

The Honorable Thad Cochran Chairman Senate Committee on Appropriations Room S-128, The Capitol Washington, D.C. 20510

The Honorable Patrick Leahy Vice Chairman Senate Committee on Appropriations Room S-128, The Capitol, Washington, D.C. 20510 The Honorable Rodney P. Frelinghuysen Chairman House Committee on Appropriations H-305, The Capitol Washington, D.C. 20515

The Honorable Nita M. Lowey Ranking Member House Committee on Appropriations 1016 Longworth House Office Building Washington D.C. 20515

May 16, 2017

Dear Chairman Cochran, Vice Chairman Leahy, Chairman Frelinghuysen, and Ranking Member Lowey:

As members of the Dietary Supplements Quality Collaborative (DSQ Collaborative), an organization committed to the advancement of policies and initiatives designed to help ensure the quality and safety of products marketed as dietary supplements in the U.S. market, we are writing to request that Congress fully fund the FY2018 U.S. Federal Food and Drug Administration (FDA) budget. The FY17 Agriculture, Rural Development, and Food and Drug Administration Appropriations bills passed by the House and Senate Appropriations Committees last year included \$2.77 billion in discretionary funding for the agency. We urge the Committees to maintain and, if possible, increase that funding level in the FY18 legislation. In particular, we urge Congress to sufficiently fund the newly elevated Office of Dietary Supplement Programs (ODSP) within the Center for Food Safety and Nutrition (CFSAN), to fully staff the ODSP and provide adequate funding and resources for the enforcement of existing laws and regulations to help provide consumers with assurances that dietary supplements in the U.S. marketplace are safe and quality products.

The DSQ Collaborative was founded in October 2016 and is composed of 26 participants representing consumer organizations, dietary ingredient and dietary supplement manufacturers, public health and patient advocacy groups, health care providers, standard setting organizations, non-profit organizations and academia. The DSQ Collaborative is committed to advancing the quality and safety of products marketed as dietary supplements in the U.S., in the interest of protecting public health.

More than 170 million U.S. consumers use dietary supplements. 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. Unfortunately, a significant public health problem is posed by unethical individuals and entities engaged in the manufacture and distribution of intentionally adulterated or misbranded products marketed as dietary supplements. These products may contain ingredients that are generally undeclared on the labeling and are the same active ingredients as FDA-approved drugs,

analogs of the active ingredients in FDA-approved drugs, or other compounds that do not qualify as dietary ingredients. These products put consumers who may take them at considerable risk for serious adverse events, as well as the potential for dangerous interactions with other products that they may be taking. And, although these illegal products do not represent the dietary supplement industry as a whole, their presence taints the marketplace.

While several federal agencies help protect U.S. consumers from adulterated and unsafe products represented as dietary supplements, FDA plays a central role with significant responsibility for identifying adulterated or misbranded dietary supplement products and removing them from the market. We strongly support FDA's work to remove these often dangerous products from the market and to hold the manufacturers and sellers of these products fully accountable under federal law. To do its job effectively, the FDA must have sufficient resources, training, and tools directed towards ODSP, as well as proper funding of the district offices responsible for performing inspections of manufacturing facilities and the Center for Drug Evaluation and Research's (CDER) and CFSAN's Offices of Compliance.

Therefore, it is critically important that Congress provide the FDA with the necessary resources to undertake its mission to protect U.S. consumers from unsafe products and to help ensure that the dietary supplements in the U.S. market are safe and quality products. As stakeholders in this effort, the DSQ Collaborative seeks to share the responsibility to keep such products from the marketplace and seeks to collaborate with all federal agencies responsible for protecting consumers against individuals and entities, who manufacture, package, hold or distribute unsafe and illegal products marketed as dietary supplements into the marketplace. We look forward to collaborating with Congress and all federal agencies that share in this effort and urge Congress to provide the FDA with the necessary funding to carry out its vital mission. We are eager to serve as a partner in the fight to ensure that all products marketed as dietary supplements are safe and quality products.

Respectfully,

The Dietary Supplements Quality Collaborative

- AARP
- Academy of Nutrition and Dietetics
- American Botanical Council
- American Medical Association
- American Pharmacists Association
- American Society of Health-System Pharmacists
- Consumer Healthcare Products Association
- Council for Responsible Nutrition
- LegitScript
- National Consumers League
- NSF International
- Pharmavite LLC
- The Children's Hospital of Philadelphia
- The Gerontological Society of America
- The Obesity Action Coalition

- The Obesity Society
- The Pew Charitable Trusts
- U.S. Pharmacopeia
- United Natural Products Alliance
- Underwriters Laboratories
- University of Missouri–Kansas City School of Pharmacy

Collaborative Observers

- American Association of Colleges of Pharmacy
- Arthritis Foundation
- National Association of Boards of Pharmacy
- National Association of Chain Drug Stores
- Purdue University School of Pharmacy Center for Medication Safety Advancement