VIA ELECTRONIC SUBMISSION

August 30, 2024

Office of Dietary Supplements
National Institutes of Health
6705 Rockledge Dr., Room 730, MSC 7991
Bethesda, MD 20817

RE: Request for Information: Inviting Comments and Suggestions on an ODS Strategic Plan 2025-2029: A Blueprint for a Coordinated Dietary Supplement Research Agenda at NIH

USP-Rockville
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Dear Sir/Madam,

On behalf of the United States Pharmacopeia (USP), I am writing to provide comments on The National Institutes of Health (NIH) Office of Dietary Supplements (ODS) draft CY 2025-2029 Strategic Plan. USP is an independent, scientific, global non-profit organization founded in 1820 and dedicated to building trust in medicines through rigorous science, public quality standards, and a range of programs to help advance the supply of quality medicines, dietary supplements, and foods.[1] We are guided by approximately 500 organizations, including scientific, healthcare practitioner, consumer, and industry organizations, as well as dozens of government agencies, who together comprise the USP Convention.[2]

Nearly 1000 experts from the scientific and healthcare community volunteer on USP's Expert Committees to establish USP's approximately 9000 public quality standards for medicines, foods, and dietary supplements. USP publishes two legally recognized Official Compendia of the United States, combined into a single publication, the *United States Pharmacopeia-National Formulary* (*USP-NF*). The *USP-NF* includes more than 800 dietary-supplement and dietary ingredient-related documentary standards and approximately 200 physical reference standards to verify that products and their ingredients can pass tests indicating adherence to quality standards. USP provides dietary supplement quality standards in a dedicated publication, the *Dietary Supplements Compendium (DSC)*, available online. The *DSC 2022* includes more than 600 standards for botanical and non-botanical dietary ingredients and dietary supplements supported by 23 General Chapters. USP also publishes a compendium of food ingredient standards in the *Food Chemicals Codex* (*FCC*) and standards for herbal ingredients used in herbal medicines in the *Herbal Medicines Compendium (HMC).*

Overall, USP supports the ODS priorities related to coordination and support for dietary supplement research focused on biological, population, and product science. We appreciate

[1] Safe and effective medicines, consistently manufactured according to established quality standards are essential to preventing disease, treating illness, and saving lives. To that end, pharmacopeias develop public quality standards that establish benchmarks to ensure that specific medical products have the quality attributes required by regulatory agencies. Manufacturers and regulatory agencies rely on clearly defined quality expectations for medicines and their ingredients, as well as methods to validate that they meet these expectations. USP's public quality standards help guide quality assurance across multiple aspects of a medicine's lifecycle, including development, manufacturing, storage, distribution, preparation, administration, and use.

[2] USP's governing bodies, in addition to the Council of the Convention, include its Board of Trustees and Council of Experts.

that the ODS CY 2024-2029 Strategic Plan contains a comprehensive, forward-looking research agenda for dietary supplements reflecting the collaboration and input from government agencies and the public and private sectors. As you work to finalize the draft strategic plan, **USP underscores that ensuring consistent, quality materials in research is vital, with a need to focus on the composition, quality, and integrity of dietary supplement ingredients and products. Without such controls and standardization, research data would be rendered unreliable, and any results should be considered inconclusive.**

Research Priority 3: Advance the study of the composition, quality, stability, safety, and efficacy of dietary supplements and their ingredients.

Dietary supplements commonly contain complex mixtures of vitamins, minerals, and/or other natural products such as botanicals. As such, any dietary supplements used in biomedical research must be rigorously identified and characterized to know exactly what is being studied. Scientifically valid analytical methods and best practice guidelines to define critical quality attributes are necessary for the study of the composition, quality, and stability of dietary supplements and their ingredients. Establishing quality attributes and analytical tools for dietary supplement research is particularly important due to variability, quality issues related to botanical articles, potential health hazards with certain ingredients, and the increase in the number of dietary supplement products in the marketplace.

Public quality standards set forth requirements related to nomenclature, identification criteria, strength and composition criteria, purity testing, limits on contaminants, and robust, scientifically valid quality testing methods. When utilized, these standards provide transparent, validated testing methods and assist with identifying adulterated and potentially dangerous botanical articles and dietary supplement ingredients. Further, standards are developed through a science-based, expert-led, transparent process and are informed by the broad expertise, knowledge, and diverse perspectives of scientific and healthcare experts.

Following public quality standards will allow for identifying and characterizing dietary supplements and their ingredients as noted in Research Priority 3. **It is imperative to help ensure the quality of investigational materials by using public standards that clearly articulate quality attributes and allow for consistent characterization.**

Research Capacity Priority 1: Strengthen and harmonize the methodologies applied to dietary supplement research

As ODS considers research best practices and aims to facilitate the use of appropriate and rigorous research paradigms, we also urge you to consider including the use of public quality standards as a best practice research protocol. In the strategic plan, ODS notes that, “[t]he ability to compare, reproduce, and replicate published research results is essential for building scientific knowledge.” ODS is already engaged in the development of research best practices through the work of the Analytical Methods and Reference Materials (AMRM) Program, Dietary Supplement Ingredient Database (DSID), and Consortium for Advancing Research on Botanical and Other Natural Products (CARBON) program, among other initiatives. In the spirit of public-private partnership, the more than 300 botanical monographs in the USP *Dietary Supplements Compendium* and the USP compendial standard-setting process involving expert volunteers complement the efforts of ODS to provide validated analytical methodologies and reference materials for the research community. Incorporation of public quality standards can complement existing efforts and further bolster the quality and

safety of dietary supplements for consumers. **As such, the use of quality standards should be considered best practice, and universally and consistently applied by researchers to ensure reproducibility and appropriate comparison of research studies.**

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USP appreciates the opportunity to provide comments on the draft ODS CY 2025-2029 Strategic Plan and share our perspectives. We would welcome further opportunities to explore how USP can leverage its convening power among stakeholders from academia, industry, healthcare practitioners, and regulatory agencies to help strengthen the ODS mission.[3] If you have any questions or would like additional follow-up, please do not hesitate to reach out to Amy B. Cadwallader, PhD, Director, Regulatory and Public Policy Development at Amy.Cadwallader@usp.org or by phone at 301.692.3567.

Sincerely,

Jaap Venema, Ph.D.
Executive Vice President and Chief Science Officer
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301.230.6318

[3] Nandakumara Sarma, Roy Upton, Ulrich Rose, De-an Guo, Robin Marles, Ikhlas Khan & Gabriel Giancaspro (2023) Pharmacopeial Standards for the Quality Control of Botanical Dietary Supplements in the United States, Journal of Dietary Supplements, 20:3, 485-504, DOI: 10.1080/19390211.2021.1990171