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Joseph M. Betz, Ph.D.
Acting Director, Office of Dietary Supplements
National Institutes of Health
6705 Rockledge Drive (Rockledge 1), Room 730
Bethesda, MD 20892-7991

Dear Dr. Betz,

The Consumer Healthcare Products Association (CHPA)[1] appreciates the opportunity to provide additional comments on the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) Strategic Plan 2022-2026. Many of our member companies manufacture and/or market dietary supplement products and are impacted by efforts undertaken by ODS to conduct and support scientific research to enhance the evidence base for dietary supplements and their ingredients.

CHPA applauds ODS for undertaking a comprehensive effort to examine the benefits and safety of dietary supplements and dietary ingredients and for prioritizing the dissemination of useful information to consumers and other stakeholders. CHPA underscores our previous comments that support ODS's research regarding how supplementation can help fill nutrient gaps that the Dietary Guidelines for Americans have identified as a public health concern. In addition, CHPA encourages ODS to involve experts from the dietary supplement industry into important dietary supplement stakeholder conversations. For example, CHPA welcomes being part of NIH workshops, meetings, and conferences that help to identify research gaps and priorities. CHPA also recommends that the Federal Working Group on Dietary Supplements include industry stakeholders.

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over the counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

CHPA members promote transparency and are long-time supporters of NIH's Dietary Supplement Label Database (DSLD). The DSLD contains 143,369 current and historical dietary supplement labels, which makes it the most comprehensive database of dietary supplement products, brands, and ingredients. CHPA is encouraged by ODS's continued progress on the DSLD through Work Strategy 3-3 ("*Develop and provide publicly accessible databases for use in clinical, epidemiological, and other population research on dietary supplements*"). The DSLD has become more important as the topic of a dietary supplement label database has become a timely priority for more than just dietary supplement researchers and consumers.

The Food and Drug Administration (FDA) and Congress are seeking to amend the Federal Food, Drug, and Cosmetic Act to require dietary supplement product listing with FDA for all marketed supplement products. The proposal, known as Mandatory Product Listing (MPL), would have significant overlap in design with the current DSLD. One noteworthy difference is MPL would be mandatory, while DSLD is voluntary. CHPA feels that now is the opportune time for ODS to educate Congress and FDA about the important technical work done over the past 10+ years on building and improving the DSLD which could serve as a successful model for the MPL system.

CHPA acknowledges that regulatory and legislative purviews are outside the scope of ODS work. However, given the significant effort and expense that ODS has invested in building, improving, and maintaining the DSLD[2] we believe that ODS could best speak to the diverse stakeholder population that would be impacted by implementation of MPL were it to become a requirement through legislation. Should FDA require that manufacturers/distributors submit listing information including labeling for all marketed dietary supplement products, the need for a database to store and maintain accurate and up-to-date labels of dietary supplements would become apparent.[3] Were FDA tasked to build this database from scratch, it would be a missed opportunity if FDA did not lean on the technical knowledge gained by the development and improvement of the DSLD.

CHPA believes ODS should seek an opportunity to provide Congress and FDA an overview of the DSLD and discuss the significant efforts undertaken, along with

[2] Saldanha LG, Dwyer JT, Bailen RA. Modernization of the National Institutes of Health Dietary Supplement Label Database. J Food Compost Anal. 2021 Sep;102:104058.

[3] The FDA Fiscal Year 2023 Budget Proposal includes an effort to "Modernize dietary supplement regulation, seeking to require annual listing with the FDA of individual dietary supplement products, including basic information about each unique product."

the Therapeutic Research Center (TRC), to improve this database. While there would be challenges to overcome in making the DSLD the official FDA mandated repository for all dietary supplement labels, we believe these would not be significant and that ODS and TRC could leverage the experience gained over the past several years to facilitate inclusion of all on-market labels in the DSLD.

Many members of the dietary supplement industry have already embraced the DSLD and are accustomed to submitting and maintaining up to date labels in the DSLD. Should MPL become an FDA requirement and provided there are no significant changes to the label submission process, we believe that all stakeholders in this process, including the entire dietary supplement industry, the FDA, and consumers would benefit from the DSLD serving as the model that informs the official FDA repository for dietary supplement labels.

We appreciate all the efforts undertaken by ODS staff to enhance the knowledge base and understanding of dietary supplements for both consumers and professionals. Should you have any questions about this proposal we would be happy to discuss.

Respectfully submitted,

D MacKay

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