3922 (2011) (adding 21 U.S.C. § 350j(a)), the agency inspects firms it deems as high risk once every 3 years and other firms once every 5 years.

^bFirms are required, under the Federal Food, Drug and Cosmetic Act, to report serious adverse events to FDA within 15 days and to report follow-up medical information received about serious adverse events to FDA within 1 year after the initial report.

- **Enforcement.** FDA and FTC both take enforcement³³ actions against dietary supplement products and firms if they identify violations.
 - Once FDA identifies a concern, it may take enforcement action against a firm through advisory and regulatory actions. Advisory actions—such as sending a warning or untitled letter³⁴ to a dietary supplement firm that manufactures, distributes, or packs a dietary supplement—notify firms that FDA has found the firm uncompliant with dietary supplement manufacturing or labeling regulations.³⁵ Regulatory actions are actions that either restrain dietary supplement firms from manufacturing dietary supplements or remove specific dietary supplements from the market, or prevent

³³For the purpose of this report, we use the term “enforcement” to refer to actions an agency takes against a dietary supplement firm or product after a violation has been identified—this includes advisory communications such as warning letters and regulatory actions (administrative and judicial court actions) such as injunctions taken by FDA as well as administrative court and judicial court actions taken by FTC. FDA officials told us that they do not always use the term enforcement in the same manner.

³⁴Untitled letters are used for less serious violations than warning letters, and also communicate that corrective action is needed.

³⁵Firms have 15 days after receiving a warning letter to begin working with FDA to resolve infractions to avoid further enforcement action. Similarly, FDA officials said they request that firms respond to an untitled letter in 30 days.

entry into U.S. commerce of imported products. Among the regulatory actions available to FDA are administrative enforcement tools such as issuing a mandatory recall,³⁶ suspending a firm's registration, administratively detaining a product, or refusing entry to an imported product; judicial court actions such as seeking an injunction against a firm, initiating prosecution of a firm, or filing a seizure action against products that are adulterated, misbranded, or otherwise in violation of federal law; and conducting rulemaking to restrict or prohibit the use of a specific ingredient. In any of these cases FDA must demonstrate that the relevant statutory standard has been met. For example, FDA can take a variety of the above actions if a dietary supplement is adulterated, which can be established by, for example, demonstrating that it, or a dietary ingredient contained within, presents a significant or unreasonable risk of illness or injury.³⁷

- Under its responsibilities, once FTC identifies potentially deceptive or untruthful advertising, it may take enforcement action against a firm or individual through administrative court actions or judicial court actions. Before taking such action, FTC may compel firms to produce documents and other information, such as marketing and labeling materials, sales information, and relevant substantiation materials. Administrative court actions are complaints issued by FTC that are adjudicated before an administrative law judge. These complaints may result in settlements through consent decrees or, in subsequent actions in a federal judicial court to enforce administrative orders, injunctions, and civil penalties.

³⁶FDA may initiate a mandatory recall if the responsible party refuses to conduct a voluntary recall after FDA has determined that there is a reasonable probability that food (including a dietary supplement or dietary ingredient) is adulterated or is misbranded for failure to declare a major allergen on the label, and the use of or the exposure of the dietary supplement will cause serious adverse consequences or death to humans or animals.

³⁷FDA can also establish that a dietary supplement is adulterated in other ways; for example, by showing that the supplement has been prepared, packed, or held under conditions that do not meet the current good manufacturing practice regulations. FDA could also demonstrate that a new dietary ingredient is adulterated by showing that there is inadequate information to provide a reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Federal judicial court actions are direct challenges in a district court and can result in injunctions and monetary relief.³⁸

Outreach. To help inform the public—including both consumers and industry—about potential health or safety issues related to dietary supplements, FDA and FTC conduct various outreach efforts. Such efforts can be educational outreach or outreach conducted in response to a specific enforcement action taken by one or both of the agencies. Examples of key outreach efforts include consumer or public education (such as alerts about Internet scams or safety problems), guidance for industry or consumers (such as on how firms can make sure their dietary supplement claims have appropriate scientific support), and publicly available press releases (such as those informing the public about the results of enforcement actions like court injunctions or product recalls that warn the public and, according to FDA officials, aim to prevent similar violations in the future).

Most Memory Supplements Were Marketed on the Internet, and, While Few Advertisements Targeted Older Adults, Some May Have Violated Federal Requirements

Most of the memory supplement marketing we identified was on the Internet, with few examples that included text or visuals (images and videos) targeting older adults. FDA determined the potential disease-related claims we identified may have violated federal requirements.

Most Examples of Memory Supplement Marketing Were on the Internet, and Few Advertisements Explicitly Targeted Older Adults

We found during our market review that memory supplements were primarily marketed on the Internet, with few advertisements containing

³⁸Federal judicial court orders can be permanent, whereas administrative court orders typically expire after 20 years, according to FTC officials.

text or visuals targeting older adults.³⁹ We identified 490 memory supplement products associated with 1,590 total examples of memory supplement marketing through a review of five media channels over a 2-month period.⁴⁰ Specifically, as table 2 below indicates, about 96 percent of marketing we identified appeared on the Internet.⁴¹ Internet advertisements accounted for 454 products identified and 1,530 of the marketing examples. Our findings from the market review and analyses conducted cannot be projected to all memory supplements or dietary supplements on the market.

³⁹Marketing consists of activities, such as product labeling, over which FDA exercises primary jurisdiction, and advertising (other than labeling), over which FTC exercises its primary jurisdiction, used by companies to promote their products to consumers. For example, companies may select stores to sell their product in, in-store shelf placement, and pay to include product advertisements in media channels, such as the Internet, television, and magazines. For the purpose of our review we will use these terms as follows: (1) marketing refers to general promotional practices such as product labeling, in-store product placement, and selecting television networks and Internet search engines to advertise products, and (2) advertising refers to marketing practices used in media channels to visually or verbally promote a product to consumers, such as Internet product reviews, television commercials, print advertisements, or in-store visual displays. While we use the term “advertising” as described here for the purposes of our report, it is important to note that from an oversight perspective, there are some cases where advertisements may also meet the definition of labeling, including Internet advertisements.

⁴⁰We reviewed the memory supplement market, specifically (1) the Internet, (2) retail store products and displays, (3) television, (4) magazines, and (5) newspapers, to identify memory supplement products and to review how these products are marketed. We selected the media channels to review using demographic and survey data relevant to older adults. Specifically, we identified retail stores based on proximity to selected senior living facilities, Internet search engines identified by older adults as being used to research health concerns online, and magazines with highest readership by older adults. We also identified three television networks to review using data on top shows for older adults, and Sunday newspapers from selected cities across the United States with the highest total print circulation. Our review of the memory supplement market cannot be projected to all memory supplements on the market (meaning available for purchase).

⁴¹We did not assess the marketing to determine the extent of consumer exposure or impact on product sales.

Table 2: Review of Memory Supplement Marketing by Media Channel

Media channels reviewed	Total instances of product marketing identified ^a	Percentage of marketing identified on media channel (percent)	Unique memory supplement products identified on media channel
Internet	1,530	96.2	454
Retail stores	56	3.5	43
Television	4	0.2	1
Magazines	0	0.0	0
Newspapers	0	0.0	0
Total	1,590	100.0^b	490^c

Source: GAO analysis of market review. | GAO-17-416

^aFor the purposes of our review, we defined marketing as including advertisements, in-store placement or displays, and product label content.

^bThe percentage of marketing identified does not equal the total percentage due to rounding.

^cThe total number of unique products identified (490) excludes duplicate products across media channels. For instance, a product could be identified on the Internet and also on television and counted as a product identified in both media channels in the table. However, the product would only be counted once for the total. For this reason, the total number of unique products is less than the sum of unique products by media channel.

Memory supplement advertisements we identified generally contained claims that products would boost, enhance, improve, increase, or maintain a healthy memory. Advertisements also contained claims related to general brain health, cognitive function, and well-being. For 91 unique memory supplement products, we identified labels or advertisements that contained sufficient information for us to review to identify examples of claims and marketing practices.⁴² We reviewed these results to identify examples of claims that products are clinically proven or studied and any references to evidence supporting the claim. Specifically:

- Of the 91 product labels and advertisements reviewed, 37 included claims that the product had been clinically proven or studied.

⁴²We determined the claims information was sufficient to review if the associated product met the definition of a memory supplement (as defined for the purposes of this review) and the claims information was at the product level, specifically the benefits are associated with taking the product. For example, an advertisement containing a product that states, “product X can prevent memory loss” would be deemed sufficient for review. We did not evaluate product claims for accuracy and truthfulness or product effectiveness.

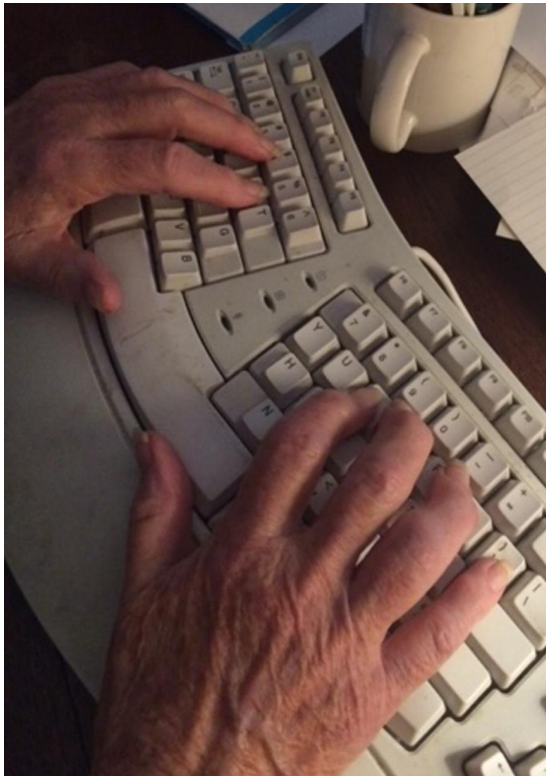
-
- Further, 24 of the 37 labels and advertisements claiming to be clinically proven or studied contained statements referencing supporting evidence.⁴³

Also, we identified examples of memory supplement advertisements on the Internet containing text and visuals (e.g., images and videos) explicitly targeting older adults.⁴⁴ Specifically, of the 1,530 memory supplement advertisements we identified on the Internet, 138 (or 9 percent) contained text and visuals targeting older adults. Targeted advertisements claimed that products can reduce “senior moments,” make aging adults feel young again, and stay sharp through later years. The 138 targeted advertisements were associated with 93 memory supplement products, which is about 20 percent of the unique products we identified. Examples of targeted text identified in memory supplement advertisements on the Internet are shown in figure 4.

⁴³FDA officials told us that firms are not required to include statements describing the level of scientific evidence supporting claims on the product labels. However, both FDA and FTC confirmed that firms must have the supporting evidence in possession. FDA guidance suggests consumers contact firms about supporting evidence, but FDA and FTC staff noted that firms are not legally required to provide supporting evidence to consumers.

⁴⁴We reviewed the 1,530 Internet memory supplement advertisements for instances of advertisements explicitly targeting older adults, including broad marketing containing text and visuals, directly or indirectly associated with a memory supplement, that are likely to appeal to older adults. For example, advertisements mentioning common traits associated with aging, such as memory loss, and showing older adults in the marketing, but not explicitly stating the benefits of product use would still qualify as an advertisement targeted towards older adults. We also reviewed the Internet advertisements for visuals that would potentially encourage a consumer to purchase the product, for example a medical professional—person in lab coat—and older adult testimonials or endorsements.

Figure 4: Examples of Text Targeting Older Adults Found in Internet Advertisements



- “Are you 55 years of age or older?”
- “Losing your memory or developing brain fog in your 40s, 50s, 60s, 70s, or even 80s is NOT normal.”
- “Avoid those embarrassing senior moments.”
- “... designed to help to stay sharp through your later years.”
- “This can help combat age-related memory loss, brain fog, and mental fuzziness.”
- “Vital nutrients to preserve your memory as you age.”
- “Improve your memory, so you stay sharp and alert into your 70s, 80s, and 90s ...”
- “... memory support supplements are perfect for occasional mild memory problems associated with aging.”
- “There are many memory supplements, memory improvement medications, or memory enhancers, that fundamentally enhance memory, reduce the risk of age-connected memory misfortune, and also help concentration.”
- “Now you’ll be able to increase your memory abilities, slow down the process of aging, and sharpen your mental focus.”
- “This herb increases blood circulation in the brain and has been shown, in multiple clinical trials, to be useful for improving memory and cognition especially in the elderly.”
- “It has been shown to be helpful with many of the complaints of the elderly such as short-term memory loss, slow thinking and reasoning, occasional headaches, and dizziness.”

Source: GAO Internet search market review (examples); GAO Stock Photography (image). | GAO-17-416

Several of the targeted advertisements, specifically 32 of 138, also contained visuals, such as images of older adults engaging in active lifestyles or looking frustrated, older adult testimonials, or images of medical professionals. We shared examples of advertisements we identified that contained images of medical professionals with FTC staff, to obtain their opinion on the images and whether they might be considered deceptive. FTC staff noted that a picture of a medical professional may contribute to the impression that the claimed benefits are scientifically proven.⁴⁵ However, they explained that the FTC would not be able to determine whether the images are considered deceptive

⁴⁵FDA officials did not review the examples we shared, but they concurred that the use of an image can imply a claim, such as the intent to market as a drug, which could be problematic. FDA staff stated that when reviewing for potential claim violations they would review the context of the total claim (use of the image and words) to determine whether there is intent to market as a drug, based on the implied claims.

without conducting a full investigation, which includes a review of each advertisement and supporting evidence.⁴⁶

FDA Determined Potential Disease Claims We Identified May Have Violated Federal Requirements

Through our market review, we found 28 examples of advertisements containing memory supplements potentially making disease-related claims,⁴⁷ and these were associated with 34 products.⁴⁸ Twenty-two of these products were in advertisements identified on informational websites—product reviews or articles discussing the use of specific dietary supplement ingredients—and one product appeared in a magazine at a store. These memory supplement advertisements claimed products protect against, reduce the risk of, and assist with symptoms of dementia, Parkinson’s disease, or Alzheimer’s disease. Examples of potential disease-related claims we identified in Internet advertisements are shown in figure 5.

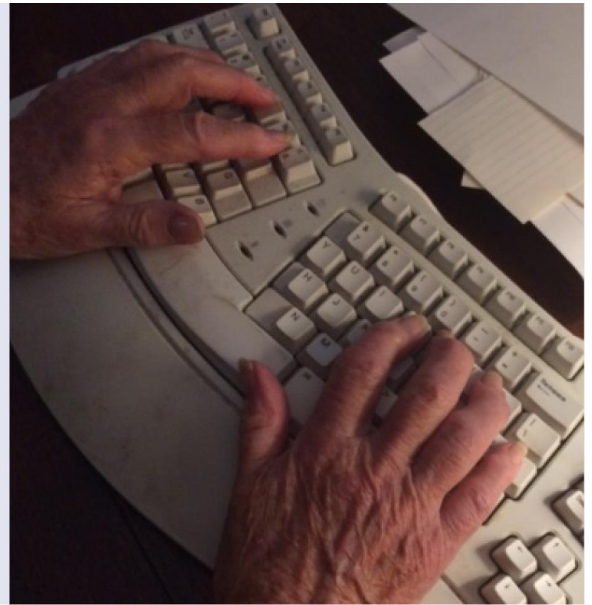
⁴⁶In June 2016, FTC published an Internet blog to consumers shopping online for health products, including dietary supplements, cautioning about websites using seals or certifications, specifically a “doctor trusted” seal with the image of a doctor, claiming that products on the site have been tested and evaluated. FTC found the websites’ advertising to be deceptive due to the paid doctors’ involved not evaluating product safety or effectiveness as claimed.

⁴⁷These 28 examples were identified through a targeted Internet search for memory supplement advertisements making claims related to diseases, and a review of the 1,590 memory supplement marketing examples identified in our market review (where claims language was available for review).

⁴⁸There were instances when an advertisement made claims for two or more memory supplement products. There were also instances when two or more advertisements contained the same product, in which case the product was counted once. For example, one advertisement contained four memory supplement products and a second advertisement contained one product that was identified in the first advertisement. In this instance, there were five total products contained in the two advertisements, but only four were unique products.

Figure 5: Examples of Potential Disease Related Claims Found in Internet Advertisements

- “Invest in yourself, protect & secure your future. Order anti-Alzheimer’s herbs.”
- “Improves Cognition and Behavioural Symptoms in Alzheimer’s patients.”
- “Consider it a preventive program for cancer, Alzheimer’s Disease and more.”
- “Studies indicate this supplement may help protect against age-related memory decline, including Parkinson’s disease.”
- “This herbal combination could reduce risk.”
- “It is also beneficial for those in initial and mid-stages of Alzheimer’s.”
- “Numerous studies have demonstrated curcumin’s ability to prevent the underlying processes involved in the disease.”
- “It is very helpful in the treatment of Alzheimer’s disease.”
- “Provides homeopathic aid in support of assistance with the symptoms of dementia.”
- “[W]e have compiled a list of the vitamins which have the most evidence for reducing the risk of developing Alzheimer’s or dementia as well as slowing their progress.”
- “... used in high doses ... to treat senile dementia. It may also be used for patients with Alzheimer’s disease.”



Source: GAO Internet search market review (examples); GAO Stock Photography (image). | GAO-17-416

We shared the 28 examples with FDA staff. After reviewing these potential disease-related claim examples, FDA preliminarily determined that 27 of the 28 examples appeared to be disease claims—claims to treat, cure, or prevent a disease—which are generally prohibited in the labeling of dietary supplements and cause the product to be regulated as a drug. As of March 2017, FDA officials reported that they had issued advisory letters to two firms who voluntarily complied with FDA’s concerns. FDA officials also reported that they would continue monitoring all of the examples that were identified. FDA identified the remaining example as a structure-function claim—a claim that describes the role of substances intended to affect the normal structure or function in humans—which, assuming other regulatory requirements are met, are allowable for dietary supplements.⁴⁹

⁴⁹We also shared the examples with FTC to get its opinion whether the claims are considered deceptive. FTC staff agreed some of the examples looked potentially problematic. However, FTC staff also could not comment on whether they are deceptive, as that determination requires a full investigation—independent review of examples, expert review of claims, and review of supporting evidence held by the firm or marketer.

Similar Types of Enforcement and Outreach for Memory Supplements Taken by FDA and FTC Align with Their Agency Priorities

FDA and FTC have taken similar types of enforcement actions for memory supplements as for other dietary supplements between 2006 and 2015—with FDA taking mostly advisory actions and a few regulatory actions (administrative and judicial court actions), and FTC taking a mix of administrative and judicial actions. Moreover, the agencies coordinate enforcement actions involving memory supplements in the same manner they do for all dietary supplements. In conducting outreach, FDA and FTC have at times conducted outreach efforts aimed at dietary supplement use by older adults, and the agencies have conducted some specific outreach about memory supplement enforcement actions. In prioritizing what enforcement actions to take and how to conduct outreach related to memory supplements, the agencies focus on safety and the egregiousness of deception or impact of the supplement's marketing, as they do with all dietary supplements.

FDA and FTC Have Taken Similar Types of Enforcement Actions for Memory Supplements as for Other Dietary Supplements

Between 2006 and 2015, FDA and FTC conducted similar types of enforcement actions for memory supplements as they did for other dietary supplements. Of the 551 dietary supplement actions taken by FDA, 19 involved memory supplements. Similar to its enforcement actions for other dietary supplements, the majority of the 19 memory supplement enforcement actions FDA took between 2006 and 2015 were advisory, namely notification by FDA that the agency has found the firm out of compliance with dietary supplement manufacturing or labeling regulations or with the prohibition against marketing an unapproved new drug. Specifically, these 19 memory supplement enforcement actions consisted

of 17 advisory actions (6 untitled letters and 11 warning letters) and 2 regulatory actions (1 injunction and 1 seizure),⁵⁰ as shown in table 3.

⁵⁰FDA conducted at least one inspection in 9 of the 19 memory supplement matters. FDA was not able to provide us with the total number of inspections that involved memory supplements, in part because FDA does not categorize dietary supplements by type of use, such as memory supplements. However, we were able to confirm through our analysis of FDA inspections data whether each memory supplement matter involved an inspection.

Table 3: Food and Drug Administration (FDA) Enforcement Actions, Fiscal Years 2006 through 2015

	Advisory Untitled letter ^a	Advisory Warning letter	Regulatory Injunction ^b	Regulatory Mandatory recall	Regulatory Seizure	Total
Memory supplements	6	11	1	0	1	19
Other dietary supplements	71	432	20	1	8	532
Total	77	443	21	1	9	551

Source: GAO analysis of FDA data. | GAO-17-416

^aUntitled letters notify firms that FDA has found the firm out of compliance with dietary supplement manufacturing or labeling regulations and provide an opportunity to take voluntary and prompt action to correct a violation. Untitled letters are used for less serious violations than warning letters.

^bWhen a violation is not corrected, FDA may initiate an action such as an injunction to enjoin a firm from continuing the problematic practice.

FDA’s two regulatory actions involving memory supplements consisted of one injunction and one seizure. FDA filed for an injunction in 2011 against a dietary supplement firm and its principals whose products’ advertising continued to contain prohibited claims to treat or cure Alzheimer’s, among other diseases, despite prior FDA warnings to stop making claims to treat the disease.⁵¹ Similarly, FDA brought action in federal court in 2012 to seize dietary supplements that were marketed for treating a variety of diseases or conditions, including dementia.⁵² In addition, FDA determined that the products were not manufactured according to the current good manufacturing practice regulations. FDA officials told us the agency has subsequently closed these cases. Such disease claims are no longer present on the memory supplement products’ websites and, according to FDA officials, the agency has not taken further public action on these cases.

FDA staff investigate and pursue actions against firms and products as individual safety concerns or other violations are identified. According to FDA officials within the Office of Dietary Supplement Programs—the office that leads and sets priorities for FDA dietary supplement enforcement efforts—the agency currently plans to prioritize actions against products presenting immediate safety concerns, given its limited

⁵¹A dietary supplement firm and its owners or principals signed a consent decree for permanent injunction by the U.S. District Court for the District of Minnesota on September 13, 2011, for violating the Federal Food, Drug and Cosmetic Act by marketing products as drugs without approval.

⁵²The court ordered the U.S. Marshals Service to seize dietary supplements and unapproved drugs from a New York firm.

resources, rather than focusing on actions against a specific therapeutic category of dietary supplements.⁵³

In terms of FTC enforcement actions involving memory supplements, the agency took some administrative and judicial actions involving memory supplements between fiscal years 2006 and 2015,⁵⁴ similar to its enforcement actions for other dietary supplements. Approximately 3 percent (2 of 78) of FTC's dietary supplement enforcement actions involved memory supplements, as shown in table 4.⁵⁵ These 2 FTC enforcement actions involving memory supplements included 1 administrative action and 1 judicial action.⁵⁶

⁵³According to Office of Dietary Supplement Program officials, the office has 26 staff and an annual budget of \$5 million, compared to a dietary supplement industry with an estimated value of \$40 billion and an estimated 80,000 different dietary supplement products.

⁵⁴In January 2017, FTC, along with the State of New York, filed a complaint in district court seeking an injunction against the marketers of a memory supplement widely marketed on television and the Internet for making false or unsubstantiated claims that the dietary supplement rapidly improves memory, provides cognitive benefit and is "clinically shown" to work. Specifically, the complaint alleges that the marketers of the dietary supplement relied on a study that failed to show the product works better than a placebo on any measure of cognitive function. This lawsuit is ongoing. In February 2017, FTC, along with the State of Maine, filed a complaint in district court seeking an injunction against the marketers of a separate dietary supplement for, among other things, allegedly using radio advertisements formatted as educational talk shows to advertise dietary supplements purporting to, among other things, improve memory. Specifically, the complaint alleges the marketers of this dietary supplement made false or misleading claims to improve memory by 44 percent, to improve memory in as little as 3 weeks, and is clinically proven to improve memory. The court prohibited the firms from making further false or unsubstantiated health claims, among other things. According to FTC officials, these actions were the only actions FTC took involving memory supplements since the end of 2015.

⁵⁵Approximately 60 percent of FTC enforcement actions related to dietary supplements involved weight loss supplements.

⁵⁶In addition to actions involving memory supplements, FTC officials told us they also pursued enforcement action against a broader category of cognitive products that included action against the marketers of brain games.

Table 4: Federal Trade Commission (FTC) Enforcement Actions, Fiscal Years 2006 through 2015

	Administrative ^a	Judicial ^b	Total
Memory supplements	1	1	2
Other dietary supplements	12	64	76
Total	13	65	78

Source: GAO analysis of FTC data. | GAO-17-416

^aAdministrative refers to administrative court actions.

^bJudicial refers to judicial court actions.

In 2014, FTC took an administrative action after it determined that advertising for a dietary supplement, that included claims that the supplement was “clinically shown to improve adult memory,” was not backed by adequate scientific evidence. The administrative action applied to two supplement firms responsible for the claims, and the settlement bars them from making such claims unless those claims are supported by reliable scientific evidence and clinical proof, among other things. In 2015, FTC took judicial action when it filed suit against a firm for deceptive advertising claims after finding that the claim that its supplement could, for example, “help users match the memory power of others 15 years younger in as little as 30 days!” were false, misleading, and unsubstantiated. According to FTC officials, the agency discovered these illegal advertisements through a targeted enforcement sweep—an enforcement effort that focuses on popular products or focuses on specific high-profile health conditions and is initiated to gather additional information after advertising is identified as potentially problematic—of dietary supplements generally. As of February 2017, according to FTC officials, they have not conducted targeted enforcement sweeps of the Internet or other media channels focusing specifically on memory supplements. Further, FTC officials would not confirm whether the agency plans to conduct enforcement sweeps focused specifically on memory supplements in the future, due to the sensitive nature of its law enforcement priorities. FTC officials also acknowledged that one approach it could take to targeted enforcement against deceptive memory supplements would be to identify a handful of firms with the most aggressive advertisements or largest market share, and then look into the validity of those claims.

In sharing jurisdiction for dietary supplements, FDA and FTC coordinate enforcement actions based on the 1971 agreement. Based on the 1971 memorandum of understanding, the agencies have articulated where each has primary responsibilities for oversight of dietary supplements (a

type of food) and their related marketing —with FDA generally responsible for supplement safety and labeling and FTC generally responsible for supplement advertising. Staff from each agency confer by phone on a quarterly basis to discuss and coordinate individual and joint efforts.⁵⁷ Agency officials also meet as needed between quarterly meetings to exchange information on specific cases. According to FDA and FTC officials, FDA scientists sometimes serve as resources or experts for FTC in investigations involving dietary supplements.

FDA and FTC have conducted joint enforcement actions involving some dietary supplements, but, to date, the agencies have not conducted a joint enforcement action specifically involving memory supplements. When asked about future plans to conduct joint enforcement actions on memory supplements, officials from both agencies noted that, due to the sensitive nature of their law enforcement role, they would not publicly disclose specific future enforcement plans or give information about ongoing investigations. However, FDA and FTC both emphasize the importance of collaborating with their partners in their strategic planning and budget documents. FTC officials noted that, while memory supplement cases to date may not have required joint enforcement action, any FTC case that involves dietary supplements will involve some level of interaction with FDA, as with the two memory supplement cases FTC took enforcement action against between 2006 and 2015.⁵⁸

In deciding how to pursue cases, and in maximizing agency resources and the effectiveness of this collaboration, FDA and FTC told us that they consider what strategies or procedures promise the greatest benefit to the public. To this end, FDA and FTC may identify the same product or firm as potentially violating federal requirements, and in such an instance the two agencies may work together to decide how best to proceed. They may choose (1) to each pursue the case independently, (2) to pursue the case jointly, or (3) that one agency is in a better position to pursue the case because it has a clearer path or stronger enforcement tools to bring the firms or products into compliance or to otherwise resolve the potential violation. For example, firms are required to possess evidence that substantiates the claims being made; that is, scientific evidence that

⁵⁷FDA and FTC staffs also meet with other law enforcement agencies for purposes of collaboration, including the U.S. Department of Justice.

⁵⁸Officials from both agencies also confirmed such interaction to have occurred in FTC's January 2017 enforcement action involving a memory supplement.

provides a reasonable basis for the claims being made on product labels and in product advertisements. Firms are not required to put this substantiation information on their websites or provide it to consumers; however, FTC has the authority to compel substantiation evidence for product claims. In contrast, FDA does not have explicit authority to compel such substantiation. Consequently, there may be some instances, according to agency officials, where the two agencies agree that FTC should pursue the case instead of or in conjunction with FDA given its authority to compel documentation. Additionally, FTC officials told us that they generally refer all instances where product safety is at issue, such as where a product claims to be acting as a drug, to FDA;⁵⁹ similarly, FDA officials told us that they may refer cases to FTC where only fraud is at issue and that they focus where FTC does not have jurisdiction over such things as manufacturing, to make sure each agency is conducting different types of work and given the agency's limited resources.

FDA and FTC Have Conducted Some Outreach on Dietary Supplement Use by Older Adults, as Well as Some Specific Outreach about Memory Supplement Enforcement Actions

FDA and FTC have conducted some outreach aimed at industry and consumers on dietary supplements generally, including dietary supplement use by older adults, as well as some outreach accompanying enforcement actions specifically involving memory supplements. According to agency officials, general dietary supplement information provided through its outreach would also apply to memory supplements as a subset of dietary supplements that are subject to the same laws and regulations. Both agencies have published information about the risks to older adults in using dietary supplements on their websites through tip sheets, consumer alerts, and blog posts, among other things. For example:

- **Tip sheets.** Both FDA and FTC have published dietary supplement “tip sheets” on their websites to help older adults become more discerning consumers. These tip sheets contain key questions for consumers to ask before purchasing dietary supplements; tips for how

⁵⁹According to FTC officials, the agency can take actions in instances where safety claims are deceptive or unfair.

to identify false claims; and information on the potentially dangerous interactions between dietary supplements and prescription drugs.

- **Consumer updates and alerts.** FDA has published Consumer Updates and Health Fraud alerts on its website that include information specifically about dietary supplements and older adults or Alzheimer's-related memory loss. FTC has published alerts on its website about "miracle health claims" and products that specifically target those with serious conditions without a cure, such as Alzheimer's disease.
- **Blog posts.** FTC publishes blog posts on its consumer and business education blogs in coordination with its press release following an enforcement action, such as the agency did for the action it took against dietary supplements claiming to improve memory and provide other cognitive benefits.

In terms of outreach to consumers and the general public, FDA and FTC each have social media presence, which they use, for example, to disseminate their alerts and blog posts. Further, both FDA and FTC use agency press releases as well as blog posts or updates to educate industry and the general public about specific enforcement actions taken involving dietary supplements, including memory supplements. For example, FDA issued a press release in October 2012 regarding a seizure of memory supplement products that claimed to treat or cure specific diseases, including senile dementia. While FDA and FTC have conducted outreach to consumers on certain general categories of dietary supplements, such as weight loss or sexual enhancement, the agencies have not conducted similar efforts aimed at the general category of memory supplements. Rather, according to agency officials, limiting outreach on memory supplements to specific enforcement actions involving memory supplements was the best use of limited resources given the size of the market and scope of violations to date. FDA and FTC officials told us they have no specific plans to coordinate outreach on memory supplements specifically beyond individual cases that may arise over time. However, FDA officials from the Office of Dietary Supplement Programs acknowledged that, as the office and its priorities evolve, they would like to coordinate more with FTC and other federal agencies on dietary supplement outreach.

In terms of industry outreach, FDA and FTC do so by, for example, issuing guidance on supplement advertising and labeling, and attending industry conferences and workshops, according to agency officials. For example, FDA has issued "A Dietary Supplement Labeling Guide" and

FTC has issued “Dietary Supplements: An Advertising Guide for Industry.” Such outreach to industry is primarily focused on advertising or labeling requirements that apply to all dietary supplements, including memory supplements. According to officials from both agencies, there is no need for industry guidance specifically on memory supplements since there is no applicable federal law or policy that makes memory supplements different from other dietary supplements.

FDA and FTC Enforcement and Outreach Efforts Prioritize Egregiousness of Deception or Impact and Ensuring Consumer Safety

In prioritizing actions related to enforcement and outreach, FDA and FTC officials told us that they focus first on ensuring consumer safety. In addition, FDA and FTC officials told us they also prioritize the egregiousness of deception or impact of supplement claims being made because of the potential harm or adverse impact to consumers—either financial (in the money spent on the supplements) or health-related (for example, if the deceptive advertising persuades consumers to take the dietary supplement and forgo prescribed medications). FTC officials told us they focus on firms and products with the greatest impact on consumers in part to most efficiently extend the reach of its resources. Similarly, FDA officials told us they focus on products with broad health implications given its public health mission. Both agencies also prioritize safety. FDA officials acknowledged that the agency focuses primarily on safety concerns in its enforcement and outreach efforts. FDA investigates a supplement if, for example, the agency suspects the supplement to contain an active pharmaceutical ingredient or if it receives reports from doctors, consumers, or the product manufacturer or distributor, documenting adverse health effects associated with the supplement. Similarly, FTC officials stated that safety is a top concern for the agency and that it refers to FDA any instances in which the safety of the supplement is at issue.

FDA does not prioritize efforts by type or category of dietary supplement, such as memory; but it does focus on populations that are particularly

vulnerable or at risk,⁶⁰ including older adults that would be consumers of memory supplements. According to officials from CFSAN's Office of Dietary Supplement Programs,⁶¹ it is currently in the process of developing its strategic priorities and confirmed it intends to prioritize future efforts according to three broad goals:

1. product safety—its top goal, given the vast size of the market, and includes postmarket enforcement reviews as well as actions to stop products from going to market where they can identify safety issues ahead of time;
2. product quality, identity, and integrity—to provide assurances that dietary supplements contain only the ingredients stated on their label and that products are being manufactured according to current good manufacturing practice regulations; and
3. informed decision making—reflecting that consumers and health-care providers need reliable information to make informed decisions before purchasing, recommending, or prescribing dietary supplements.

Moreover, officials from the Office of Dietary Supplement Programs stated that the office also intends to focus internally on four operational areas interconnected to its oversight goals, including developing relevant policies for industry and consumers. According to FDA officials, prioritizing supplement use by older adults is not a subject the office is currently focused on. However, according to these same officials, as the office moves towards a more proactive paradigm and once it has more information about the dietary supplement market—what supplements are on the market, what these supplements are being used for, and who is using these supplements—the office will be better positioned to identify

⁶⁰The FDA Food Safety Modernization Act of 2011 directs FDA to take a risk-based management approach. To this end, FDA's Foods and Veterinary Medicine Program Strategic Plan (2012-2016) states that, as part of its effort to improve the safety of dietary supplements and fully implement DSHEA, FDA will develop and implement strategic, risk-based, and innovative compliance and regulatory strategies to address dietary supplement safety issues. This strategic plan does not specifically identify the protection of older adults from dietary supplement risks as a priority. Further, FDA's Foods and Veterinary Medicine Program Strategic Plan for Fiscal Years 2016 to 2025 also states the agency's imperative to take a "risk-informed approach."

⁶¹In December 2015, the Office of Dietary Supplement Programs was elevated—from a division under the former FDA Office of Nutrition Labeling and Dietary Supplements (now called the Office of Nutrition and Food Labeling)—to an independent office-level entity within CFSAN. According to FDA officials, this elevation reflected a higher priority placed by FDA on dietary supplements.

vulnerable populations with respect to dietary supplements, potentially including older adults, that need specific focus.

Like FDA, FTC also does not prioritize efforts by category of dietary supplement, but the agency does focus on addressing vulnerable populations in its efforts. In terms of enforcement and outreach efforts by FTC, agency officials told us they consider it a priority to protect older adults from economic and health risks associated with using dietary supplements—echoing FTC’s written statement for the record to the Senate Special Committee on Aging in 2010.⁶² While FTC’s strategic goals do not specifically address dietary supplements, FTC’s Strategic Plan for Fiscal Years 2014 to 2018 acknowledges “the agency strives to understand the issues affecting consumers, including any newly emerging methods of fraud or deceit, so that it can target its enforcement, education, and advocacy on those areas where consumers suffer the most harm or where there will be the greatest impact.” To this end, FTC officials told us that, as the U.S. population ages, health fraud related to memory is becoming an area of increasing concern and focus for the agency. This is illustrated by FTC’s 2017 complaint filed in federal court against a major memory supplement manufacturer for making false or unsubstantiated claims that the product could, among other things, improve memory within 90 days and reduce memory problems associated with aging.

Limited Market Information Poses Oversight Challenge for FDA, While Consumer Groups Reported Uncertainty about FDA and FTC Roles Overseeing Internet Marketing

FDA faces oversight challenges related to limited information about the dietary supplement market, including memory supplements, and limited information on NDIs to inform oversight efforts. FDA officials said the agency is exploring ways to improve information available for oversight by obtaining additional market information. Also, while dietary supplement marketing on the Internet was said to be a concern for agencies and

⁶²Federal Trade Commission, *Prepared Statement of the Federal Trade Commission on Deceptive Marketing of Dietary Supplements: FTC Enforcement Activities*, Before the Senate Special Committee on Aging, 111th Cong., May 26, 2010.

consumer and industry groups, we found that consumer groups were unclear about how FDA and FTC share oversight of Internet marketing. Few documents explicitly delineate their differing roles and coordination in oversight, or communicate the differing roles to industry and consumers. As a result, consumers may be unclear on which agency to report concerns to involving Internet marketing of dietary supplements. Consumer complaints are an important tool for both agencies to learn about potential dietary supplement problems, according to agency officials.

FDA Has Limited Information on the Memory Supplement Market

FDA faces oversight challenges related to limited information about the dietary supplement market, including memory supplements, such as a lack of current and accurate data on ingredients and products on the market, including NDIs, that could inform oversight. These challenges have been ongoing issues, and we reported on them in our previous work on dietary supplements.⁶³ However, FDA officials told us that the agency is exploring ways to obtain better market information and issued new draft guidance on NDIs, and these efforts may improve information available to inform oversight efforts.

Information on the Memory Supplement Market

While FDA currently has limited information about dietary supplements on the market, including memory supplements, officials are considering how it might be able to obtain better and more current information to help improve oversight capabilities, according to officials. FDA and FTC generally are not alerted to memory supplement products going to market because the agencies do not have premarket approval authorities for dietary supplements, resulting in limited information on the memory supplement market. As we stated previously, there is no definitive source for memory supplements on the market, as is the case with all dietary supplements. The number of dietary supplement products is estimated between 50,000 and 90,000 based on different estimates, but the exact

⁶³GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, [GAO-09-250](#) (Washington, D.C.: Jan. 29, 2009); *Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products*, [GAO-13-244](#) (Washington, D.C.: Mar. 18, 2013).

number is unknown.⁶⁴ This has been an ongoing challenge for dietary supplement oversight, as we previously reported on this issue in our prior work.⁶⁵ Specifically, in 2009 we found that FDA oversight efforts were hindered by limited information on dietary supplement firms and the types of products currently available on the market. We therefore recommended that FDA pursue additional authority to require that firms report all supplement products to FDA. Multiple bills were introduced on the issue, but none became law.⁶⁶

FDA officials stated that their ability to access reliable and current information on the dietary supplement market is a challenge, and they are reviewing options for acquiring data sources that could provide more insights into the supplement market, such as market studies. They also said that, in addition to considering data sources that could provide information within their current legal authorities, they are evaluating whether any structural or other changes might increase their ability to have accurate and current meaningful information about dietary supplement products on the market.

The information constraints described above largely focus on FDA given the agency's broad regulatory authority over memory supplements and other dietary supplements. FTC officials told us that the limited market information does not affect their work since, as a law enforcement agency, they focus on supplement issues on a case by case basis. FTC officials feel their existing tools and information to identify supplement issues—such as consumer tips, and proactive media monitoring—are sufficient to identify issues.

Information on New Dietary Ingredients

FDA faces a challenge determining whether a dietary supplement firm should submit an NDI notification for a dietary supplement product, including memory supplements. The NDI notification is important to help FDA review whether new ingredients used in memory supplements and other dietary supplements are safe for consumption. To review the NDI

⁶⁴Estimate sources include FDA, the National Institutes of Health and the Natural Medicines Comprehensive Database.

⁶⁵[GAO-09-250](#).

⁶⁶[GAO-09-250](#). Some examples of the legislation are S. 3002, 111th Cong., S. 1310, 112th Cong., S. 1425, 113th Cong.

notification process, we analyzed three highly advertised memory supplement products for any ingredients that may be NDIs subject to notification, and we then provided FDA with a list of these memory supplement products and their ingredients, asking FDA officials to confirm whether the products included an NDI and whether a notification was filed, to the extent possible.⁶⁷ The selected products contained a total of 39 ingredients, and we identified 9 unique ingredients as possible NDIs based on data on previous NDI notifications. FDA officials provided information indicating whether ingredients in the products potentially matched a previous NDI notification, but told us that they would have to conduct a full investigation of a supplement and its ingredients to determine whether it is subject to NDI notification requirements. According to FDA officials, supplement firms have initial responsibility for determining if a supplement product contains an NDI subject to the notification requirement before marketing the product, and the agency has the burden of showing that a firm has not met this requirement. FDA has limited information to readily make such a determination given that there is no authoritative list of ingredients on the market prior to DSHEA (“grandfathered” ingredients) that could help rule out ingredients subject to the NDI notification requirement.

FDA issued revised draft NDI guidance in August 2016, and is in the process of reviewing public comments on the guidance. The draft guidance states that FDA is willing to develop an authoritative list of grandfathered dietary ingredients based on documentation from industry. The creation of an authoritative list of pre-DSHEA ingredients not subject to NDI notification could improve FDA oversight of NDIs, allowing FDA to more easily rule out supplement products that are not subject to notification and better target supplement firms that should be submitting notifications and requisite safety information for products containing NDIs. In addition, three of the four supplement industry groups we spoke with during the course of this review also stated that additional guidance on NDI notification is needed to help supplement firms better understand the notification process. As stated earlier, we previously found issues related to FDA’s oversight of dietary supplements containing NDIs, and

⁶⁷We used memory supplement market review data, as described previously, to identify highly advertised memory supplements by determining the total number of advertisements for memory supplement products, and then identifying those products with the most advertisements.

recommended that FDA provide additional guidance on the NDI notification process.⁶⁸

FDA and FTC Have Provided Limited Guidance Delineating Their Shared Oversight of Memory Supplement Marketing on the Internet

FDA and FTC share oversight of dietary supplement Internet marketing, including memory supplements, but consumer groups told us the delineation of their differing roles was unclear—particularly with regard to FDA’s role—and we found that few documents explain the agencies’ differing roles and coordination in overseeing Internet marketing. As stated earlier, while FTC exercises primary jurisdiction over advertising, FDA exercises primary jurisdiction over dietary supplement labeling, which includes marketing information used in the sale of the product. This would apply to dietary supplements that are marketed and sold on the Internet. For example, if a dietary supplement product is promoted on a website and consumers are able to purchase the product directly from the website, FDA would likely consider the website labeling over which it would have jurisdiction.⁶⁹ FDA and FTC officials, as well as industry and consumer groups, expressed concern to us about supplement marketing on the Internet, particularly the risks posed to consumers by smaller “fly-by-night” supplement companies that operate primarily on the Internet and may not follow dietary supplement requirements. Officials from both agencies told us that the low barrier to entry—the ease with which firms can start websites to sell products—and the vastness of the Internet presents a challenge to oversight. Also, as described earlier in this report, our market review found the Internet to be the primary vehicle for memory supplement advertising, and we also identified instances of Internet marketing that may have violated federal requirements. While it is not reasonable to expect that FDA and FTC can catch all deceptive claims on the Internet given its vast nature, these findings illustrate the risks to consumers related to the marketing of memory supplements on the Internet, and indicate the importance of oversight in this media channel.

⁶⁸[GAO-09-250](#) and [GAO-13-244](#).

⁶⁹Under these circumstances, a website could be both labeling and advertising, and both agencies could take action based on the claims made on the website.

Consumer groups we spoke to were either unaware of FDA's role with regard to Internet sales and marketing of dietary supplements, or said that the shared oversight roles between the two agencies was unclear. Specifically, two of the five consumer groups we spoke with were unclear about FDA's particular role in overseeing aspects of Internet marketing. For example, one of these consumer groups was not aware that FDA had a role in overseeing aspects of Internet marketing, and told us that they believed all Internet marketing fell under FTC authorities. Two other consumer groups told us that they thought there was an overall lack of clarity in the delineation of the two agencies' roles. For example, one of these consumer groups told us that there is no satisfactory guidance on how the agencies coordinate and their different areas of authority over Internet marketing. The fifth consumer group we spoke to did not respond to our requests for comment on this subject, and our previous meeting with them did not cover the issue.

When we asked industry groups about this issue, the two groups that responded to our inquiry said that they understood that FDA has authority over Internet marketing that falls under the definition of labeling. One of the industry groups stated that there is some overlap between FDA's and FTC's oversight of the Internet, while another told us that the nature of labeling regulations does not always align easily with the advertising nature of most Internet sites.

When we discussed this issue with FDA and FTC, we found that the agencies had published limited guidance on their roles overseeing dietary supplement marketing on the Internet. FDA officials told us that the agency had provided some guidance on its authority over Internet marketing that is considered labeling in a 2007 letter to industry.⁷⁰ However, the FDA letter may not be easily accessible to the public as a link to this letter is not included on FDA's guidance webpage for dietary supplements. Furthermore, while the letter can be found on a webpage with other FDA labeling guidance, the title of the letter—"Dear Manufacturer Letter Regarding Food Labeling"—does not indicate that it

⁷⁰The 2007 letter specified that a website would generally be considered labeling, and subject to the applicable FDA rules, if it promotes a supplement and allows consumers to directly purchase the supplement on the website. The letter also stated that if a product label referred to a website for additional information about a claim for the product, the website is likely considered labeling. See FDA, *Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling*, issued January 2007. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053425.htm>.

covers definitions of labeling on the Internet that fall under FDA authority, making it unlikely that consumers would know to look at the letter for guidance on this issue.⁷¹ FTC officials told us that it has no written guidance delineating the differing agency roles. The agencies told us that they see their authorities related to Internet supplement marketing as overlapping, and stated that they generally determine which agency should take the lead on a particular issue on a case-by-case basis. FDA officials also stated that they see a benefit to taking an overlapping approach to Internet oversight with FTC given the medium's fast pace of change in marketing practices.

While the agencies may find it beneficial to decide on a case-by-case basis which agency will pursue dietary supplement issues involving Internet marketing, providing some clarifying information could help consumers better understand how the two agencies share oversight roles, and which agency to report concerns to regarding Internet marketing of memory supplements and other dietary supplements. Consumer complaints on supplement issues are an important tool for both agencies to identify issues with memory supplement products, according to officials. If consumers do not understand the different agency authorities over Internet marketing, there is a risk that consumers will not report issues to the proper agency, and there is a risk that it may take longer for the appropriate agency to learn about a potential problem and take action. Along these lines, one of the consumer groups we spoke to told us that it was not always clear which agency they should report potential issues to involving Internet marketing, and in these cases, they chose to report all issues to FTC because the agency had been more responsive to their past referrals. Developing and publishing additional guidance delineating agency roles could help consumers better understand where to report concerns about supplement issues that involve Internet marketing. Such actions would be in line with federal internal control standards that state that agencies should communicate quality information with external parties to achieve objectives.⁷² In this

⁷¹In addition to the webpage's referenced above, FDA has a consumer information webpage related to dietary supplement use, and this site includes a link to general information on reporting problems and also a link to information on FTC. However, the webpage does not include specific information for consumers on FDA and FTC shared oversight of Internet marketing and determining where to report related issues.

⁷²GAO, *Standards for Internal Control in the Federal Government*. [GAO-14-704G](#) (Washington, D.C.: Sept. 2014). Principle 15: Management should externally communicate the necessary quality information to achieve the entity's objectives.

case, clearer communication of agency roles and authorities could contribute to the effectiveness of oversight activities. We have also previously reported that delineating roles and responsibilities, as well as developing ways to continually update and monitor written agreements, are issues agencies should consider when collaborating.⁷³ Moreover, FDA and FTC have articulated in either their strategic planning or budget documents, their emphasis on consumer education as part of outreach efforts. While both FDA and FTC have stated that they believe the agencies coordinate well through their current processes, it would be beneficial for consumers to have more clarity about how the two agencies share oversight roles related to dietary supplement marketing on the Internet. The ability for consumers to correctly identify which agency they should reach out to directly with Internet marketing concerns may also benefit the agencies as it could potentially allow them to learn about dietary supplement concerns sooner in some cases, by eliminating the time it takes to receive a referral from the other agency.

Conclusions

Memory supplements are a growing industry that may target a particularly vulnerable population—older adults experiencing memory loss and decline, including conditions such as dementia for which there is no known cure. The prevalence we identified of memory supplement marketing on the Internet, as well as the presence of certain Internet advertisements making inappropriate claims tying memory supplements to treatment of memory-related diseases, underscores the importance of agency oversight over supplement marketing on the Internet. FDA and FTC have provided limited guidance explaining their roles overseeing such marketing. Given the lack of understanding of some of these roles expressed by some consumer groups we contacted, the agencies have an opportunity to better explain and clarify to consumers their shared oversight of Internet marketing of memory supplements and other dietary supplements. Such clarification would allow consumers to better understand which agency they should directly report potential dietary supplement problems to, and may also allow agencies to receive information about concerns more quickly by eliminating the time it takes for the other agency to refer the complaint. By more quickly and efficiently identifying potential dietary and memory supplement problems involving

⁷³GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

Internet marketing, agencies may be able to act to address potential problems and violations faster, improving their oversight of Internet marketing.

Recommendations for Executive Action

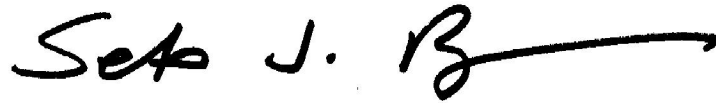
To enhance consumer understanding of agency oversight roles and to strengthen agency oversight of Internet marketing, we recommend that the Secretary of the Department of Health and Human Services and the Chair of the FTC develop and provide additional guidance to consumers delineating the agencies' differing roles in their shared oversight of memory supplement and other dietary supplement marketing on the Internet.

Agency Comments

We provided a draft of this product to HHS and FTC for review and comment. In their written comments, both agencies generally concurred with our recommendation (comments from HHS are reproduced in appendix II and comments from FTC are reproduced in appendix III). Both agencies stated that they have been in communication about working together and FDA noted that the two agencies have already begun to develop materials to address the recommendation. The agencies also provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Commissioner of Food and Drugs, the Commissioner of Federal Trade, and other relevant parties. This report will also be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Seto Bagdoyan at (202) 512-6722 or bagdoyans@gao.gov, or Steve Morris at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

A handwritten signature in black ink that reads "Seto J. Bagdoyan". The signature is written in a cursive style, with a long horizontal stroke extending to the right from the end of the name.

Seto J. Bagdoyan
Director
Forensic Audits and Investigative Service

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive style.

Steve D. Morris
Director
Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report examines: (1) how memory supplements are marketed, and the extent to which the marketing targets older adults and is potentially deceptive or inconsistent with federal requirements; (2) what enforcement and outreach actions the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) have undertaken in overseeing memory supplements and their marketing; and (3) what challenges FDA and FTC face in overseeing memory supplements. For all three objectives, we reviewed relevant laws and regulations related to each agency's oversight of dietary supplements.

Review of Memory Supplement Market

To determine how memory supplements are marketed, and the extent to which the marketing practices target older adults and is potentially deceptive or inconsistent with federal requirements, we monitored five media channels (the Internet, retail stores, television, magazines, and newspapers) in April and May of 2016. We reviewed media channels most likely used by older adults, to identify, catalogue, and review memory supplement advertisements for marketing techniques and product claims information.¹ We identified five media channels for review based on demographic and survey data as described below, focusing on media popular with older adults. Although our review of the memory supplement market is not generalizable and cannot be projected to the entire memory supplement market, we believe that our sampling methodology provides us with the ability to obtain important insights into memory supplement marketing practices.

¹We did not find a consistent definition in the federal sphere as to what age constitutes "older", with some federal laws and agencies using 60 or 65 years as the threshold and other sources using 50 years. For the purposes of this review, we define the term older adults to include persons age 50 years and older to be consistent with relevant FDA educational material aimed at older users of dietary supplements, which use 50 years of age as the threshold for defining older. This definition was also consistent with AARP representation (an advocacy group for older adults). By using this lower threshold, we are also able to capture consumers of dietary supplements aiming to prevent memory loss before it begins.

- **Internet:** We identified pertinent sources for memory supplement marketing on the Internet using relevant demographic survey data. Specifically, we identified search engines used by older adults based on a 2012 Health Tracking Survey conducted by the PEW Research Center, in which at least 70 percent of survey respondents ages 50 and older stated that the last time they went online to look for health information they started with a search engine such as Google, Bing, or Yahoo. We conducted structured searches for memory supplement marketing on Google, Bing, and Yahoo search engines, using the same key search terms (“memory supplements” and “memory support”), and reviewed all webpage links results appearing in the first three pages of search results.
- **Retail stores:** We visited three retail stores to review memory supplement marketing in stores, including two grocery stores and one dietary supplement retailer. We identified appropriate retail stores based on retail store data and also considered proximity to an older adult living facility given the review’s focus on older adults. Specifically, we identified senior living facilities in the Washington, D.C., metropolitan area and used an annual market survey conducted by Food World, a trade news publication, to identify the top 10 grocery retailers in the Washington, D.C., area. We then identified a senior living facility with a grocery retailer in close proximity and the next closest grocery store in the same chain, as well as the closest supplement retailer. For all three stores, we reviewed and catalogued all memory supplements for sale, as well as any marketing displays for memory supplements.
- **Television:** We selected three television networks to review for memory supplement marketing using data on top shows for older adults. Due to technical constraints, we could only record two broadcast and one cable channel simultaneously, which limited our review to three channels. Specifically, we used data on the top 10 prime-time broadcast shows viewed by older adults to select two broadcast networks. We also identified the number one program among older adults and conducted a TV listing search using TV Guide, a magazine that provides television program listings, to identify the equivalent cable network that airs the program. We recorded and reviewed 4 days of television programming for the three selected stations, cataloguing any memory supplement advertisements.
- **Magazines:** We identified appropriate magazines using Mediamark’s “Fall 2015 Magazine Audience Estimates,” a market research report on magazine readership and demographics. Specifically, we identified all magazines in the report where the median age of the audience was

50 or greater and then identified the three magazines with the largest readership. The three magazines did not include a health-related magazine, which we thought would be pertinent to the topic of the review, so we used the data to identify the health-related magazine with the largest readership within the 50 and older age group. We reviewed an issue of each magazine consistent with the market review period—April and May 2016—cataloguing any memory supplement advertisements.

- **Newspapers:** We reviewed three Sunday newspapers published on April 3, 2016. We selected the Sunday newspapers based on highest total print circulation for newspapers published in the Washington, D.C.; Seattle; and Dallas areas, locations that coincided with GAO staff offices and covered different regions across the country. Specifically, we determined the highest total print circulation numbers for the Sunday newspapers for the Washington, D.C.; Seattle; and Dallas areas using the “Average Circulation at the Top 25 U.S. Sunday Newspapers” published by the Alliance for Audited Media, an organization that provides independently verified media data. We reviewed the selected newspapers for the same Sunday to identify any memory supplement advertisements.

We conducted a number of analyses on the market review data to identify memory supplement marketing practices as described below:

For all the examples of memory supplement marketing that we identified on the Internet, in-store, and TV media channels—1,590 in total—we assessed whether there was sufficient information for review; specifically, that the associated product met the definition of a memory supplement and the advertisement provided claims information was at the product level. For 91 unique memory supplement products identified on the three media channels, we identified labels or advertisements that contained sufficient information.² We reviewed these results for instances where advertisements claimed products are clinically proven or studied and provided supporting evidence for the claim. We did not evaluate product claims for accuracy and truthfulness or product effectiveness.

²We determined the claims information was sufficient to review if the associated product met the definition of a memory supplement and the claims information was at the product level, specifically the benefits are associated with taking the product. For example, an advertisement containing a product that states, “product X can prevent memory loss” would be deemed sufficient for review.

We also conducted a targeted review of the marketing examples from the Internet to identify examples of memory supplement marketing targeting older adults. Specifically, we conducted a targeted word search of the Internet search results using the Adobe search function to identify examples of targeted text, and manually reviewed advertisement screenshots and the Internet search results to identify visuals depicting older adults.³ We also reviewed the Internet search results to identify additional visuals that may encourage a consumer to purchase the product, such as pictures of medical professionals or older adult testimonials and endorsements.

To identify marketing claims that may be considered deceptive or in violation of federal requirements, we reviewed memory supplement marketing for disease-related claims that a product can treat, cure, or prevent a memory-related disease. Such claims are generally prohibited. Specifically, we conducted targeted online searches using a variety of search terms, and we reviewed all memory supplement marketing identified on the five media channels for potentially inappropriate claims.⁴ Marketing examples we identified as potentially deceptive or in violation of federal requirements were shared with staff from FDA and FTC for their review as to whether the claims may be considered deceptive or in violation of requirements.

Memory Supplement Enforcement Actions and Outreach

To determine what enforcement and outreach actions FDA and FTC have undertaken in overseeing memory supplements and their marketing, we interviewed FDA and FTC officials on the definition of memory supplements and collected and analyzed agency oversight policies. We

³The search terms we used were: “age,” “aging,” “young,” “senior,” and “elderly.” We identified advertisements using images depicting older adults and common traits associated with aging, such as mild memory loss or cognitive decline.

⁴The search terms included: “Memory supplement Alzheimer’s”; “Alzheimer’s pill dietary supplement”; “Alzheimer’s vitamin”; “cure Alzheimer’s supplement”; “cure dementia supplement”; “dementia vitamin”; “dementia drops”; “prevent Alzheimer’s”; “treat Alzheimer’s”; “dietary supplements to treat dementia”; “supplement products for dementia”; “Parkinson’s cure”; “Parkinson’s supplement”; “Parkinson’s disease vitamins”; “dietary supplements to prevent Parkinson’s”; and “dietary supplements to treat Parkinson’s disease.”

worked with officials from FDA and FTC, as well as representatives from the U.S. Department of Health and Human Services' (HHS) National Institutes of Health, to develop and obtain concurrence on a single definition of memory supplements for the purposes of this review. In addition, we conducted semistructured interviews with FDA and FTC officials to review their activities and guidance related to dietary supplement enforcement⁵ and outreach efforts. We also interviewed agency officials about strategic plans and program priorities as well as reviewed documents showing how each agency prioritizes dietary supplement work, including whether memory supplements or older adults are an area of focus in their enforcement or outreach efforts. Additionally, we conducted semistructured interviews with consumer groups and industry associations regarding FDA and FTC oversight efforts of dietary supplements, including memory supplements and efforts specific to older adults. Finally, we obtained and analyzed enforcement data involving dietary supplements and memory supplements from FDA and FTC for fiscal year 2006 through fiscal year 2015—the most recent years for which such data were available at the time of our review.⁶ As part of this analysis, we interviewed FDA and FTC officials about these memory supplements actions. Based on our analysis of the data provided on memory supplements enforcement actions as well as the responses by FDA and FTC officials to our questions about these data, we determined these data to be sufficiently reliable for the purposes of providing the number of enforcement actions taken by each agency that involved dietary supplements as well as the number of enforcement actions taken by each agency that involved memory supplements.

⁵For the purpose of this report, we use the term “enforcement” to refer to actions an agency takes against a dietary supplement firm or product after a violation has been identified—this includes advisory communications and regulatory actions (administrative and judicial court actions) taken by FDA as well as administrative court and judicial court actions taken by FTC. FDA officials told us that they do not always use the term enforcement in the same manner.

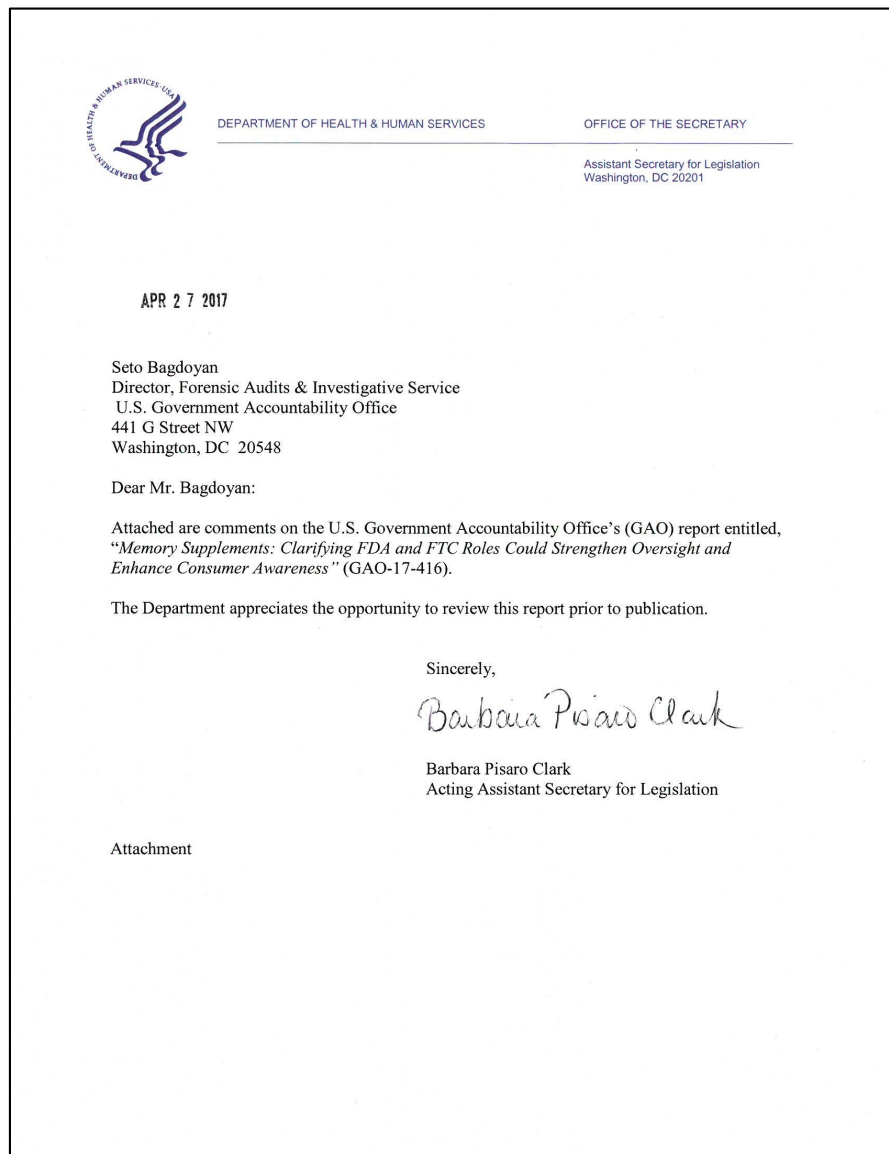
⁶At the time we undertook our review in 2016, FDA and FTC were able to provide information on actions taken through 2015; complete data for 2016 were not available at the time we concluded our audit work. According to FTC staff, the agency took no actions involving memory supplements in 2016. We subsequently received information about two memory supplement-related actions taken by FTC in 2017, shortly before the issuance of this report; we included information related to these actions, as appropriate.

Challenges to Memory Supplement Oversight

To identify what challenges FDA and FTC face in overseeing memory supplements, we interviewed agency officials and reviewed relevant documentation. In addition, we conducted a series of semistructured interviews with five consumer groups and four industry groups. The consumer groups we spoke to include AARP, Center for Science and the Public Interest, Consumer Union Consumer Reports, Public Citizen, and Truth in Advertising. The industry groups we spoke to include the Better Business Bureau's Advertising Self-Regulatory Council National Advertising Division, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, and the Natural Products Association. We identified the consumer groups actively working on dietary supplement issues as well as the dietary supplement industry groups through a review of past GAO reports on dietary supplements, Internet searches for groups actively engaged in dietary supplement issues, referrals from agency officials, and interviews with other consumer groups and industry associations. To review challenges around oversight of new dietary ingredients (NDI), we analyzed the ingredients for highly advertised memory supplement products to identify potential NDIs. We used data from our review of the memory supplement market, as described above, to identify highly advertised memory supplements by determining the total number of advertisements for memory supplement products, and then identifying those products with the most advertisements. We provided FDA officials with three highly advertised supplements that we identified as containing potential NDIs, based on a comparison of the ingredients to a list of past NDI notifications. We asked FDA officials to confirm whether the supplements contained an NDI and whether a notification was filed for the product, to the extent possible. Where applicable, we also assessed FDA and FTC oversight issues and challenges against federal internal control standards for communicating quality information with external parties to achieve objectives.

We conducted this performance audit from February 2016 to May 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Comments from the U.S. Department of Health and Human Services



GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: MEMORY SUPPLEMENTS: CLARIFYING FDA AND FTC ROLES COULD STRENGTHEN OVERSIGHT AND ENHANCE CONSUMER AWARENESS (GAO-17-416)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation

To enhance consumer understanding of agency oversight roles and to strengthen agency oversight of Internet marketing, we recommend that the Secretary of the Department of Health and Human Services and the Chair of the Federal Trade Commission (FTC) develop and provide additional guidance to consumers delineating the agencies' differing roles in their shared oversight of memory supplement and other dietary supplement marketing on the Internet.

HHS Response

HHS concurs with GAO's recommendation.

HHS agrees that collaborating with FTC to provide further clarification to the public about the Food and Drug Administration and FTC's respective oversight roles regarding dietary supplement marketing would be beneficial. Our two agencies have already been in communication about working together to develop materials toward this end.

Appendix III: Comments from the U.S. Federal Trade Commission

**Appendix III: Comments from the U.S. Federal
Trade Commission**



Office of the Secretary

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

April 26, 2017

Seto J. Bagdoyan
Director, Forensic Audits and Investigative Service
United States Government Accountability Office
441 G Street NW
Washington, DC 20548

Steve D. Morris
Director, Natural Resources and the Environment
United States Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Messrs. Bagdoyan and Morris:

The Government Accountability Office (“GAO”) recently forwarded for the Federal Trade Commission’s (“FTC” or “Commission”) review and comment a draft of a GAO report entitled *MEMORY SUPPLEMENTS: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness* (GAO-17-416). FTC staff provided GAO with information about the FTC’s enforcement and education efforts in connection with the preparation of the draft report, and the Commission appreciates the opportunity to have assisted GAO in its work. The Commission also appreciates having the chance to respond to the specific recommendation set forth in the draft report: that the Food and Drug Administration (“FDA”) and FTC provide additional guidance to consumers clarifying the agencies’ roles in their shared oversight of memory supplement and other dietary supplement marketing on the Internet. The draft report notes that this could assist consumers in filing complaints and the agencies in following up on such complaints.

As the draft report notes, the FTC has established outreach programs directed at both consumers and businesses. In addition to guidance such as tip sheets and alerts for older adults, the FTC regularly posts blogs aimed at consumers and businesses in connection with its dietary supplement enforcement actions, including actions targeting memory supplements. *See* GAO draft report at 27-28. Most recently, the FTC issued a consumer alert warning that some companies are deceptively promoting “brain booster” supplements via websites that look like news websites and feature fake endorsements purportedly from public figures such as Stephen

Seto J. Bagdoyan and Steve D. Morris – Page 2

Hawking.¹ We have collaborated on consumer education pieces with the FDA in the past,² but we agree that additional guidance may be useful and have discussed GAO's recommendation with FDA personnel. We will continue to work with the FDA to educate consumers and businesses about the agencies' roles and efforts in the area.

By direction of the Commission.



Donald S. Clark
Secretary

¹ FTC, Consumer Information: "Scammers are spoofing news sites to promote health products" (Feb. 23, 2017), *available at* <https://www.consumer.ftc.gov/blog/scammers-are-spoofing-news-sites-promote-health-products>.

² *See, e.g.*, FTC, Consumer Information: Dietary Supplements (Feb. 2011), *available at* <https://www.consumer.ftc.gov/articles/0261-dietary-supplements>; FTC, Consumer Information: Dietary Supplement Ads Infographic (Nov. 2015), *available at* <https://www.consumer.ftc.gov/articles/0538-dietary-supplement-ads-infographic>.

Appendix IV: GAO Contacts and Staff Acknowledgments

GAO Contacts

Seto J. Bagdoyan, (202) 512-6722 or bagdoyans@gao.gov
Steve D. Morris, (202) 512-3841 or morriss@gao.gov

Staff Acknowledgments

In addition to those mentioned above, the following staff members made significant contributions to this report: Gabrielle Fagan and Thomas Cook, Assistant Directors; Celina Davidson and Tama Weinberg, Analysts-in-Charge; Jennifer Felder; and Joshua Parr. Additionally, Colin Fallon, Ellen Fried and Maria McMullen provided technical support; Andrew Stavisky provided methodological guidance; and Kevin Bray provided legal counsel.

Appendix V: Accessible Data

Data Tables

Data table for Figure 1: Growth in Sales of Memory Supplements and Dietary Supplements, 2006 through 2015

Year	Percentage growth: Dietary supplement growth from base year (2006)	Percentage growth: Memory supplement growth from base year (2006)
2006	0	0
2007	6	13.6
2008	12.8	30.6
2009	19.6	44.2
2010	25	54.1
2011	33.8	65.7
2012	43.8	78.8
2013	54.7	79.6
2014	62.6	79.6
2015	72.1	82.2

Accessible Text for Figure 2: FDA Oversight Roles and Responsibilities

1. Food and Drug Administration (FDA)
 - a. Office of Foods and Veterinary Medicine
 - i. Center for Food Safety and Applied Nutrition (CFSAN) (primarily responsible for dietary supplement oversight)
 1. manages dietary supplement oversight through its Office of Dietary Supplement Programs
 - a. Office of Dietary Supplement Programs

- i. is responsible for developing dietary supplement policy, regulations, and guidance; providing scientific and technical expertise, reviewing new dietary ingredient (NDI) notifications and structure-function claims,^b and directing dietary supplement priorities across the agency, among other things

b. Office of Compliance

- i. has primary responsibility for compliance and enforcement of FDA regulations and federal laws within FDA's jurisdiction with respect to foods—including dietary supplements
- ii. reviews incoming investigational findings and recommendations to determine whether a proposed action or remedy is supported by the documented observations and other evidence
- iii. assesses the integrity and relevance of the evidence
- iv. obtains necessary scientific verification and policy guidance from appropriate subject-matter experts

b. Office of Regulatory Affairs

- i. Office of Regulatory Affairs (primarily responsible for dietary supplement oversight)

-
1. is responsible for managing the agency's field operations in 25 regional and district offices
 2. supports FDA centers^a on dietary supplement oversight by performing inspections and import operations, and by taking advisory and regulatory enforcement actions, generally in coordination with CFSAN's Office of Compliance
- c. Office of Enforcement and Import Operations
- i. Health Fraud Team
 1. primarily looks for labeling claims that indicate a violation of federal law and for undeclared ingredients (such as pharmaceuticals) in dietary supplements

Accessible Text for Figure 3: FTC Oversight Roles and Responsibilities

1. Federal Trade Commission (FTC)

a. Bureau of Consumer Protection

- i. is responsible for protecting consumers against unfair, deceptive, or fraudulent practices
 1. Division of Advertising Practices
 - a. manages FTC's health fraud work, of which dietary supplement oversight is a part. The division works to protect consumers from unfair or deceptive advertising and marketing practices that raise health and safety concerns, as well as those that cause economic injury-as part of FTC's law enforcement efforts to prevent unfair competition and protect consumers, including older adults, from unfair or deceptive

practices in the marketplace. The Division

- i. collects complaints and conducts investigations and sues companies and people to stop deceptive advertising practices
- ii. develops guidance to maintain a fair marketplace, and educates consumers and businesses about their rights and responsibilities, among other things
- iii. develops rules, reviews and enforces a variety of consumer-protection laws, and develops guidance-including its Dietary Supplement Advertising Guide,^a which provides business with guidance for claims they make for dietary supplements
- iv. coordinates and addresses consumer-protection issues with law enforcement agencies and industry self-regulation groups by, for example, issuing joint warning letters with the Food and Drug Administration to combat fraudulent products on the Internet

Data table for Figure 4: Examples of Text Targeting Older Adults Found in Internet Advertisements

- “Are you 55 years of age or older?”
- “Losing your memory or developing brain fog in your 40s, 50s, 60s, 70s, or even 80s is NOT normal.”
- “Avoid those embarrassing senior moments.”
- “... designed to help to stay sharp through your later years.”
- “This can help combat age-related memory loss, brain fog, and mental fuzziness.”
- “Vital nutrients to preserve your memory as you age.”
- “Improve your memory, so you stay sharp and alert into your 70s, 80s, and 90s ...”
- “... memory support supplements are perfect for occasional mild memory problems associated with aging.”
- “There are many memory supplements, memory improvement medications, or memory enhancers, that fundamentally enhance memory, reduce the risk of age-connected memory misfortune, and also help concentration.”
- “Now you’ll be able to increase your memory abilities, slow down the process of aging, and sharpen your mental focus.”
- “This herb increases blood circulation in the brain and has been shown, in multiple clinical trials, to be useful for improving memory and cognition especially in the elderly.”
- “It has been shown to be helpful with many of the complaints of the elderly such as short-term memory loss, slow thinking and reasoning, occasional headaches, and dizziness.”

Figure 5: Examples of Potential Disease Related Claims Found in Internet Advertisements

- "Invest in yourself, protect & secure your future. Order anti-Alzheimer's herbs."
- "Improves Cognition and Behavioural Symptoms in Alzheimer's patients."
- "Consider it a preventive program for cancer, Alzheimer's Disease and more."

- "Studies indicate this supplement may help protect against age-related memory decline, including Parkinson's disease."
- "This herbal combination could reduce risk."
- "It is also beneficial for those in initial and mid-stages of Alzheimer's."
- "Numerous studies have demonstrated curcumin's ability to prevent the underlying processes involved in the disease."
- "It is very helpful in the treatment of Alzheimer's disease."
- "Provides homeopathic aid in support of assistance with the symptoms of dementia."
- "[W]e have compiled a list of the vitamins which have the most evidence for reducing the risk of developing Alzheimer's or dementia as well as slowing their progress."
- .. used in high doses ... to treat senile dementia. It may also be used for patients with Alzheimer's disease."

Source: GAO Internet search market review (examples); GAO Stock Photography (image). GA0-17-416

Agency Comment Letters

Accessible Text for Appendix II: Comments from the U.S. Department of Health and Human Services

Page 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation Washington, DC 20201

APR 27 2017

Seto Bagdoyan

Director, Forensic Audits & Investigative Service U.S. Government
Accountability Office

441 G Street NW Washington, DC 20548

Dear Mr. Bagdoyan:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness" (GAO-17-416).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Barbara Pisaro Clark

Acting Assistant Secretary for Legislation

Attachment

Page 2

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: MEMORY SUPPLEMENTS: CLARIFYING FDA AND FTC ROLES COULD STRENGTHEN OVERSIGHT AND ENHANCE CONSUMER AWARENESS (GAO-17-416)

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in their shared oversight of memory supplement and other dietary supplement marketing on the Internet.

HHS Response

HHS concurs with GAO's recommendation.

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Accessible Text for Appendix III: Comments from the U.S. Federal Trade Commission

Page 1

Office of the Secretary

UNITED STATES OF AMERICA

Federal Trade Commission

WASHINGTON, D.C. 20580

April 26, 2017

Seto J. Bagdoyan

Director, Forensic Audits and Investigative Service United States
Government Accountability Office 441 G Street NW

Washington, DC 20548

Steve D. Morris

Director, Natural Resources and the Environment United States
Government Accountability Office 441 G Street NW

Washington, DC 20548

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Seto J. Bagdoyan and Steve D. Morris -Page 2

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By direction of the Commission.

Donald S. Clark Secretary

Page 2

1 FTC, Consumer Information: "Scammers are spoofing news sites to promote health products" (Feb. 23, 2017), available at <https://www.consumer.ftc.gov/blog/scammers-are-spoofing-news-sites-promote-health-products>.

2 See, e.g., FTC, Consumer Information: Dietary Supplements (Feb. 2011), available at <https://www.consumer.ftc.gov/articles/0261-dietary-supplements>; FTC, Consumer Information: Dietary Supplement Ads Infographic (Nov. 2015), available at <https://www.consumer.ftc.gov/articles/0538-dietary-supplement-ads-infographic>.

Accessible Text for

Related GAO Products

Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products, [GAO-13-244](#). Washington, D.C.: March 18, 2013.

Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims, [GAO-11-102](#). Washington, D.C.: January 14, 2011.

Herbal Dietary Supplements: Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice, [GAO-10-662T](#). Washington, D.C.: May 26, 2010.

Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding, [GAO-09-250](#). Washington, D.C.: January 29, 2009.

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