United States Senate
WASHINGTON, DC 20510

June 17, 2021

The Honorable Tammy Baldwin
Chairwoman
Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies
United States Senate
Washington, D.C. 20510

The Honorable John Hoeven
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies
United States Senate
Washington, D.C. 20510

Dear Chairwoman Baldwin and Ranking Member Hoeven:

We are writing today to express our support for the Office of Dietary Supplement Programs (ODSP) within the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA), and to request $14.75 million in funding for this office in FY2022. ODSP is the main policy driver for strategic priorities on dietary supplements within the agency and is responsible for ensuring that limited agency resources are used in a risk-based manner to protect consumers and public health. This increase in funding ($3.75 million over FY2021 levels) will enable ODSP to strengthen and expand its crucial inspection and enforcement activities.

The dietary supplement industry has grown and changed tremendously since the passage of the Dietary Supplement Health and Education Act (DSHEA) over twenty-six years ago. With one in four Americans now taking a supplement as part of a regular health or nutritional program, and a range of 50,000 to 80,000 supplements on the market today, it is more important than ever to ensure that these products are safely manufactured and appropriately labeled. This growth in the marketplace also brings new regulatory responsibilities for the agency. For example, while dietary supplements enter the market under the assumption that they are safe, the FDA has well documented that there are instances of products that are contaminated, either intentionally or unintentionally, with inherently unsafe ingredients - including active pharmaceutical ingredients like Selective Androgen Receptor Modulators (SARMs). These products violate DSHEA and pose potential risk to consumers.

In 2016, the FDA rightly recognized the rapid growth of the industry and created the ODSP to keep pace with the evolving marketplace and to make dietary supplement regulation a higher priority within the agency. While many offices within FDA are involved in the regulation of dietary supplements in some way, ODSP serves as a central hub for the Agency's efforts related to supplement guidelines, regulations, safety assessments, and compliance strategy. ODSP personnel also provide subject matter expertise for dietary supplement enforcement activities across the FDA. In FY2017, ODSP reviewed more than 3,000 adverse event reports tied to dietary supplements. That year the Office also reviewed the scientific and safety claims of

103 new dietary ingredients (NDIs), acting as one of the only premarket safety checks for new supplement products before they reach consumers.

Given the widening use of dietary supplements, increased funding will allow ODSP to expand its inspection and enforcement activities around strengthening protections for consumers and improving the overall quality of dietary supplements. This requested level of funding will enable ODSP to increase its workforce and oversight of dietary supplement manufacturing; provide greater clarity for all stakeholders on the agency's policies and requirements; and to expand its research, education, and communications work related to adverse events and informed decision-making around supplement use.

Thank you for your leadership in this important area. We appreciate your attention to this issue and others related to the health and safety of all Americans, and we look forward to continuing to working with you in the future.

Sincerely,

RICHARD BLUMENTHAL

EDWARD J. MARKEY

RICHARD J. DURBIN
United States Senate

CHRIS VAN HOLLEN
United States Senate

KYRSTEN SINEMA
United States Senate