May 21, 2020

Steven Tave
Director, Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Via e-mail: steven.tave@fda.hhs.gov

Subject: Proposed Framework for the NDI Master File

Dear Mr. Tave:

A year ago, FDA conducted a Public Meeting on Responsible Innovation in Dietary Supplements on May 16, 2019. The trade associations representing the dietary supplement industry all provided oral testimony at that meeting along with subsequent written comments. Since that time, our members have had the opportunity to continue our thinking on the important matter of establishing dietary ingredient master files in connection with the notifying new dietary ingredients to FDA. We hereby present a framework for new dietary ingredient (NDI) master files for consideration.

As stated in the prior comments submitted by CRN,[1] the associations believe FDA should play an active role in protecting innovation in dietary ingredients. By doing so, the agency incentivizes the submission of NDI notifications and increases compliance that provides more data to inform FDA about NDIs that enter the market. It facilitates agency actions to protect public safety. We recognize there are other aspects of improving compliance with the NDI notification requirement, including reaching consensus around the scope of permissible dietary ingredients and exceptions to the requirement, and the industry has submitted extensive comments on those issues. However, our goal with the proposed NDI master file (NDI-MF) framework is to address the protection of innovation.

Responsible companies in the dietary supplement industry invest in generating the necessary data to establish the safety of their ingredients. A significant concern for these ingredient manufacturers is that they must compete on an uneven playing field with companies that fail to generate and submit safety data specific to their NDIs and claim that their ingredients are identical to NDIs that other firms properly notified. In numerous cases, product testing has demonstrated that their ingredients are indeed not identical, and in some cases, pose safety risks to consumers. The lack of deterrence for unscrupulous companies that bypass the notification requirement frustrates and discourages responsible companies.

The NDI-MF is a tool to streamline the collection and protection of data investments made by ingredient manufacturers. It provides a way to keep secured confidential information such as safety

[1] Comment from Council for Responsible Nutrition. Responsible Innovation in Dietary Supplements; Public Meeting; Request for Comments. Docket No. FDA-2019-N-1388. Available from: https://www.regulations.gov/document?D=FDA-2019-N-1388-0053.

data related to an NDI and enables companies to authorize others to properly reference master file data. Without proof of authorization, a company cannot claim to have the same ingredient as another. With use of the NDI-MF, FDA would be able to identify and enforce against certain marketers of NDIs that fail to comply with the notification requirement.

The proposed framework is modeled after that of the U.S. Drug Master File, which the agency has accepted for decades. While there are differences in the details, the key elements are similar regarding the submission and authorization process and protection of confidential information. This framework was developed by the members of CRN's Master File Working Group and has been reviewed by the other undersigned associations.

As partners in this industry effort, we jointly submit the proposed framework to encourage and assist FDA in implementing an NDI-MF system that will serve both the industry and the agency. We underscore, however, that the utility, and ultimate success, of the NDI-MF will depend largely on FDA's support and a strong commitment to enforcement of its proper use—establishing a master file program without the agency's resolve and resources to enforce it, and to prosecute companies who ignore it, only perpetuates continued indifference and leaves the intellectual property of responsible and innovative companies unprotected. Should FDA pursue implementation, industry would welcome agency guidance to clarify the NDI-MF submission process, as well as template forms (e.g., Letter of Authorization template).

Thank you for your consideration. We are available for further discussions should the agency have questions or comments.

Sincerely yours,

Scott Melville
President & CEO
Consumer Healthcare Products Association

Steve Mister
President & CEO
Council for Responsible Nutrition

Loren Israelsen
President
United Natural Products Alliance

The Consumer Healthcare Products Association (CHPA) is the 137-year-old trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. Every dollar spent by consumers on OTC medicines saves the U.S. healthcare system $6-$7, contributing a total of $102 billion in savings each year. CHPA is committed to promoting the increasingly vital role of over-the-counter medicines and dietary supplements in America's healthcare system through science, education, and advocacy. Visit www.chpa.org and www.KnowYourOTCs.org.

The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on Twitter @CRN_Supplements, Facebook, and LinkedIn.

The United Natural Products Alliance (UNPA) is an international trade association representing many leading natural products, dietary supplement, functional food, scientific and technology and related service companies that share a commitment to provide consumers with natural health products of superior quality, benefit and reliability. Founded in Utah in 1992, UNPA was instrumental in the passage of the 1994 Dietary Supplement Health and Education Act (DSHEA) and continues to take a leadership position in legislative and regulatory issues and industry best practices. Visit www.unpa.com.

Enclosure: Proposed NDI Master File Framework