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September 24, 2019

The Honorable Nita M. Lowey
Chairwoman
House Committee on Appropriations
H-307 The Capitol
Washington, DC 20515

The Honorable Kay Granger
Ranking Member
House Committee on Appropriations
1016 Longworth House Office Building
Washington, DC 20515

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

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Lowey, Ranking Member Granger, Chairman Pallone, and Ranking Member Walden:

As the committees consider further action to address the growing cannabidiol (CBD) industry, we urge you take the opportunity to protect consumers from potentially unsafe dietary supplements, including those that contain CBD. Since enactment of the Dietary Supplement Health and Education Act (DSHEA) 25 years ago, the dietary supplement industry has grown from around 4,000 products in 1994 to as many as 80,000 today. This number will only increase as the CBD market—which already includes a substantial number of products sold as supplements—is expected to reach $16 billion by 2025.[1] Given that over half of all Americans consume supplements,[2] it is important that Congress use this occasion to update dietary supplement oversight by authorizing a product listing requirement. This tool—proposed by the Administration in its FY2020 Budget—will better protect public health by providing greater transparency, enabling prioritization of limited agency resources, and enhancing efforts to respond to emerging safety concerns.

Product listing would give FDA vital insight into the dietary supplement market.

Currently, the U.S. Food and Drug Administration (FDA)—the federal agency tasked with dietary supplement oversight—has no mechanism to know what dietary supplement products are on the market. A mandatory product listing requirement would be a simple, low-burden way for the agency to obtain a complete picture of this growing marketplace. With basic information, including the names, ingredients, and labels of all products, the FDA could effectively prioritize its resources and expertise across the thousands of products being sold.

[1] https://www.cowen.com/reports/cowen-collective-view-of-cbd/
[2] https://jamanetwork.com/journals/jama/fullarticle/2565748

Additionally, product listing would strengthen the FDA's ability to respond effectively to emerging safety concerns and to exercise its authorities under DSHEA. Listing would enable the agency to quickly alert consumers about products that may be contaminated or contain unsafe ingredients. This is especially important as novel ingredients are introduced and in cases where evidence of previously unknown consumer risks arise. For example, the FDA recently issued a warning about supplements containing the synthetic compound vinpocetine after a National Institutes of Health study revealed the significant risks it poses to pregnant women.[3] If the FDA had a comprehensive listing of all supplements on the market, it could have quickly identified those that contained this ingredient and more effectively warned consumers or mandated a recall. Moreover, if the information captured through a mandatory listing requirement was publicly available, consumers could make more informed decisions and retailers would have a mechanism to ensure that the supplements they sell are known to FDA and subject to the agency's oversight.

CBD supplement manufacturers should be required to list their products with the FDA.

Since the passage of the 2018 Farm Bill—which legalized the production of industrial hemp—the dietary supplement market has seen a surge in CBD products, despite the fact that they violate Section 201(ff)(3)(B) of the Food, Drug, and Cosmetic Act, which prohibits the inclusion of a substance in food or supplements if it has been the subject of a clinical investigation or is an active ingredient in a drug product. [4] (CBD was investigated in trials that eventually led to the FDA approval of the anti-seizure drug, Epidiolex.) Independent of the pathway the FDA or Congress may choose to allow for the legal marketing of CBD products, it is essential that the agency knows what products are on the market. The FDA's limited information on dietary supplements makes it difficult to accurately assess the magnitude and quality of CBD supplement products being sold to American consumers.

A listing requirement arms the agency with this information and provides a safety net for consumers while the agency explores outstanding public health questions. Additionally, the FDA has had to act against a handful of CBD companies making unsubstantiated health claims that their products are capable of "slowing progression of Alzheimer's" and are "effective for treating substance use disorders." If a listing requirement is included as a component of any CBD legislation or appropriations provision, then the agency will have a mechanism to quickly assess claims associated with specific products, enabling it to utilize its limited enforcement resources more efficiently.

FDA needs adequate resources to oversee this growing industry.

Furthermore, we are pleased that both the House and Senate Appropriations Committees included in their FY2020 funding bills a $3 million increase for FDA's Office of Dietary Supplement Programs (ODSP). If the agency were to establish a legal pathway to market for

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[3] https://www.fda.gov/news-events/press-announcements/statement-warning-women-childbearing-age-about-possible-safety-risks-dietary-supplements-containing

[4] See "FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers" https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers

CBD dietary supplements, ODSP would be responsible for overseeing this burgeoning industry, along with the other 80,000 supplements already on the market. We hope that, going forward, the Committees will recognize the growth of the dietary supplement industry and prioritize additional ODSP resources so that the office will have the necessary capacity to undertake increased oversight duties.

As the FDA works to develop an understanding of CBD's safety and risks associated with its use, we urge you to protect consumers by including a mandatory product listing requirement for dietary supplements in any CBD or other supplement-related legislative provision—including those in appropriations measures. We thank you for your commitment to public health and to the important role that the FDA plays in regulating dietary supplements, and we look forward to working with you to ensure enactment and implementation of improvements to supplement oversight. Should you have any questions, or if we can provide any assistance, please do not hesitate to contact Elise Ackley at the Pew Charitable Trusts at eackley@pewtrusts.org or (202) 540-6464.

Sincerely,

Elizabeth Richardson
Project Director, Health Care Products
The Pew Charitable Trusts