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Regulation of Dietary Supplements: Background and Issues for Congress

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Summary

Many Americans take dietary supplements (e.g., vitamins, herbs, sports nutrition supplements) with the intention of meeting their nutritional needs, as well as to improve or maintain their overall health. These consumers want accurate information on the effectiveness and proper use of dietary supplements and access to the dietary supplements of their choice. The federal government has an interest in ensuring that the supplements Americans consume are high quality, free from contaminants, and accurately labeled. Because dietary supplements are intended to supplement the diet, their processing and manufacture are regulated by the U.S. Food and Drug Administration (FDA) in a manner similar to food, with some differences that will be outlined in this report. The Federal Trade Commission (FTC), in coordination with the FDA, regulates dietary supplement advertising.

In contrast with the authority under which drugs and medical devices are regulated, dietary supplements are regulated as food under the Federal Food, Drug, and Cosmetic Act (FFDCA), and the FDA generally does not take regulatory action on food or dietary supplements until something goes wrong with a product that is on the market. The FDA has the authority to take action regarding supplements that are labeled incorrectly (misbranded) or contain unsafe ingredients (adulterated). The FDA is made aware of potential misbranding or adulteration through inspections, adverse event reports, and citizen petitions.

FDA's authority to regulate dietary supplements has changed over time. The Dietary Supplement Health and Education Act of 1994 (DSHEA, P.L. 103-417) amended the FFDCA and FDA's authority to regulate dietary supplements. Specifically, DSHEA defined the term *dietary supplement*; established requirements for new dietary ingredients (NDIs), labeling, and certain claims for dietary supplements; and authorized FDA to promulgate regulations for dietary supplement-specific current good manufacturing practices (CGMPs). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) required the registration of any facility manufacturing, processing, packing, or holding food (including dietary supplements). In 2006, the Dietary Supplement and Non-Prescription Drug Consumer Protection Act (P.L. 109-462) further amended the FFDCA to establish requirements for mandatory reporting of adverse events associated with dietary supplements. In 2011, the FDA Food Safety Modernization Act (FSMA, P.L. 111-353) provided FDA with mandatory recall authority for adulterated food (including dietary supplements) and food containing undisclosed allergens.

According to the 2014 FDA Health and Diet Survey, more than half of vitamin and mineral supplement users reported thinking that the government preapproves these products before they are marketed. While this is generally the case for drugs, it is not the case for dietary supplements.

Consumers, the health care and dietary supplement industries, Congress, and federal regulators all have a stake in supplement identification, effectiveness, and safety. Current federal policy toward regulating dietary supplements was intended to balance these competing interests. DSHEA provided FDA the authority to take action against products that were unsafe or adulterated, but emphasized that FDA should not take actions that would impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers. As the supplement market has grown and diversified, the regulatory and research questions have become more complex. This report discusses recent areas of regulatory and legislative concern, including the exclusion of certain drug ingredients from the dietary supplement definition, issues surrounding supplement safety, and the role of supplements in individuals' health.

Contents

Dietary Supplements: An Overview	1
FDA’s Authority to Regulate Dietary Supplements.....	2
Adulterated and Misbranded Supplements.....	3
Definition of “Dietary Supplement”.....	4
FDA Dietary Supplement-Specific Requirements and Guidance.....	4
New Dietary Ingredients.....	5
Current Good Manufacturing Practices	7
Labeling	8
Claims	9
Serious Adverse Event Reporting.....	11
Compliance and Enforcement.....	12
Dietary Supplement Marketing.....	13
Issues for Congress	14
Dietary Supplements and Drug Exclusion.....	15
Dietary Supplement Safety.....	17
The Role of Dietary Supplements in Health and Health Care.....	18
Concluding Comments.....	21

Figures

Figure B-1. Example of a Dietary Supplement Principal Display Panel.....	23
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Appendixes

Appendix A. Selected Laws Regulating Dietary Supplements	22
Appendix B. Principal Display Panel, Dietary Supplements.....	23
Appendix C. Acronyms Used in This Report.....	24

Contacts

Author Information	25
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Dietary Supplements: An Overview

Dietary supplements are marketed for nutritional support and health promotion, as well as for a number of other uses, including weight loss and sports performance enhancement. These products come in pill, capsule, and liquid form, as well as in forms that may appear similar to conventional food or beverages. Supplements contain dietary ingredients such as vitamins, minerals, and botanicals, among others.

Dietary supplement use is common in the U.S. population. Data from the 2017-2018 National Health and Nutrition Examination Survey (NHANES) indicate that 57.6% of U.S. adults reported using any dietary supplement in the past 30 days, with higher use among women than men (63.8% compared to 50.8%) and use increasing with age.¹ Among all age groups, the most commonly used dietary supplements were multivitamin-mineral supplements, followed by vitamin D and omega-3 fatty acid supplements.²

The dietary supplement market has grown over time. According to a 2019 Food and Drug Administration (FDA) press release, “what was once a \$4 billion industry comprised of about 4,000 unique products, is now an industry worth more than \$40 billion, with more than 50,000—and possibly as many as 80,000 or even more—different products available to consumers.”³ In 2020, the dietary supplement industry reported record sales, with the U.S. supplement market’s valuation reaching \$55.75 billion by the end of the year.⁴

This report outlines the authority of the FDA to regulate dietary supplements and summarizes dietary supplement-specific requirements for new dietary ingredients (NDIs), current good manufacturing practices (CGMPs), labeling, and claims. The report also discusses adverse event reporting for dietary supplements and other means of ensuring consumer safety through enforcement of these authorities and regulations. Dietary supplement advertising, which is regulated by the Federal Trade Commission (FTC) in coordination with FDA, is also discussed. The report concludes with a discussion of policy issues related to the manufacture, regulation, and use of dietary supplements, including the exclusion of certain drug ingredients from the dietary supplement definition, issues surrounding dietary supplement safety, and the role of dietary supplements in health.

¹ Suruchi Mishra, Bryan Stierman, and Jaime J. Gahche et al., “Dietary Supplement Use Among Adults: United States, 2017–2018,” National Center for Health Statistics (NCHS) Data Brief No. 399, February 2021, <https://www.cdc.gov/nchs/products/databriefs/db399.htm>.

² Ibid.

³ FDA, “Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency’s new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA’s oversight,” February 11, 2019, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>.

⁴ Grebow, Jennifer, “Dietary supplement sales success post-COVID: How can industry keep the momentum going after the pandemic?,” *Nutritional Outlook*, May 26, 2021, <https://www.nutritionaloutlook.com/view/dietary-supplement-sales-success-post-covid-how-can-industry-keep-the-momentum-going-after-the-pandemic>. “Supplement Market Hits Record Growth of 14.5%, According to Nutrition Business Journal’s 2021 Supplement Business Report,” *Globe Newswire*, June 28, 2021, <https://www.globenewswire.com/news-release/2021/06/28/2254146/0/en/Supplement-Market-Hits-Record-Growth-of-14-5-According-to-Nutrition-Business-Journal-s-2021-Supplement-Business-Report.html>.

FDA's Authority to Regulate Dietary Supplements

The FDA,⁵ an agency within the U.S. Department of Health and Human Services (HHS), regulates the processing, manufacture, and packaging of dietary supplements under the Federal Food, Drug, and Cosmetic Act (FFDCA). The agency has the authority to deem food (and dietary supplements) misbranded (i.e., inaccurately labeled or presenting false or misleading claims)⁶ and adulterated (i.e., containing ingredients that pose a significant or unreasonable risk of illness or injury).⁷ FDA may recall food (including dietary supplements) under specified circumstances.⁸

As enacted in 1938, the FFDCA did not explicitly establish requirements for dietary supplements, except that the law deemed a food misbranded if it was represented for “special dietary uses” but its label did not include the required information about “its vitamin, mineral, and other dietary properties.”⁹ In enacting this provision, Congress intended to allow FDA to more closely regulate claims for vitamins, minerals, and botanicals than those for conventional foods.¹⁰ In the 1940s, FDA began to take action against vitamins, minerals, and botanical products if they made claims about the treatment or prevention of disease, as the agency considered such products to be unapproved drugs.¹¹

FDA later tried to apply the Food Additive Amendments Act of 1958¹² to dietary supplements. However, FDA's approach to broadly interpret the food additive definition was struck down by the courts.¹³ The Food Additive Amendments Act defined a *food additive* as “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food,” unless the substance is generally recognized as safe (i.e., GRAS) under the conditions of its intended use, among qualified experts.¹⁴ Food additives must be approved by FDA prior to marketing, unless GRAS or otherwise excepted from the food additive definition. To obtain approval of a substance as a food additive, a person may submit to FDA a food additive petition, which proposes the issuance of a regulation prescribing the conditions under which the additive may be safely used.¹⁵ The Food Additive Amendments Act generally shifted the burden of proof of safety of new food additives from FDA to the manufacturer.¹⁶

⁵ Within the FDA, regulation of both food and dietary supplements falls within the purview of the Center for Food Safety and Applied Nutrition (CFSAN), along with the Office of Regulatory Affairs (ORA).

⁶ FFDCA §403 [21 U.S.C. §343].

⁷ FFDCA §402 [21 U.S.C. §342].

⁸ FFDCA §423 [21 U.S.C. §3501].

⁹ P.L. 75-717, FFDCA §403(j) [1938].

¹⁰ National Research Council, “Dietary Supplements: A Framework for Evaluating Safety,” 2005, Washington, DC: The National Academies Press, pp. 28-31.

¹¹ *Ibid.*

¹² Food Additive Amendments Act of 1958, P.L. 85-929.

¹³ National Research Council, “Dietary Supplements: A Framework for Evaluating Safety,” 2005, Washington, DC: The National Academies Press, p. 31.

¹⁴ FFDCA §201(s) and §409 [21 U.S.C. §321(s) and §348].

¹⁵ FFDCA §409(b) [21 U.S.C. §348(b)].

¹⁶ National Research Council, “Dietary Supplements: A Framework for Evaluating Safety,” 2005, Washington, DC: The National Academies Press, pp. 28-31.

FDA's efforts to regulate supplements as drugs and food additives were met with resistance from the industry and some in Congress and in 1994, DSHEA was enacted.¹⁷ DSHEA excluded dietary supplement ingredients from the definition of a *food additive*¹⁸ and deemed that dietary supplements are food under the FFDCA.¹⁹ DSHEA also made changes to FDA's authority to differentiate certain aspects of dietary supplement regulation from regulation of conventional foods, specifically with respect to 1) NDIs, 2) CGMPs, 3) labeling, and 4) certain claims for dietary supplements. Notably, DSHEA placed the burden of proof concerning dietary supplement safety on FDA, requiring the agency to show that a dietary supplement ingredient is adulterated rather than requiring the manufacturer to prove a supplement is safe prior to marketing.²⁰ This is in contrast to new food additives, which require submission of safety information in a food additive petition prior to marketing, or drugs, which generally require submission of safety data as part of a new drug application prior to marketing.

FDA's authority with respect to dietary supplements has been further amended by subsequent legislation. **Appendix A** provides a list of selected laws that have modified the dietary supplement regulatory framework.

Adulterated and Misbranded Supplements

FDA has the authority to take enforcement action against misbranded (i.e., inaccurately labeled or presenting unapproved claims)²¹ and adulterated (i.e., containing ingredients that pose a significant or unreasonable risk of illness or injury)²² dietary supplements in the form of warning letters, product seizures, and in certain cases, mandatory recalls. It may also ban an ingredient through the rule-making process.

Under the FFDCA, a dietary supplement is considered adulterated under specified circumstances related to the product's contents and manufacturing processes, including if

- the dietary supplement or dietary ingredient presents a significant or unreasonable risk of illness or injury either (1) under conditions of use recommended or suggested in the product's labeling, or (2) under normal conditions of use, if none are set forth in the product's labeling;
- the dietary supplement contains a NDI for which there is inadequate information as to whether or not it presents a significant or unreasonable risk of illness or injury;

¹⁷ P.L. 103-417. Stephen H. McNamara and A. Wes Siegner, Jr., "FDA Has Substantial and Sufficient Authority to Regulate Dietary Supplements," *Food and Drug Law Journal*, 2002, vol. 57, no. 1, pp. 15-24. National Research Council, "Dietary Supplements: A Framework for Evaluating Safety," 2005, Washington, DC: The National Academies Press, p. 28-39.

¹⁸ FFDCA §201(s) [21 U.S.C. §321(s)], as amended by DHSEA §3(f). FDA regulations define a food additive as any substance "the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food." 21 C.F.R. §170.3.

¹⁹ FFDCA §201(ff) [21 U.S.C. §321(ff)]. FDA regulates food labeling, bottled water, food additives, infant formulas, and the safety of food products (except for most meat and poultry products, which are regulated by the U.S. Department of Agriculture). See <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>. See also CRS Report RS22600, *The Federal Food Safety System: A Primer*.

²⁰ FFDCA §402(f) [21 U.S.C. §342(f)]. National Research Council, "Dietary Supplements: A Framework for Evaluating Safety," 2005, Washington, DC: The National Academies Press, p. 24.

²¹ FFDCA §403 [21 U.S.C. §343].

²² FFDCA §402 [21 U.S.C. §342].

- the Secretary declares the dietary supplement or a dietary ingredient therein to pose an imminent hazard to public health or safety; or
- the dietary supplement contains a dietary ingredient that renders it adulterated because it is a poisonous or deleterious substance rendering the product injurious to one's health.²³

As mentioned, FDA bears the burden of proving that a dietary supplement is unsafe.²⁴ A dietary supplement is also considered adulterated if it has been prepared, packed, or held under conditions that do not meet FDA's CGMP regulations.²⁵ A dietary supplement is considered misbranded if its labeling is false or misleading or if it does not comply with supplement labeling or claims requirements (see the "Labeling" section of this report).

Definition of "Dietary Supplement"

Prior to DSHEA, there was no statutory definition of dietary supplements. As amended by DSHEA, the FFDCA defines a dietary supplement as a product (other than tobacco) that is not represented as a conventional food and

- is intended to supplement the diet;
- contains one or more of the following dietary ingredients: 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, powder, tablet, or liquid; and
- is labeled on the front panel as being a dietary supplement.²⁶

Under the FFDCA, an article²⁷ that is an active ingredient in an approved drug, or that has been authorized for investigation as a new drug and for which the existence of such clinical investigations has been made public, is excluded from the definition of a dietary supplement and may not be marketed as such.²⁸ An exception to this is if FDA issues a regulation finding that the use of the article in a dietary supplement is lawful.

An article that is approved as a drug or being investigated as a drug may be marketed in or as a dietary supplement if it was marketed as a dietary supplement or as a food prior to such approval or clinical investigation, unless FDA issues a regulation to the contrary.²⁹

FDA Dietary Supplement-Specific Requirements and Guidance

Dietary supplements are generally regulated as food under the FFDCA. As such, they are subject to fewer premarket regulations than other items within the FDA's regulatory purview, such as

²³ FFDCA §402(f) [21 U.S.C. §342(f)].

²⁴ FFDCA §402(f) [21 U.S.C. §342(f)]. National Research Council, "Dietary Supplements: A Framework for Evaluating Safety," 2005, Washington, DC: The National Academies Press, p. 24.

²⁵ FFDCA §402(g) [21 U.S.C. §342(g)].

²⁶ FFDCA §201(ff) [21 U.S.C. §321(ff)].

²⁷ An article that is approved as a new drug can refer to the whole product or a component of the product. See FDA, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry," Draft Guidance, p. 43.

²⁸ FFDCA §201(ff)(3)(B) [21 U.S.C. §321(ff)(3)(B)].

²⁹ FFDCA §201(ff)(3)(A) [21 U.S.C. §321(ff)(3)(A)].

drugs and medical devices.³⁰ Similar to food manufacturers, dietary supplement manufacturers must register their establishments with FDA,³¹ follow CGMPs,³² and must abide by nutrition labeling and claims requirements.³³ However, by law, some of these requirements are dietary supplement-specific. Unlike food manufacturers, dietary supplement manufacturers are required to report serious adverse events to the FDA.

In contrast to drugs, dietary supplements and their ingredients are generally presumed safe. Although processors, manufacturers, and packers of dietary supplements are expected to adhere to FDA regulations when bringing a new product to market, there is no pre-market approval process for dietary supplements. However, the FDA must be notified of dietary supplements containing NDIs and of dietary supplements labeled with certain claims prior to entering the market. After a supplement is on the market, FDA has the authority to deem dietary supplements misbranded or adulterated and may issue warnings or order a mandatory recall in certain circumstances.³⁴

The following sections provide details on FDA's dietary supplement-specific authorities, regulations, and guidance on NDIs, CGMPs, labeling (including packaging, inserts, and information at the point of sale), claims, and serious adverse event reporting.

New Dietary Ingredients

A dietary ingredient is a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance intended to supplement the diet by increasing total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of the aforementioned ingredients.³⁵ As defined by DSHEA, an NDI is a dietary ingredient that was not marketed in the United States before October 15, 1994.³⁶ A firm that seeks to market a dietary supplement containing an NDI must submit a notification to FDA, at least 75 days prior to marketing, establishing that a dietary supplement containing the ingredient “will reasonably be expected to be safe.”³⁷ An exception to the NDI notification requirement is if the dietary ingredient was “present in the food supply as an article used for food in a form in which the food has not been chemically altered.”³⁸ In this case, the dietary ingredient would still be considered an NDI because it was not marketed as a dietary ingredient (i.e., as or in a dietary supplement) prior to October 15, 1994, but it would be exempt from the notification requirement.³⁹

Dietary ingredients sold in the United States before October 15, 1994 are presumed safe based on their history of use by humans and do not need to be reviewed for safety by the FDA (so called “grandfathered” ingredients). Currently, there is no authoritative list of dietary ingredients that were on the market prior to October 15, 1994, although FDA has announced its intent to develop

³⁰ For more information on drug and device regulation at the FDA, see CRS Report R42130, *FDA Regulation of Medical Devices*, and CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*.

³¹ FFDC 415 [21 U.S.C. §350d].

³² FFDC 402(g) [21 U.S.C. §342(g)].

³³ FFDC 403 [21 U.S.C. §343].

³⁴ FFDC 423 [21 U.S.C. §350].

³⁵ FFDC 201(ff)(1) [21 U.S.C. §321(ff)(1)].

³⁶ FFDC 413(d) [21 U.S.C. §350b(d)].

³⁷ FFDC 413(a)(2) [21 U.S.C. §350b(a)(2)].

³⁸ FFDC 413(a)(1) [21 U.S.C. §350b(a)(1)].

³⁹ FDA, Draft Guidance, “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry,” August 2016, pp. 14-15, <https://www.fda.gov/media/99538/download>.

such a list.⁴⁰ The FDA Food Safety Modernization Act (FSMA), enacted in December 2010, required FDA to clarify the definition of an NDI and to explain the requirements for safety evaluation of NDIs within 180 days of enactment.⁴¹ The FDA published draft NDI guidance on July 5, 2011.⁴² The draft guidance generated controversy, with some industry advocates expressing concerns that the proposed guidance was burdensome and not in keeping with DSHEA.⁴³ In August 2016, FDA published a revised draft guidance, which has not been finalized.⁴⁴ FDA's 2016 update elicited similar criticisms from some stakeholders as the 2011 version.⁴⁵ In particular, industry expressed concerns about what constitutes an NDI, as well as the agency's stance on synthetic botanicals and grandfathered ingredients.⁴⁶ Public health advocates contend that scientific evidence is necessary to demonstrate safety, particularly for NDIs, as supplements continue to grow in popularity and usage.⁴⁷ Industry advocates have stated the cost of proving NDI safety would be too burdensome and would cause some manufacturers to drop production of certain supplements.⁴⁸

FDA regulations outline the information that must be included as part of an NDI notification, including a "history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe."⁴⁹ Specifically, an NDI must include (1) the name and complete address of the manufacturer or distributor of the dietary supplement that contains the NDI, or of the NDI; (2) the name of the NDI subject to the notification; (3) a description of the dietary supplement(s) that contains the NDI, including the level of the NDI in the supplement and conditions of its use; (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe; and (5) the signature of the designated person.⁵⁰ The 2016 NDI draft guidance provides additional detail

⁴⁰ FDA, "Public Meeting to Discuss the Development of a List of Pre-DSHEA Dietary Ingredients," October 3, 2017, <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-discuss-development-list-pre-dshea-dietary-ingredients>.

⁴¹ P.L. 111-353, §113(b).

⁴² FDA, "Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability," 76 *Federal Register* 39111.

⁴³ For example, see Hyman Phelps & McNamara, P.C., "HP&M Files Comments on Draft NDI Guidance; Request Withdrawal and Reissuance Reflecting DSHEA Intent," press release, December 7, 2011, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/12/hpm-files-comments-to-draft-ndi-guidance-request-withdrawal-and-reissuance-reflecting-dshea-intent.html.

⁴⁴ FDA, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry," 81 *Federal Register* 53486, August 12, 2016.

⁴⁵ For example, see Hyman Phelps & McNamara, P.C., "FDA Issues Long-Awaited Revised Dietary Supplement NDI Draft Guidance," August 14, 2016, <https://www.thefdalawblog.com/2016/08/fda-issues-long-awaited-revised-dietary-supplement-ndi-draft-guidance/>. New Hope Network, "Trades unite in opposition to FDA's NDI guidance document," December 14, 2016, <https://www.newhope.com/regulatory/trades-unite-opposition-fdas-ndi-guidance-document>.

⁴⁶ New Hope Network, "Trades unite in opposition to FDA's NDI guidance document," December 14, 2016, <https://www.newhope.com/regulatory/trades-unite-opposition-fdas-ndi-guidance-document>.

⁴⁷ Pieter Cohen and Scott Bass, "Injecting Safety into Supplements—Modernizing the Dietary Supplement Law," *New England Journal of Medicine*, December 19, 2019, vol. 381, no. 25, pp. 2387-2389.

⁴⁸ Natural Products Insider, "NPA: Costs of NDI Submissions Could Be Overly Burdensome Based on FDA Guidance," January 12, 2017, <https://www.naturalproductsinsider.com/regulatory/npa-costs-ndi-submissions-could-be-overly-burdensome-based-fda-guidance>.

⁴⁹ 21 C.F.R. §190.6.

⁵⁰ *Ibid.*

about the information that FDA believes should be submitted to the agency as part of the NDI notification.

FDA must keep the information in an NDI notification confidential for the first 90 days after receiving it.⁵¹ If the manufacturer or distributor submits additional information in support of the NDI notification, FDA may reset the 75-day period and assign a new filing date.⁵² FDA does not approve NDI notifications. Instead, as indicated in the draft guidance, the agency generally issues one of four response letters: (1) a letter of acknowledgment without objection; (2) a letter listing deficiencies that make the notification incomplete; (3) an objection letter raising safety concerns based on information in the notification or identifying gaps in the history of use or other evidence of safety; or (4) a letter raising other regulatory issues with the NDI or dietary supplement (e.g., the NDI or supplement is excluded from the definition of a dietary supplement).⁵³

Current Good Manufacturing Practices

Dietary supplement processors, manufacturers, and packers are responsible for ensuring that a dietary supplement or dietary supplement ingredient is safe by following CGMPs.⁵⁴ CGMPs establish the minimum standards for activities related to manufacturing, packaging, labeling, or holding dietary supplements for the purposes of ensuring the product's quality throughout the manufacturing process to minimize the risks of a potentially unsafe or otherwise illegal product from reaching the marketplace.

DSHEA authorized FDA to establish, by regulation, CGMPs specific to dietary supplements modeled after the existing CGMPs for food.⁵⁵ Dietary supplement-specific CGMPs were requested by industry, citing concerns that CGMPs developed for conventional food products did not adequately address the unique characteristics of dietary supplements. These regulations were finalized in 2007,⁵⁶ and largely addressed the concerns raised by the industry. Dietary supplement CGMPs contain sections that detail additional quality control procedures and recordkeeping requirements for each step in the manufacturing process.⁵⁷ Following CGMPs should ensure that final products do not include the wrong ingredients; too much or too little of a dietary ingredient;⁵⁸ contaminants such as natural toxins, bacteria, pesticides, glass, lead or other heavy metals; or improper packaging or labeling. FDA noted in the final rule that “the focus of CGMP is on process controls to ensure that the desired outcome is consistently achieved, and not on the inherent safety of the ingredients used.”⁵⁹

⁵¹ FFDC 413(a) [21 U.S.C. §350b(a)].

⁵² 21 C.F.R. §190.6(d).

⁵³ FDA, “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry,” Draft Guidance, p. 54.

⁵⁴ FFDC 402(g) [21 U.S.C. §342(g)];

⁵⁵ FFDC 402(g)(2) [21 U.S.C. §342(g)(2)], as amended by P.L. 103-417, §9.

⁵⁶ 21 C.F.R. §111. FDA, “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Final Rule,” 72 *Federal Register* 34752-34958, June 25, 2007.

⁵⁷ FDA, “Dietary Supplement Current Good Manufacturing Practices (CGMPs) and Interim Final Rule (IFR) Facts,” press release, June 22, 2007, <http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110858.htm>.

⁵⁸ Some researchers note that, for most botanicals, consensus has not been reached on analytical markers or standardized analytical methods for determining the presence or quantity of the botanical. For example, see J Kemsley, “Botanical Scrutiny,” *Chemical and Engineering News*, March 18, 2013, pp. 12-17.

⁵⁹ FDA, “Dietary Supplement Current Good Manufacturing Practices (CGMPs) and Interim Final Rule (IFR) Facts,” press release, June 22, 2007, <http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110858.htm>.

CGMP for dietary supplements apply to all domestic and foreign companies that manufacture, package, label, or hold a dietary supplement for import and sale in any state or territory of the United States, the District of Columbia, or Puerto Rico.⁶⁰ This includes those involved with testing, quality control, packaging and labeling, and distribution of dietary supplements, but excludes retail establishments that are solely involved in the direct sale of dietary supplements to individual consumers.

Labeling

Although dietary supplements are generally considered food for purposes of FDA regulation, they have different labeling requirements set forth under the FFDCA. Dietary supplement labeling includes packaging, inserts, and information at the point of sale. The Nutrition Labeling and Education Act (NLEA) of 1990 amended the FFDCA to require that all foods, with certain exceptions, bear nutritional content labels.⁶¹ The Dietary Supplement Act of 1992 created a one-year moratorium on the implementation of NLEA with respect to dietary supplement labeling.⁶² In 1994, DSHEA provided FDA the authority to promulgate labeling regulations specific to dietary supplements,⁶³ and in 1997, FDA issued regulations addressing the statement of identity, nutrition labeling, ingredient labeling, and nutrient content and health claims for dietary supplements.⁶⁴ While similar to the requirements for nutrition labeling of food, dietary supplement labeling requirements differ in several specific aspects.⁶⁵

Dietary supplements are required to have a supplement facts panel (as opposed to a nutrition facts panel for conventional foods).⁶⁶ Dietary supplement labels may display certain claims, discussed in more detail below, but they must also display a standard disclaimer, and may not link the supplement or its ingredients to the treatment of a specific disease. The FDA's *Dietary Supplement Labeling Guide* sets forth the general display (principal display panel, or PDP) and placement requirements of dietary supplement labeling.⁶⁷ An example of a dietary supplement PDP is shown in **Figure B-1**. Dietary supplement labels are required to have the following information:

- a statement of identity (name of the dietary supplement, the term “dietary supplement,” which may be modified);⁶⁸
- the net quantity of contents statement (amount of the dietary supplement);⁶⁹

⁶⁰ 21 C.F.R. §111.1

⁶¹ P.L. 101-535, §2.

⁶² P.L. 102-571, §202.

⁶³ P.L. 103-417, §7.

⁶⁴ FDA, “Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation,” 62 *Federal Register* 49826, September 23, 1997.

⁶⁵ For specific information on these differences, see FDA, *Guidance for Industry: A Dietary Supplement Labeling Guide*, April 2005, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm>.

⁶⁶ Regulations regarding the layout and content of the supplement facts panel are at 21 C.F.R. §101.36.

⁶⁷ FDA, *Guidance for Industry: A Dietary Supplement Labeling Guide*, April 2005, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm>.

⁶⁸ FFDCA §403(s)(2)(B) [21 U.S.C. §342(s)(2)(B)], 21 C.F.R. §101.3.

⁶⁹ 21 C.F.R. §101.7.

- a Supplement Facts Panel (nutrition labeling);⁷⁰
- an ingredients list, and the quantity of such ingredients in the product; with the exception of quantities for the ingredients included in “proprietary blends,” which do not need to be listed;⁷¹ and
- the name and place of business of the manufacturer, packer, or distributor.⁷²

Claims

In addition to the required labeling, the FFDCFA permits (but does not require) manufacturers to make certain types of claims about supplements’ benefits.⁷³ Dietary supplement manufacturers may not legally claim that their product will diagnose, cure, mitigate, treat, or prevent a specific disease, and certain claims require FDA-approved disclaimers.⁷⁴ FDA guidance provides details on the disclaimers that must accompany certain claims on the product label.⁷⁵ Similar to food manufacturers, dietary supplement manufacturers may make nutrient content claims and health claims.⁷⁶ They may also make structure/function claims.⁷⁷ These claims are explained below.

Nutrient Content Claims

A nutrient content claim is one that expressly or implicitly characterizes the level of a nutrient in a dietary supplement.⁷⁸ An expressed nutrient content claim (e.g., “contains 100 calories”) is one that contains a direct statement about the level or range of a nutrient within the dietary supplement.⁷⁹ An implied nutrient content claim is one that either (1) describes the nutrient in a manner that suggests that it is absent or present in a certain amount (e.g., “high in oat bran”) or (2) suggests that the dietary supplement, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an express claim or statement about a nutrient (e.g., “healthy”).⁸⁰

Health Claims

Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition;⁸¹ for example, “While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.” These claims can be made through written statements, symbols, or vignettes.

⁷⁰ 21 C.F.R. §101.36.

⁷¹ FFDCFA §403(s)(2)(A) [21 U.S.C. §342(s)(2)(A)], 21 C.F.R. §101.4, and 21 C.F.R. §101.36.

⁷² 21 C.F.R. §101.5.

⁷³ FFDCFA §403(r) [21 U.S.C. §343(r)].

⁷⁴ FFDCFA §403(r)(6) [21 U.S.C. §343(r)(6)].

⁷⁵ FDA, Guidance for Industry: A Dietary Supplement Labeling Guide, April 2005, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm>.

⁷⁶ FFDCFA §403(r) [21 U.S.C. §343(r)].

⁷⁷ While structure/function claims are only authorized for dietary supplements (21 USC §343(r)(6) and 21 CFR §101.93(f)), they are also widely used for food, and their use is not prohibited in statute, regulations, or guidance.

⁷⁸ 21 C.F.R. §101.13(b).

⁷⁹ 21 C.F.R. §101.13(b)(1).

⁸⁰ 21 C.F.R. §101.13(b)(1) and (2); and 21 C.F.R. §101.65.

⁸¹ 21 C.F.R. §101.14.

For the FDA to authorize use of a health claim on dietary supplement labeling, it must meet certain criteria.⁸² Generally, they must meet a significant scientific agreement (SSA) standard, as determined by the FDA, in order to be authorized in regulation by the FDA.⁸³ The FDA authorizes health claims only when the agency “determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”⁸⁴

Health claims may also be authorized based on authoritative statements from federal scientific bodies. The latter type of claim was authorized in the FDA Modernization Act (FDAMA), although not for dietary supplements.⁸⁵

Another type of health claim, known as a qualified health claim, may be used for dietary supplements. Qualified health claims are based on less scientific evidence than the SSA required for other health claims, but must be approved by the FDA (however, they are not required to be authorized in statute or an authorizing regulation).⁸⁶ FDA guidance provides standardized qualifying language to use with qualified health claims.⁸⁷

Structure/Function Claims

In addition to health and nutrient content claims, dietary supplement manufacturers are allowed to make statements describing the role of their nutrients’ or dietary ingredients’ intended effect on the structure or function of the body.⁸⁸ Structure/function claims describe how a product may affect the organs or systems of the body, but cannot mention any specific disease⁸⁹ (for example, “calcium builds strong bones”). A structure/function claim describes the role of a dietary supplement in the structure and functions of the body, and must provide truthful and non-misleading claims that describe this role.⁹⁰

Although FDA preapproval is not required for structure/function claims, manufacturers must have substantiation (evidence) for these claims, notify FDA within 30 days of a product being marketed with a structure/function claim on its label, and provide a two-part disclaimer on the

⁸² 21 C.F.R. §101.14(b)(1)-(3).

⁸³ FFDC §403(r)(5)(D) [21 U.S.C. §343(r)(5)(D)]; 21 C.F.R. §101.14(c).

⁸⁴ 21 C.F.R. §101.14(c). This standard is referred to as the significant scientific agreement (SSA) standard. For more information on the SSA review process, see *FDA Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims*, Silver Spring, MD, January 2009, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm>.

⁸⁵ P.L. 105-115, §303. FDA, “Label Claims for Conventional Foods and Dietary Supplements,” current as of June 19, 2018, <https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements>.

⁸⁶ FDA, *Guidance for Industry: A Food Labeling Guide*, October 2009, p. Appendix D, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064923.htm>.

⁸⁷ FDA, *Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*, July 2003, current as of September 20, 2018, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-interim-procedures-qualified-health-claims-labeling-conventional-human-food-and>.

⁸⁸ FFDC §403(r)(6) [21 U.S.C. §343(r)(6)].

⁸⁹ *Ibid.* 21 C.F.R. 101.93(f).

⁹⁰ FDA, *Guidance for Industry: A Dietary Supplement Labeling Guide*, April 2005, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm070613.htm#6-43>.

supplement label.⁹¹ First, the label must state that the statement or claim has not been evaluated by the FDA. It must also state that the dietary supplement product is not intended to “diagnose, treat, cure, or prevent any disease.”⁹²

Serious Adverse Event Reporting

Dietary supplements are not required to undergo premarket review for safety. To identify safety issues, the FDA mainly relies on information provided by manufacturers under the adverse event reporting system. The FDA created a voluntary adverse event reporting system for supplements in 1993.⁹³ This system was designed to (1) detect adverse events; (2) generate and assess signals of potential public health concerns; (3) take appropriate actions based on these assessments. According to an HHS Office of the Inspector General (OIG) report, that system provided inadequate data on adverse events, due to its voluntary nature and limited scope.⁹⁴ The OIG report concluded that the reporting system detected relatively few adverse events, lacked adequate information to assess possible health concerns, and contained limited medical, product, and consumer information.⁹⁵

The Dietary Supplement and Non-Prescription Drug Consumer Protection Act, enacted in 2006, required several changes to the adverse event reporting system for dietary supplements.⁹⁶ It amended the FFDCA to require supplement manufacturers, packers, and distributors to submit reports of serious adverse events involving their products that occur in the United States, and it also required the FDA to create and maintain a system to track adverse events related to dietary supplements.⁹⁷ The CFSAN Adverse Event Reporting System (CAERS) contains information on adverse event and product complaint reports submitted to FDA for foods, dietary supplements, and cosmetics.⁹⁸ The public may also submit adverse event reports to this adverse event reporting system. Public submission of adverse event reports is voluntary.

A GAO report identified 6,307 reports of adverse events from 2008 through 2011, of which 71% came as serious adverse events from industry, as mandated by the Dietary Supplement and Non-Prescription Drug Consumer Protection Act.⁹⁹ Another study from CFSAN reported that between 2004 and 2013, based on CAERS data, FDA received more than 15,000 adverse event reports (67% of which were mandatory), with serious reported outcomes such as death and

⁹¹ FFDCA §403(r)(6) [21 U.S.C. §343(r)(6)].

⁹² Ibid; 21 CFR §101.93(f)-(g).

⁹³ Office of the Inspector General, Department of Health and Human Services, *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve*, April 2001, <https://oig.hhs.gov/oei/reports/oei-01-00-00180.pdf>.

⁹⁴ Ibid.

⁹⁵ Ibid.

⁹⁶ FFDCA §761 [21 U.S.C. §379aa-1], as amended by P.L. 109-462, §3. An adverse event is defined as “any health-related event associated with the use of a dietary supplement that is adverse;” and a serious adverse event is defined as “an adverse event that—(A) results in—(i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (b) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).”

⁹⁷ P.L. 109-462, Section 3. Information on how to submit an adverse event report can be found at <http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/default.htm>.

⁹⁸ FDA, “CFSAN Adverse Event Reporting System (CAERS),” current as of July 29, 2020, <https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers>.

⁹⁹ GAO, *Dietary Supplements: FDA May Have Opportunities to Expand its Use of Reported Health Problems to Oversee Products*, GAO-13-244, March 2013, p. 1, <http://www.gao.gov/products/GAO-13-244>.

hospitalizations, among others.¹⁰⁰ In FY2020, FDA reported receiving more than 3,112 adverse event reports related to dietary supplements,¹⁰¹ an increase from FY2019, during which FDA received more than 2,559 such adverse event reports.¹⁰² FDA has estimated that, due to significant underreporting, the annual number of adverse events linked to dietary supplements may be 50,000.¹⁰³ This may be because consumers may not consistently report adverse events to the FDA, and/or they may be contacting poison control centers, which generally do not send information about adverse events to the FDA.

Another study looked at visits to U.S. emergency departments from 2004 through 2013 that were due to adverse events related to dietary supplements.¹⁰⁴ The study estimated that 23,005 emergency department visits each year were attributed to adverse events related to dietary supplements.¹⁰⁵

Adverse events that are linked to a dietary supplement or a dietary supplement ingredient by an adverse event report are usually not considered sufficient to warrant action against a product.¹⁰⁶ A pattern of seemingly related events linked to a dietary supplement may cause FDA to investigate the product or take further action.¹⁰⁷

Compliance and Enforcement

Consistent with FDA's regulation of conventional foods, the agency does not approve dietary supplements prior to marketing. This contrasts with drug regulation, where the manufacturer must prove the safety and effectiveness prior to marketing a product.¹⁰⁸ Because the bulk of FDA's regulatory authority with respect to dietary supplements exists for products that are already on the market, this is generally where FDA concentrates its enforcement activities to determine compliance with its regulations.

In addition to the serious adverse event reporting system, several other mechanisms exist to identify potential safety concerns. These include conducting inspections, screenings, and recalls. Through these efforts, FDA has identified dietary supplements that contain undeclared or deceptively labeled ingredients.¹⁰⁹ For example, one analysis of FDA data reported that 776 adulterated dietary supplements were identified by the agency from 2007 through 2016, of which

¹⁰⁰ Babgaleh B Timbo, Stuart J Chirtel, John Ihrle, et al., "Dietary Supplement Adverse Event Report Data From the FDA Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS), 2004-2013," May 2018, vol. 52, no. 5, pp. 431-438.

¹⁰¹ FDA, FY2022 Justification of Estimates for Appropriations Committees, p. 69, <https://www.fda.gov/media/149616/download>.

¹⁰² FDA, FY2021 Justification of Estimates for Appropriations Committees, p. 59, <https://www.fda.gov/media/135078/download>.

¹⁰³ GAO, *FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, 09-250, January 2009, <http://www.gao.gov/products/GAO-09-250>.

¹⁰⁴ Andrew Geller, Nadine Shehab, Nina Weidle, et al., "Emergency Department Visits for Adverse Events Related to Dietary Supplements," *New England Journal of Medicine*, October 2015 vol. 373, pp. 1531-1540.

¹⁰⁵ Ibid.

¹⁰⁶ GAO, *Dietary Supplements: FDA May Have Opportunities to Expand its Use of Reported Health Problems to Oversee Products*, GAO-13-244, March 2013, p. 1, <http://www.gao.gov/products/GAO-13-244>, p. 32.

¹⁰⁷ Ibid.

¹⁰⁸ For more information on drug approval and regulation, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*.

¹⁰⁹ These may include, but are not limited to, active ingredients in FDA-approved drugs or their analogues and other compounds that do not qualify as dietary ingredients, such as novel synthetic steroids.

619 were found to contain one unapproved drug ingredient, and 157 products were found to contain more than one pharmaceutical ingredient.¹¹⁰ Such products are often promoted for weight loss, sexual enhancement, and bodybuilding. FSMA provided FDA the authority to notify the DEA when it determines that an NDI may contain an anabolic steroid or its analogue.¹¹¹ FDA maintains a database of “tainted products” that are marketed as dietary supplements, noting that “this list only includes a small fraction of the potentially hazardous products with hidden ingredients marketed to consumers on the internet and in retail establishments.”¹¹² While the agency may take steps to remove unsafe dietary supplements from the market, in the past, the process for FDA to prove a significant or unreasonable risk was lengthy. For example, it took the FDA 10 years to amass enough data to meet the statutory burden of proof for banning Ephedra from the market.¹¹³

According to the FDA’s FY2022 Congressional Budget Justification, in FY2020, the agency’s operations and oversight, including inspection activities, were significantly affected by the Coronavirus Disease 2019 (COVID-19) pandemic, resulting in fewer dietary supplement inspections conducted than in previous years. At the same time, the dietary supplement market grew, reaching record sales in 2020.¹¹⁴ The agency’s FY2020 compliance activities resulted in 49 warning letters, 15 detentions, and one injunction filed with respect to dietary supplements.¹¹⁵

Dietary Supplement Marketing

Although the FDA has broad regulatory authority over dietary supplements, the agency shares some responsibility with the Federal Trade Commission (FTC).¹¹⁶ While the FDA regulates claims made on product labeling (including packaging, inserts, and information at the point of sale), the FTC has primary responsibility to regulate dietary supplement advertising.¹¹⁷ This includes print and broadcast advertisements, infomercials, catalogs, Internet marketing, and similar direct marketing materials. The FDA and FTC have the responsibility to ensure that both

¹¹⁰ Jenna Tucker, Tessa Fischer, Laurence Upjohn, et al., “Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated With US Food and Drug Administration Warnings,” October 12, 2018, *JAMA Network Open*, vol. 1, no. 6.

¹¹¹ FDCA §413(c) [21 U.S.C. §350b(c)], as amended by P.L. 111-353, §113.

¹¹² FDA, “Tainted Products Marketed as Dietary Supplements_CDERR,” page last updated March 29, 2021, https://www.accessdata.fda.gov/scripts/sda/sdnavigation.cfm?sd=tainted_supplements_cder.

¹¹³ GAO, *Food Safety: FDA Has Begun to Take Action to Address Weaknesses in Food Safety Research, but Gaps Remain*, 10-182R, April 23, 2010, p. 10, <http://www.gao.gov/assets/100/96676.pdf>.

¹¹⁴ Grebow, Jennifer, “Dietary supplement sales success post-COVID: How can industry keep the momentum going after the pandemic?,” *Nutritional Outlook*, May 26, 2021, <https://www.nutritionaloutlook.com/view/dietary-supplement-sales-success-post-covid-how-can-industry-keep-the-momentum-going-after-the-pandemic>. “Supplement Market Hits Record Growth of 14.5%, According to Nutrition Business Journal’s 2021 Supplement Business Report,” *Globe Newswire*, June 28, 2021, <https://www.globenewswire.com/news-release/2021/06/28/2254146/0/en/Supplement-Market-Hits-Record-Growth-of-14-5-According-to-Nutrition-Business-Journal-s-2021-Supplement-Business-Report.html>.

¹¹⁵ FDA, FY2022 Justification of Estimates for Appropriations Committees, p. 68-69, <https://www.fda.gov/media/149616/download>.

¹¹⁶ FDA, Memorandum of Understanding (MOU) with Federal Trade Commission Concerning Exchange of Information (FDA-225-71-8003), <https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003>.

¹¹⁷ 15 U.S.C. §45(a)(1).

dietary supplement labeling and advertising is truthful, not misleading, and that any claims made may be substantiated.¹¹⁸

The FTC's authority derives from Section 5 of the Federal Trade Commission Act that prohibits "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce."¹¹⁹ Additionally, the FTC Act prohibits dissemination of false advertisements by any means for the purpose of inducing the purchase of food, drugs, devices, services, or cosmetics.¹²⁰ The FTC Act defines false advertisements as "any advertisement, other than labeling, which is misleading in any material respect."¹²¹

Similar to the FDA, the FTC requires that supplement manufacturers' claims are adequately substantiated. The FTC has created a guide for industry, which outlines its expectations, role, and enforcement efforts regarding substantiation.¹²² The FTC standard is summed up as the following:

- Advertising must be truthful and not misleading.
- Before disseminating an advertisement, advertisers must have adequate substantiation for all objective product claims.

The FTC defines a deceptive advertisement as one that "contains a misrepresentation or an omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment."¹²³ The FTC's standard of substantiation for express and implied claims is one of "competent and reliable scientific evidence,"¹²⁴ which differs from FDA's requirements for health, nutrient content, and structure/function claims. The FTC generally enforces these standards through targeted law enforcement action.¹²⁵

Issues for Congress

Consumers, the dietary supplement industry, Congress, and federal regulators all have a stake in supplement safety and quality. Current federal policy toward regulating dietary supplements was intended to balance these competing interests. DSHEA provided FDA the authority to step in against products that were unsafe or adulterated, but "not to take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers."¹²⁶

Under current law, dietary supplements are generally regulated as food—meaning that the FDA does not take regulatory action until something goes wrong (as opposed to drug regulation, where

¹¹⁸ "Business Guide for Dietary Supplement Industry Released by FTC Staff: Guide Will Assist Industry in Ensuring Truthful Ads," *Federal Trade Commission*, November 18, 1998, <http://www.ftc.gov/news-events/press-releases/1998/11/business-guide-dietary-supplement-industry-released-ftc-staff>.

¹¹⁹ 15 U.S.C. §45(a)(1).

¹²⁰ 15 U.S.C. §52.

¹²¹ 15 U.S.C. §55(a).

¹²² FTC, Bureau of Consumer Protection, *Dietary Supplements: An Advertising Guide for Industry*, April 2001, <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry>.

¹²³ *Ibid.*

¹²⁴ *Ibid.*

¹²⁵ FTC, *Deceptive Marketing of Dietary Supplements FTC Enforcement Activities*, Prepared Statement Before the Senate Special Committee on Aging, Washington, DC, May 26, 2010, <http://www.ftc.gov/os/testimony/100526dietarysupplementstatement.pdf>.

¹²⁶ P.L. 103-417, §2.

proof of safety and effectiveness are required prior to putting a product on the market). Whether this is an appropriate level of regulation has been a long-standing concern. The general framework for regulation of dietary supplements has remained largely unchanged since 1994, when DSHEA was enacted, with some exceptions (e.g., mandatory serious adverse event reporting, facility registration). However, since then, the dietary supplement market has grown, and regulatory and research questions have become more complex. These questions continue to reflect the fundamental balance between personal choice and safety. The following sections discuss recent areas of regulatory and legislative concern, including the exclusion of certain drug ingredients from the dietary supplement definition, issues surrounding supplement safety, and the role of supplements in individuals' health.

Dietary Supplements and Drug Exclusion

The definition of a dietary supplement explicitly excludes any article that is an active ingredient in an approved drug, or that has been authorized for investigation as a new drug under an investigational new drug application (IND).¹²⁷ Although FDA *could* issue a regulation allowing such an article to be used as or in a dietary supplement, to date, the agency has never issued such a regulation for any article. This exclusion was intended, at least in part, to maintain incentives for pharmaceutical companies to invest in clinical trials needed to obtain FDA approval of new drugs. However, an article that is approved as a drug or being investigated as a drug may be marketed in or as a dietary supplement if it was marketed as a dietary supplement or as a food *prior* to its approval or clinical investigation—unless FDA issues a regulation to the contrary.¹²⁸ According to FDA, this prior market clause “establishes a system for determining whether articles will be deemed dietary supplements or drugs, and regulated accordingly, depending on how such articles were marketed and categorized when they first entered the marketplace.”¹²⁹

In recent years, regulators, Congress, and stakeholders have proposed modifying the drug exclusion provision, albeit for different reasons. For example, former FDA Principal Associate Commissioner for Policy Lowell Schiller noted in his remarks during a meeting of the Council for Responsible Nutrition (a dietary supplement trade association) that the drug exclusion provision, at times, creates enforcement challenges for FDA. Specifically,

if a product is labeled as a dietary supplement, but it contains one of those same drug substances, it may not actually be a dietary supplement at all. In such situations, there might be other violations of the [FFDCA] that provide a clear path to removing the product from the market. But establishing those violations can be tricky, depending on the circumstances.

For example, sometimes we see products that are marketed as dietary supplements with express claims about treating impotence, but it turns out that the secret ingredient is undisclosed sildenafil (i.e., Viagra). In such cases, the claims about impotence establish that the product is intended for use as a drug, and classifying the product as an unapproved new drug will be a fairly straightforward determination for us to make.

But other cases may be more complicated. For example, if a drug substance is mislabeled as a dietary supplement, but there are no express claims, then depending on the facts, it could be resource-intensive or otherwise challenging to determine the best path forward.

¹²⁷ FFDCA §201(ff)(3)(B) [21 U.S.C. §321(ff)(3)(B)].

¹²⁸ FFDCA §201(ff)(3)(A) [21 U.S.C. §321(ff)(3)(A)].

¹²⁹ Docket No. FDA-2005-P-0259 (formerly Docket No. 2005P-0305), FDA response to Ms. Kathleen M. Sanzo, Esq. Morgan, Lewis & Bockius LLP, January 12, 2009, p. 3.

One way to help address this issue would be to move the drug substance exclusion out of the definition of “dietary supplement,” and make it clear that the presence of such substances in a dietary supplement renders the product an adulterated dietary supplement – which would be in addition to any other potential violations. The universe of what could be a lawful supplement wouldn’t change, but FDA would have a clear and direct way to use our authorities over adulterated dietary supplements to move against these unlawful and potentially dangerous products containing drug ingredients.¹³⁰

Other stakeholders, as well as some Members of Congress, also have proposed that the drug exclusion provision should be modified, but to allow for certain ingredients to be marketed in dietary supplements, particularly with respect to the cannabis derivative cannabidiol (CBD). CBD is a nonpsychoactive compound found in cannabis that has been marketed as a dietary supplement and promoted as treatment for a range of conditions, including anxiety, pain, and post-traumatic stress disorder. FDA has determined that because CBD is an active ingredient in an FDA-approved drug (Epidiolex) and was under clinical investigation under an IND prior to its use in dietary supplements, at this time, CBD cannot be marketed as a dietary supplement.¹³¹ FDA may issue a regulation creating an exception for CBD, but the agency has never issued such a regulation for any substance (see the text box below for additional information).

In determining whether amending the dietary supplement definition is appropriate, particularly with respect to substances such as CBD, Congress may consider the potential for adverse health effects and other unintended consequences. For example, clinical trials to support the approval of Epidiolex demonstrated the potential for liver injury at certain doses, and CBD may interact with other drugs or dietary supplements.¹³² Other concerns include the potential dosing and cumulative effects of exposure to an ingredient from multiple sources (e.g., supplements and cosmetics); whether there are populations for whom an ingredient is not appropriate (e.g., pregnant or lactating women); and whether allowing an ingredient to be marketed as a supplement could undermine incentives for conducting clinical trials and obtaining evidence of safety and effectiveness.¹³³ In addition, excepting one substance from the drug exclusion provision may set a precedent for other substances in the future.

Cannabidiol and the 2018 Farm Bill

The 2018 farm bill (Agriculture Improvement Act of 2018, P.L. 115-334) removed cannabis and cannabis derivatives that meet the definition of hemp (i.e., containing less than 0.3% concentration of delta-9 tetrahydrocannabinol [THC]) from the definition of marijuana in the Controlled Substances Act, effectively making them no longer subject to regulation as controlled substances by the Drug Enforcement Administration (DEA). However, the 2018 farm bill also explicitly preserved FDA’s authority under the FDCA and Section 351 of the Public Health Service Act, including for hemp-derived products. Since enactment of the farm bill, FDA has maintained that it is unlawful to market CBD (or THC) as, or in, dietary supplements, regardless of whether they are hemp-derived, citing the drug exclusion provision of the dietary supplement definition.

¹³⁰ FDA, “Remarks by Lowell Schiller, JD at the Council for Responsible Nutrition Conference - 11/7/2019,” <https://www.fda.gov/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019>.

¹³¹ See question 9 in “FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers,” updated April 2, 2019, <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#dietarysupplements>.

¹³² FDA, “What You Need to Know (And What We’re Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD,” current as of March 5, 2020, <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>.

¹³³ FDA, “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments,” *Federal Register*, vol. 84, no. 64, 12969-12975, April 3, 2019.

In providing its reasoning for this determination, FDA explains that in June 2018, the agency approved a new drug application (NDA) for the prescription drug Epidiolex, submitted by GW Pharmaceuticals, for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients two years old and older. The active ingredient in Epidiolex is CBD. FDA has determined that because CBD is an active ingredient in an FDA-approved drug (Epidiolex) and was under clinical investigation under an IND prior to its use in dietary supplements, at this time, CBD cannot be marketed as a dietary supplement. FDA may issue a regulation creating an exception for CBD, but the agency has never issued such a regulation for any substance.

Despite FDA's determination that marketing CBD as a dietary supplement is unlawful, these products remain on the market. On November 14, 2019, the Consumer Healthcare Products Association (CHPA) submitted a citizen petition to FDA, asking the agency to "exercise its statutory authority and discretion to engage in rulemaking that establishes a regulatory pathway to legally market dietary supplements containing [CBD] derived from hemp (as defined in 7 U.S.C. §1639o(1))" and to require that manufacturers of CBD-containing dietary supplements submit NDI notifications. In the explanatory statement accompanying the enacted FY2020 appropriations, Congress directed FDA to issue a policy of enforcement discretion with respect to CBD products that meet the definition of hemp, but the agency has not done so.

In the absence of FDA action, legislation has been introduced that would amend the dietary supplement definition to except hemp-derived CBD and related substances from the drug exclusion provision of the dietary supplement definition. Even if either of these provisions were to become law, CBD-containing supplements may still be subject to other FDCA requirements. For example, to lawfully market a CBD product as a dietary supplement, a firm may need to submit an NDI notification to FDA, in addition to meeting the other statutory and regulatory requirements.

For additional information about CBD regulation, see CRS Report R46189, *FDA Regulation of Cannabidiol (CBD) Consumer Products: Overview and Considerations for Congress*, coordinated by Agata Bodie.

Dietary Supplement Safety

Regardless of the form or the reasons for which they are consumed, there is consensus that dietary supplements consumed by Americans should be safe. There remains disagreement on how to achieve the goals of safety. According to the 2014 FDA Health and Diet Survey, more than half of vitamin and mineral supplement users reported thinking that the government preapproves these products before they are marketed.¹³⁴ While this is generally the case for drugs, it is not the case for dietary supplements. Some stakeholders have raised that FDA's ability to identify safety concerns associated with dietary supplements is undermined by a lack of information that is available for other regulated products, such as drugs.¹³⁵

FDA and public health stakeholders have identified several limitations in FDA's current authority over dietary supplements. Among these limitations is that under the current statutory framework, while entities that manufacture, process, pack, or hold supplements must register with FDA, the agency is not authorized to require listing of individual dietary supplement products. As a result, the agency is not aware of all the products currently on the market. FDA,¹³⁶ Congress,¹³⁷ and

¹³⁴ FDA Center for Food Safety and Applied Nutrition, "2014 FDA Health and Diet Survey," May 6, 2016, p. 15, <https://www.fda.gov/media/96883/download>.

¹³⁵ Pieter Cohen and Scott Bass, "Injecting Safety into Supplements—Modernizing the Dietary Supplement Law," *New England Journal of Medicine*, December 19, 2019, vol. 381, no. 25, pp. 2387-2389. Bryan Denham, "Dietary Supplements—Regulatory Issues and Implications for Public Health," *JAMA*, vol. 306, no. 4 (July 27, 2011), pp. 428-429. See also *Dietary Supplements: FDA May Have Opportunities to Expand its Use of Reported Health Problems to Oversee Products*, GAO-13-244, March 2013, p. 1, <http://www.gao.gov/products/GAO-13-244>.

¹³⁶ FDA, FY2021 Justification of Estimates for Appropriations Committees, p. 43, <https://www.fda.gov/media/135078/download>. FDA, FY2020 Justification of Estimates for Appropriations Committees, p. 41, <https://www.fda.gov/media/121408/download>.

¹³⁷ See, for example, S. 1425 (113th Congress), the Dietary Supplement Labeling Act of 2013.

some stakeholders¹³⁸ have proposed establishing a product listing requirement for supplements, similar to that which exists for drugs. According to the agency, “this would allow FDA to know when new products are introduced, quickly identify and act against dangerous or otherwise illegal products, and improve transparency and promote risk-based regulation.”¹³⁹ Some industry trade groups have indicated support for FDA’s proposal, while others have expressed opposition, calling it “redundant” and “unnecessary.”¹⁴⁰

Another limitation concerns submission of NDI notifications to FDA, specifically a reported lack of industry compliance with submission of complete notifications, as well as a so-called loophole in the current NDI framework. In its 2016 draft NDI guidance, the agency indicated that a goal of the guidance was to improve the rate of compliance with the notification requirements,¹⁴¹ and FDA has issued warning letters to manufacturers who may not be following the NDI requirements. In FY2020, FDA responded to 43 NDI notifications, of which the agency acknowledged 16 with no objection, deemed 9 to be incomplete, and raised safety or identity concerns with 18.¹⁴²

In addition to compliance challenges, some stakeholders have proposed that legislative changes are needed to require that safety data be submitted for all NDIs. Under current law, an NDI notification is not required if the NDI was “present in the food supply as an article used for food in a form in which the food has not been chemically altered.”¹⁴³ Some observers have referred to this exception as a “loophole,” which allows companies to circumvent the NDI notification process.¹⁴⁴ Specifically, manufacturers reportedly are marketing ingredients as food in energy bars or drinks pursuant to a GRAS determination, which does not require a notification to FDA. Then, once the ingredient has been in the food supply for a few months, the manufacturer will market it in a dietary supplement as a dietary ingredient without submitting an NDI notification to FDA.¹⁴⁵

The Role of Dietary Supplements in Health and Health Care

Experts recommend that individuals meet their nutritional needs by eating a variety of foods, as outlined in the *2020-2025 Dietary Guidelines for Americans*, consistent with previous versions of

¹³⁸ Pieter Cohen and Scott Bass, “Injecting Safety into Supplements—Modernizing the Dietary Supplement Law,” *New England Journal of Medicine*, December 19, 2019, vol. 381, no. 25, pp. 2387-2389. The Pew Charitable Trusts, “Congress Should Prioritize Dietary Supplement Reform as Part of Its Efforts to Strengthen Public Health,” April 22, 2021, <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2021/04/congress-should-prioritize-dietary-supplement-reform-as-part-of-efforts-to-strengthen-public-health>.

¹³⁹ FDA, FY2021 Justification of Estimates for Appropriations Committees, p. 43, <https://www.fda.gov/media/135078/download>.

¹⁴⁰ Natural Products Insider, “FDA, consumer groups in favor of mandatory listing of dietary supplement products,” October 12, 2020, <https://www.naturalproductsinsider.com/regulatory/fda-consumer-groups-favor-mandatory-listing-dietary-supplement-products>.

¹⁴¹ FDA, “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry,” Draft Guidance, p. 12.

¹⁴² FDA, FY2022 Justification of Estimates for Appropriations Committees, p. 69, <https://www.fda.gov/media/149616/download>.

¹⁴³ FDCA §413(a)(1) [21 U.S.C. §350b(a)(1)].

¹⁴⁴ Pieter Cohen and Scott Bass, “Injecting Safety into Supplements—Modernizing the Dietary Supplement Law,” *New England Journal of Medicine*, December 19, 2019, vol. 381, no. 25, pp. 2387-2389. Natural Products Inside, “‘GRAS loophole’ rears head in FDA supplements letter,” August 12, 2021, <https://www.naturalproductsinsider.com/regulatory/gras-loophole-rears-head-fda-supplements-letter>.

¹⁴⁵ *Ibid.*

the policy document.¹⁴⁶ Some individuals take dietary supplements in order to meet those nutritional goals. Surveys show that over half of all Americans take dietary supplements, and that number has been increasing.¹⁴⁷

Consensus has not been reached on the effectiveness of most dietary supplements, but privately and publicly funded research is ongoing.¹⁴⁸ Specific supplements, such as folic acid, have been shown to greatly reduce the incidence of neural tube defects in infants; as a result of scientific consensus, folic acid supplementation is now considered a vital component of prenatal care.¹⁴⁹ Calcium supplementation is also often recommended by physicians for bone health, and FDA has approved a health claim associating supplements containing calcium or calcium and vitamin D with reduced risk of osteoporosis.¹⁵⁰ Not all studies support this claim.¹⁵¹ In general, there is a lack of peer-reviewed research on the effectiveness of many other supplements. For example, in recent years, CBD has been promoted as a treatment for a range of conditions, including post-traumatic stress disorder, anxiety, inflammation, and sleeplessness. However, limited scientific evidence is available to substantiate or disprove the effectiveness of CBD in treating these conditions.

Even if research were to support certain effectiveness claims for dietary supplements, as mentioned, supplements may not be promoted for the treatment, cure, or prevention of a specific disease or condition. Products that make such claims may be subject to FDA and FTC enforcement action. For example, the agencies have issued warning letters to companies marketing CBD supplements claiming to treat pain, cancer, diabetes, and Alzheimer's disease.¹⁵² As FDA noted in its warning letters, the agency considers those products to be unapproved new drugs "because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body." The agency further contends that allowing dietary supplements such as CBD to make therapeutic claims may discourage individuals from seeking treatments that have been proven to be effective and could undermine incentives for conducting clinical trials and obtaining evidence of safety and

¹⁴⁶ USDA, HHS, "Dietary Guidelines for Americans, 2020-2025," Washington, DC, December 2020, https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf.

¹⁴⁷ Suruchi Mishra, Bryan Stierman, Jaime J. Gahche, et al., "Dietary Supplement Use Among Adults: United States, 2017–2018," National Center for Health Statistics (NCHS) Data Brief No. 399, February 2021, <https://www.cdc.gov/nchs/products/databriefs/db399.htm>.

¹⁴⁸ The Office of Dietary Supplements at NIH, which funds dietary supplement research, was established under DHSEA. For more information, see <http://ods.od.nih.gov/>.

¹⁴⁹ For more information on folic acid, see <http://www.cdc.gov/ncbddd/folicacid/index.html>.

¹⁵⁰ 21 C.F.R. §101.71.

¹⁵¹ For more information on calcium, see NIH Office of Dietary Supplements, "Calcium: Fact Sheet for Health Professionals," updated August 11, 2021, <https://ods.od.nih.gov/factsheets/Calcium-HealthProfessional/>.

¹⁵² FTC, "FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases," April 2, 2019, <https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companies-advertising>. FDA, "FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns," November 25, 2019, <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>. FDA, "FDA Warns Companies Illegally Selling Over-the-Counter CBD Products for Pain Relief," March 25, 2021, <https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-over-counter-cbd-products-pain-relief>.

effectiveness for drug approval.¹⁵³ Others have supported allowing dietary supplement manufacturers to make claims that are generally permitted only for drugs.¹⁵⁴

Many physicians and their patients are reported to have a limited understanding of dietary supplement regulation, safety, and effectiveness, which may be compounded by the limited availability of peer-reviewed medical research on the effects of dietary supplements.¹⁵⁵ A 2010 report by the GAO found that consumers and medical professionals may be faced with a lack of objective information on the safety and efficacy of certain types of dietary supplements, dietary supplement ingredients, and potential side-effects or interactions with other medications.¹⁵⁶ While prescription medications can be accounted for in their medical record, patients may or may not share information about their supplement intake with physicians. Additionally, some consumers may have limited understanding of the information provided on dietary supplement marketing materials.¹⁵⁷ However, some physicians recommend dietary supplements to their patients based on the available literature, and still more patients take supplements based on their own research and concerns.

The federal government and the dietary supplement industry have taken steps to address consumer and health care provider understanding of dietary supplements through investment in research and the promotion of industry standards.¹⁵⁸ The NIH, FDA, and Department of Defense also have created websites to provide consumers with dietary supplement information.¹⁵⁹ The NIH Office of Dietary Supplements also maintains two databases that provide information on dietary supplements: the Dietary Supplement Ingredient Database (DSID) and the Dietary Supplement Label Database (DSLDB). The DSID provides estimated levels of ingredients in commonly used nutrient-containing supplements (e.g., Vitamin D and omega-3 fatty acid supplements), while the DSLDB catalogs product labels.¹⁶⁰ There are several limitations to both of these databases. The DSID is intended primarily for research applications, particularly for use in population studies of nutrient intake rather than for assessing content of individual

¹⁵³ FDA, “FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns,” November 25, 2019, <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>. FDA, “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments,” *Federal Register*, vol. 84, no. 64, 12969-12975, April 3, 2019.

¹⁵⁴ That is, to make claims that their products “diagnose, mitigate, treat, cure, or prevent a disease or specific class of diseases” as long as that claim is supported by “legitimate scientific research” as defined in H.R. 1364, 112th Congress.

¹⁵⁵ Bimal Ashar, Tasha Rice, and Stephen Sisson, “Physicians’ Understanding of the Regulation of Dietary Supplements,” *Arch Int Med*, vol. 167, no. 9 (2007), pp. 966-969.

¹⁵⁶ GAO, *Herbal Dietary Supplements: Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice*, 10-662T, March 2010, <http://www.gao.gov/assets/130/124769.pdf>.

¹⁵⁷ *Ibid.*

¹⁵⁸ For more information on government manufacturing standards for dietary supplements, see the on “Current Good Manufacturing Practices” section of this report. For examples of proposed or adopted industry standards, see the American Herbal Products Association (www.ahpa.org), the Natural Products Association (www.npainfo.org), and the Council for Responsible Nutrition (www.crnusa.org).

¹⁵⁹ For example, see NIH’s Office of Dietary Supplements webpage, <http://ods.od.nih.gov/>; FDA’s webpage, “Information for Consumers on Using Dietary Supplements,” <https://www.fda.gov/food/dietary-supplements/information-consumers-using-dietary-supplements>; and DOD’s Human Performance Readiness Center, <http://hprc-online.org/>.

¹⁶⁰ NIH and the U.S. Department of Agriculture (USDA), “Dietary Supplement Ingredient Database,” <https://dietarysupplementdatabase.usda.nih.gov/>. NIH, “The Dietary Supplement Label Database,” https://ods.od.nih.gov/Research/Dietary_Supplement_Label_Database.aspx.

supplements.¹⁶¹ The DSID also lacks information on other supplement ingredients that may be of public health concern, such as weight-loss products.¹⁶² The DSLD, on the other hand, contains more than 100,000 labels. The information is sourced from products reported in national population-based surveys and voluntary submissions by dietary supplement manufacturers. The information is taken from manufacturers' printed labels, which may not comply with FDA labeling requirements.¹⁶³ Further, the database does not provide information about the amounts of specific ingredients if a proprietary blend is listed on the label as an ingredient.

As discussed in the “Dietary Supplement Safety,” section of this report, there is no mandatory reporting mechanism through which dietary supplement manufacturers must register their products, although FDA, Congress, and some stakeholders have supported creating such a requirement. Some stakeholders have proposed that in addition to product listing, manufacturers should be required to submit all product labels to FDA to enhance transparency and FDA's ability to take action against unsafe products.¹⁶⁴

Concluding Comments

Consumers, the health care and dietary supplement industries, Congress, and federal regulators all have a stake in supplement identification, effectiveness, and safety. Research into the effectiveness and safety of supplements, industry compliance, surveillance and effective reporting strategies, and enforcement of current authorities are perennial concerns in this area.

With each legislative and regulatory action over the years, Congress and FDA have tried to balance often conflicting goals:

- safety;
- access to up-to-date, complete, and unbiased information on dietary supplements;
- accurate reporting of adverse events; and
- consumer choice.

Congress has demonstrated a sustained interest in dietary supplement related issues. It is uncertain if the 117th Congress will consider any new dietary supplement related legislation. Such issues may arise in the broader context of congressional interest in nutrition and food safety.

¹⁶¹ NIH and USDA, “Dietary Supplement Ingredient Database,” <https://dietarysupplementdatabase.usda.nih.gov/>.

¹⁶² Johanna Dwyer and Paul Coates, “Why Americans Need Information on Dietary Supplements,” *Journal of Nutrition*, August 2018, vol. 148, iss. supplement 2, pp. 1401S-1405S.

¹⁶³ Johanna Dwyer, Richard Bailen, Leila Saldanha, et al., “The Dietary Supplement Label Database: Recent Developments and Applications,” *Journal of Nutrition*, August 2018, vol. 148, iss. supplement 2, pp. 1428S-1435S.

¹⁶⁴ Pieter Cohen and Scott Bass, “Injecting Safety into Supplements—Modernizing the Dietary Supplement Law,” *New England Journal of Medicine*, December 19, 2019, vol. 381, no. 25, pp. 2387-2389.

Appendix A. Selected Laws Regulating Dietary Supplements

Federal Food, Drug, and Cosmetic Act (P.L. 75-717)

The FDCA provides FDA with the authority to oversee the safety of food, drugs, and cosmetics.

Nutrition Labeling and Education Act of 1990 (P.L. 101-535)

The Nutrition Labeling and Education Act (NLEA) amended the FDCA to require most foods, including dietary supplements, to bear nutrition labeling. It specified required information for labels and required the FDA to promulgate regulations regarding nutrition labeling and health claim requirements for foods and dietary supplements.

To Amend the Federal Food, Drug, and Cosmetic Act to Authorize Human Drug Application, Prescription Drug Establishment, and Prescription Drug Product Fees and for Other Purposes (P.L. 102-571)

Title II is the “Dietary Supplement Act of 1992,” which required a one-year moratorium on FDA’s implementation of dietary supplement labeling under NLEA.

Dietary Supplement Health and Education Act of 1994 (P.L. 103-417)

The Dietary Supplement Health and Education Act (DSHEA) amended the FDCA to create new manufacturing and labeling requirements for dietary supplements, and established the Office of Dietary Supplements within the National Institutes of Health.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188)

This law required the registration of any facility manufacturing, processing, packing, or holding food (including dietary supplements).

Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462)

This law mandates the reporting of any dietary supplement related serious adverse event to the FDA within 15 days of the event. Serious adverse event reporting is mandatory for manufacturers, packers, or distributors whose name appears on the dietary supplement label.

FDA Food Safety Modernization Act (P.L. 111-353)

FSMA provides FDA with mandatory recall authority for food, including dietary supplements. This law also required FDA to issue NDI guidance no later than 180 after its enactment.

Appendix B. Principal Display Panel, Dietary Supplements

Figure B-1. Example of a Dietary Supplement Principal Display Panel

5 Dietary Supplements Online Co.
1227 Supplement Drive
Supplementary, UT 94100

For more information:
877-777-7777

0
12270
07221
9

Lot: QK1227
Exp: OCT 2020

DSOL

1 **Vitameatavegamin 50 Plus**

2 Dietary Supplement

Healthy Aging Program for Seniors

- » Heart & cholesterol support*
- » Memory support*
- » Eye health*

3 30 caplets

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

4 DIRECTIONS: Take one caplet daily, with a meal.

6 **Supplement Facts**

	Amount per Serving	% Daily Value*
Serving Size	1 caplet	
Servings per Container	30	
Sodium	15 mg	<1%
Total Carbohydrate	<1 g	<1%
		% Daily Value*
Vitamin A	5000 IU	100%
Vitamin B	250 mg	417%
Vitamin C	400 IU	100%
Vitamin D	30 IU	100%
Thiamin (B1)	1.5 mg	100%
Riboflavin (B2)	1.7 mg	100%
Niacin (B3)	20 mg	100%
Vitamin B6	2 mg	100%
Folic Acid	400 mcg	100%
Vitamin B12	6 mcg	100%
Biotin	40 mcg	13%
Ginkgo Biloba	2 mg	**

** Daily Value not established.
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

7 **Other Ingredients:** Cellulose, Titanium Dioxide, Caramel Color, Ethyl Vanillin. No Artificial Colors, No Preservatives, No Yeast, No Gluten

8 → **WARNING:** Not for use by individuals under the age of 18 years. Do not use if pregnant or nursing.
Keep bottle tightly closed. Store in a cool, dry place, out of reach of children.
© DeLima Associates

KEY

- 1** Product Name
- 2** Indicates product is a "Dietary Supplement"
- 3** Net quantity of contents
- 4** Directions for use
- 5** Name and Address of product manufacturer
- 6** Supplement Facts
- 7** Other ingredient
- 8** Warnings

Source: National Institutes of Health, Dietary Supplements Labels Database at the National Library of Medicine, accessed May 2013, drawing from *I Love Lucy* and *Our Miss Brooks*.

Appendix C. Acronyms Used in This Report

Government Agencies

- **CDC**—Centers for Disease Control and Prevention
- **CFSAN**—Center for Food Safety and Applied Nutrition, Office of Foods, FDA
- **DEA**—Drug Enforcement Administration
- **DOD**—Department of Defense
- **FDA**—U.S. Food and Drug Administration
- **FTC**—Federal Trade Commission
- **GAO**—U.S. Government Accountability Office
- **HHS**—U.S. Department of Health and Human Services
- **NIH**—National Institutes of Health
- **OIG**—Office of the Inspector General, U.S. Department of Health and Human Services

Legislation

- **DSHEA**—Dietary Supplement Health and Education Act of 1994
- **FDAMA**—FDA Modernization Act
- **FFDCA**—Federal Food, Drug, and Cosmetics Act
- **FSMA**—FDA Food Safety Modernization Act of 2011
- **NLEA**—Nutrition Labeling and Education Act of 1990

Miscellaneous

- **CFR**—Code of Federal Regulations
- **CAERS**—CFSAN Adverse Event Reporting System
- **CGMP**—Current Good Manufacturing Practices
- **GRAS**—Generally Recognized as Safe
- **NDI**—New Dietary Ingredient
- **SSA**—FDA’s Significant Scientific Agreement Standard for approved health claims
- **IND**—Investigational New Drug

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