

The Honorable Patty Murray
Chairwoman
Senate Health, Education, Labor & Pensions Committee
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Senate Health, Education, Labor & Pensions Committee
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Frank Pallone, Jr.
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
House Committee on Energy & Commerce
2322 Rayburn House Office Building
Washington, DC 20510

March 1, 2021

Dear Chairwoman Murray, Ranking Member Burr, Chairman Pallone, and Ranking Member McMorris Rodgers:

As your Committees establish their legislative agendas for the 117th Congress, we, as members of the Dietary Supplements Quality Collaborative (DSQC),¹ an organization committed to advancing the quality and safety of dietary supplements in the United States, write to encourage you to take the opportunity to protect consumers from potentially unsafe products marketed as dietary supplements.

Three quarters of Americans take dietary supplements to help maintain their health and address nutrient shortfalls in their diets.² Consumers and health care providers rightly expect the dietary supplements that they purchase and recommend are quality products and are safe for use as directed. In the 25-plus years since the Dietary Supplement Health and Education Act (DSHEA) was signed into law, the dietary supplement industry has grown from \$4 billion with 4,000 products to \$40 billion in 2019 with 50,000-plus products,³ and this number will only increase in the future.

Strengthening dietary supplement oversight is crucial to protecting public health. Measures such as clarifying U.S. Food and Drug Administration's (FDA) authority over products marketed as dietary supplements and a mandatory product listing requirement – both of which are supported by FDA⁴ – can help enhance efforts to respond to emerging safety

¹ The DSQC was founded in October 2016 with more than 25 organizations across the public health spectrum representing consumers, practitioners, manufacturing industry, research, standard-setting and academic organizations committed to advancing the quality and safety of dietary supplements in the United States. See <https://www.dsqcollaborative.org/>.

² 2019 CRN Consumer Survey on Dietary Supplements, available at <https://www.crnusa.org/resources/2019-crn-consumer-survey-dietary-supplements-consumer-intelligence-enhance-business>.

³ 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, available at <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>.

⁴ See FDA Fiscal Year 2020 Justification of Estimates for Appropriations Committees, available at <https://www.fda.gov/media/121408/download> and 'Supplements' tainted with drugs pose jurisdictional challenge for FDA, Natural Products Insider, Nov. 5, 2020, available at <https://www.naturalproductsinsider.com/regulatory/supplements-tainted-drugs-pose-jurisdictional-challenge-fda>.

concerns, provide greater transparency into the dietary supplement marketplace, and support FDA’s efforts to prioritize its resources and expertise.

1. Current law creates a “loophole” in which certain products marketed as dietary supplements may be outside of FDA’s dietary supplement jurisdiction.

Products marketed as dietary supplements but containing illegal and sometimes undeclared ingredients, including certain active ingredients found in FDA-approved drugs, or analogs of those ingredients, can present significant public health concerns. For instance, 965 of the products tested by the FDA from 2007 to 2019 were identified to include potentially hazardous substances or hidden ingredients—such as sildenafil or steroids.⁵ These products put consumers at considerable risk for serious adverse events, including potentially dangerous interactions with other products they are taking.

Although labeled and marketed as dietary supplements, many of these products do not meet the statutory definition of a dietary supplement⁶ creating a potential legal loophole that they fall outside of FDA’s jurisdiction to use its dietary supplement authorities to enforce against these products. While some of these products are marketed with disease claims and could be classified as unapproved new drugs, some are sold without any claims on the packaging at all, making it difficult for FDA to establish jurisdiction over the product as a drug. Either way, this loophole in the law creates more administratively complicated, resource intensive, and challenging paths for the agency to protect the public health. Closing this loophole – by clarifying FDA’s authority over products illegally marketed as dietary supplements – would provide a clear and direct way for FDA to take enforcement action against these unlawful and potentially dangerous products. To put simply, if the product displays a “Supplement Facts” box or otherwise markets itself as a Dietary Supplement, then its marketers should be subject to FDA’s jurisdiction for dietary supplements.

We support inclusion of the following FDA-suggested language in any dietary supplement-related legislation, including CBD-related legislation, considered by the Committees that would subject all products labeled as dietary supplements—regardless of the product contents—to the same legal prohibitions, import exclusions, and seizure authorities:

(d) NEW PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

“(fff) The introduction or delivery for introduction into interstate commerce of any product labeled as a dietary supplement that fails to meet the definition of a dietary supplement in section 201(ff).”

(e) NEW IMPORT EXCLUSION.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended in paragraph (3) of the third sentence by striking “section 301(II)” and inserting “subsection (II) or (fff) of section 301”.

⁵ See https://www.accessdata.fda.gov/scripts/sda/sdnavigation.cfm?sd=tainted_supplements_cder. Of these products, most fell into three categories: Fifty-two percent were used for sexual enhancement, 37 percent were used for weight management and 10 percent were used for muscle building.

⁶ See, e.g., Food, Drug, and Cosmetic Act section 201(ff)(3)(B).

(f) NEW SEIZURE AUTHORITIES.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(1) in subsection (a)(1), in the first sentence, by inserting “, or any article which may not be introduced or delivered for introduction into interstate commerce under section 301(fff),” before “shall be liable”;

(2) in subsection (d)(1), in the first sentence, by inserting “or any product otherwise introduced or delivered for introduction into interstate commerce in violation of section 301(fff) of this Act and condemned under this section,” before “shall, after entry of the decree”.

2. Mandatory product listing would give FDA important insight into the dietary supplement market.

Current law does not authorize FDA to require companies to submit certain product information about marketed dietary supplement products. That leaves FDA with limited knowledge about the products, their labels, ingredients, and manufacturers. A product listing requirement would be a relatively simple way for the agency to obtain a more complete picture of the marketplace. This knowledge would help FDA narrow its focus and prioritize its resources on those products that pose the highest risk to the public health.

In addition, a listing requirement would strengthen FDA’s ability to respond effectively to emerging safety concerns. For example, listing would allow the agency to effectively alert consumers about supplements that may be contaminated or contain unsafe ingredients. Moreover, if publicly available, listing information would also allow consumers and retailers to make more informed decisions about the supplements they purchase. Public support for mandatory product listing is very strong. A Pew survey of US adults found that 95% supported the proposal.⁷ The DSQC urges you to enact a mandatory listing for dietary supplements that would allow for transparency into the supplement marketplace. We stand ready to assist the Committees in any consideration of legislative language authorizing FDA to require supplement manufacturers to list their products.

Taken together, these reforms to dietary supplement oversight would significantly enhance FDA’s ability to protect public health. As you consider action to address products marketed as dietary supplements containing CBD, or dietary supplements more generally, we urge you to protect consumers by including these measures in any CBD or dietary supplement-related legislative provision. We appreciate your consideration of this request to ensure that all products marketed as dietary supplements are subject to FDA jurisdiction. We look forward to working with you on these improvements to supplement oversight. If you have any questions, or if we can provide any assistance, please contact Carrie Harney, DSQC Secretariat, at cxh@usp.org or 202-239-4136.

Respectfully,

The Dietary Supplements Quality Collaborative

⁷ Pew Charitable Trusts. “Most Supplement Users Back Enhanced FDA Oversight of These Products”. October 1, 2019, available at <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/10/01/most-supplement-users-back-enhanced-fda-oversight-of-these-products>.