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Food and Drug Administration
*Via e-mail: Cara.Welch@fda.hhs.gov*

**Subject: Planned FDA Draft Guidance for Industry on Dietary Supplement Master Files**

Dear Dr. Welch:

On July 6th, amid the recently announced plans to reimagine the Human Foods Program, including its new organization structure and resource allocation for the oversight of foods, including dietary supplements, FDA added among its list of priority guidance documents for 2023 "Dietary Supplement Master Files: Draft Guidance for Industry."[1] CRN understands FDA anticipates releasing the long-awaited New Dietary Ingredient (NDI) Notification final guidance in parts later this year, but we were surprised, however, to see a separate guidance on dietary supplement master files as being one part. In response to this announcement, CRN strongly urges the agency to allocate necessary resources toward effective enforcement of the dietary supplement master file framework in parallel with issuing this guidance—or to reconsider issuing any guidance on the master file issue at all, and to redirect resources toward other topics that are likely to produce a positive impact for dietary supplement consumers. Guidance without corresponding enforcement is not likely to serve the industry or its consumers.

As much as 75 percent of Americans use at least one dietary supplement,[2] and these products have grown into a nearly $60 billion industry.[3] Dietary supplements are ubiquitous healthcare products helping over 200 million Americans achieve better health. With the elevation of the Human Foods Program at FDA, we would hope for additional resources (both funding and staffing) for dietary supplements. However, we are concerned the proposed consolidation of the Office of Dietary Supplement Programs (ODSP) into the "Office of Food Chemical Safety, Dietary Supplements, and Innovation" will effectively diminish attention and resources towards dietary supplement oversight and the agency's ability to support supplement innovation.

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[1]Center for Food Safety and Applied Nutrition. Foods program guidance under development. U.S. Food and Drug Administration. Updated July 6, 2023. Accessed August 8, 2023. https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development.
[2]CRN, Ipsos. 2022 Consumer Survey on Dietary Supplements. https://www.crnusa.org/resources/consumer-intelligence-enhance-business-outcomes.
[3]Schofield L. Supplement business forecast – special report. Natural Products INSIDER. August 29, 2022. Accessed August 8, 2023. https://www.naturalproductsinsider.com/business-operations/supplement-business-forecast-special-report.

In May 2020, CRN, along with two other dietary supplement trade associations, submitted a joint letter and a framework for NDI master files for FDA to consider implementing to promote innovation and protect public safety. (A copy of that submission is attached hereto.) We emphasized in that letter, and in a subsequent meeting with ODSP staff, that a successful NDI master file system would level the playing field for responsible companies that invest significant resources in generating necessary safety data for NDIs to bring them to market; it would deter bad actors that bypass the notification requirement; and it would protect the public from these bad actors' potentially adulterated products.

CRN stressed at the time the connection between master files and assuring consumer health and safety related to the use of supplements. If firms are marketing a new dietary ingredient without having filed an NDI notification, or being expressly authorized to use the new ingredient by the firm that originally filed the successful NDI notification, FDA has no assurance that the ingredient or the finished product is made according to the same processes and adheres to conditions of use described in the NDI notification. Altered ingredient identity, lack of control for potentially harmful contaminants and heavy metals, and other safety issues may occur in the unnotified ingredients without FDA being aware. Master files and appropriate authorization for use of successfully notified NDIs—*if properly enforced*—assure that secondary companies claiming to use the same NDIs are indeed following all the necessary procedures to ensure ingredient safety.

We also underscored that NDI master files can only succeed when FDA commits to rigorous enforcement of its use. This means FDA must be willing to allocate resources to identifying and prosecuting bad actors who ignore their obligation under the law to submit their own NDI notification and instead claim that their ingredient is identical to the innovator company's ingredient. Effective deterrence requires FDA to prosecute some of these offenders to establish that a negative consequence may result from flouting the requirements. Proper enforcement of a master file program is essential to protect public health as well as to provide assurances to the innovating firms that there is sufficient economic incentive to invest the funds and time necessary to properly submit the NDI notification. The assurance of protection of the ingredient innovator's intellectual property goes hand-in-hand with consumer safety. Unfortunately, three years ago, ODSP indicated to CRN that the agency could not commit resources to enforcement in this area.

Indeed, FDA's enforcement of the NDI program thus far has been negligible, with only occasional warning letters issued to firms that have not filed the requisite NDI notifications for their new ingredients. We were disappointed when FDA informed CRN that it did not intend to devote resources for enforcement of a master file program for dietary supplements three years ago and surprised last month when the agency announced it is moving forward with a guidance on master files. Unless resources are allocated to the regulation of dietary supplements, including enforcement of NDI notification requirements, FDA should rethink prioritizing a master files guidance. Other pressing dietary supplement issues are awaiting the agency's action, including issuing other parts of the NDI guidance to address major concerns related to the agency's revised NDI draft guidance issued in August 2016, as well as a response to industry's citizen petition on the application of section 201(ff)(3)(B) of the federal Food, Drug, and Cosmetic Act—the drug preclusion provision. FDA's attentions would be better spent on these endeavors.

Without meaningful enforcement, FDA guidance on master files does little to support responsible companies desiring to innovate, to protect investment while doing so, and to fairly compete; and bad actors will continue to circumvent the law thereby posing risk to public safety. We strongly urge FDA to pair guidance on NDI master files with unwavering commitment to enforce its proper use. We urge FDA to clarify its intentions to advance dietary supplement oversight and innovation in new plans for the Human Foods Program.

We would be happy to discuss further should you have questions or comments.

Sincerely yours,

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