March 16, 2018

The Honorable Robert Aderholt
Chairman
Subcommittee on Agriculture, Rural Development, Food and Drug Administration
House Committee on Appropriations
2362-A Rayburn House Office Building
Washington, DC 20515

The Honorable John Hoeven,
Chairman
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
Senate Committee on Appropriations
129 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Sanford Bishop
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration
House Committee on Appropriations
1016 Longworth House Office Building
Washington, DC 20515

The Honorable Jeff Merkley
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
190 Dirksen Senate Office Building
Senate Committee on Appropriations
Washington, DC 20510

Re: Additional Funding for FDA Office of Dietary Supplement Programs

Dear Chairmen Aderholt and Hoeven, and Ranking Members Bishop and Merkley:

The public health and consumer organizations below write to express support for the mission of the Office of Dietary Supplement Programs within the Food and Drug Administration (FDA), and to request an increase in the office's funding and personnel to help create and maintain a safer, fairer, and more transparent dietary supplement marketplace. Specifically, to ensure the office can adequately oversee the market and take action to protect consumers, the organizations below believe the current annual budget of $5 million should be doubled, at a minimum, beginning in fiscal year 2019.

When Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA), there were approximately 4,000 dietary supplement products on the market; today, there are about 80,000 products, which garner an estimated $40 billion in annual sales.[1] FDA's funding, and therefore its ability to robustly monitor the marketplace, has not kept pace with industry growth. Under DSHEA, most dietary supplements (with the exception of new dietary ingredients) do not undergo premarket safety evaluation or approval before they are on store shelves, and therefore FDA must use post-market surveillance and enforcement to ensure product safety and quality.

[1] U.S. Government Accountability Office, "Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness" (2017), https://www.gao.gov/assets/690/684620.pdf.

Since 2007, FDA has identified nearly 900 products marketed as dietary supplements that violate DSHEA and pose potential health risks for consumers.[2] For example, in 2017, FDA issued warning letters to companies distributing products containing selective androgen receptor modulators (SARMs),[3] chemicals that when ingested can lead to life-threatening reactions, including liver toxicity, and increase the risk for heart attack or stroke.[4] In addition, in 2013, FDA sent warning letters to companies selling products that unlawfully claimed to treat diabetes; some of these products were sold as dietary supplements.[5] FDA warned that the illegal products could be ineffective, cause patients to delay seeking treatment, or contain undisclosed active pharmaceutical ingredients or other harmful ingredients.[6] Moreover, FDA recently issued warnings letters to multiple companies regarding the misleading marketing of supplements, which purported to address the symptoms of opiate addiction but were in fact unapproved drugs.[7]

Increased funding and staff is needed to help FDA monitor and curtail companies like these that put consumers at risk, including unscrupulous companies that do so knowingly. More than 170 million consumers in the United States use dietary supplements,[8] and those Americans should be confident that those supplements are safe, quality products that are manufactured appropriately and are accurately labeled regarding ingredients and claims. An annual budget of $10 million would help ensure that the Office of Dietary Supplement Programs at FDA is better equipped to meet consumers' expectations about the products they use to promote their health.

Thank you in advance for your consideration of this request. Should you have any questions, please do not hesitate to reach out to Libby Jones at The Pew Charitable Trusts (ejones@pewtrusts.org) or any other organization listed below.

Sincerely,

The Pew Charitable Trusts

Center for Science in the Public Interest

Consumers Union

National Consumers League

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[2] U.S. Food and Drug Administration, "Tainted Products Marketed as Dietary Supplements_CDER," last modified Dec. 14, 2017, https://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder.

[3] U.S. Food and Drug Administration, "FDA In Brief: FDA warns against using SARMs in body-building products," last modified Oct. 31, 2017, https://www.fda.gov/newsevents/newsroom/fdainbrief/ucm583021.htm.

[4] Ibid.

[5] U.S. Food and Drug Administration, "Illegally Sold Diabetes Treatments," accessed Feb. 22, 2018, https://www.fda.gov/forconsumers/protectyourself/healthfraud/ucm352276.htm.

[6] Ibid.

[7] U.S. Food and Drug Administration, "FDA, FTC warn companies for selling illegal, unapproved opioid cessation products using deceptive claims," accessed March 15, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm593602.htm.

[8] Council for Responsible Nutrition, "CRN 2016 Annual Survey on Dietary Supplements," accessed Feb. 22, 2018, http://www.crnusa.org/resources/crn-2016-annual-survey-dietary-supplements.