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June 03, 2024

By Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: New Dietary Ingredient Notification Master Files for Dietary Supplements: Guidance for Industry; Draft Guidance. Docket No. FDA-2024-D-0706.

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) Draft Guidance for Industry "New Dietary Ingredient Notification Master Files for Dietary Supplements" (Draft Guidance).[2] CRN appreciates that FDA has proposed to include many elements of the new dietary ingredient (NDI) master file framework we submitted to the agency in 2020. We recognize the Draft Guidance is a step forward in FDA's efforts to finalize guidance on NDI notifications and related issues by expanding on how NDI master files can be submitted and used as part of an NDI notification. However, much time has passed since FDA's 2016 revised draft guidance. Final guidance that does not create new regulatory requirements that would be inconsistent with the Federal Food Drug and Cosmetic Act[3] is needed to provide clarity on NDI notification requirements to

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

[2] Food and Drug Administration. Draft Guidance for Industry: New Dietary Ingredient Notification Master Files for Dietary Supplements. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-new-dietary-ingredient-notification-master-files-dietary-supplements. Last updated 3 April 2024. Accessed 26 April 2024.

[3] See CRN's comment letter dated June 3, 2024 on "Guidance for Industry: New Dietary Ingredient Notification Procedures and Timeframes - Dietary Supplements." Docket (FDA-2023-D-5280); CRN Comments on 2011 Draft Guidance.

facilitate proper NDI notification submissions, to increase overall NDI notification submissions, and to provide a cohesive policy that brings together efforts by FDA and industry to improve supplement industry compliance.

Recommendation for the Master File Guidance

Regarding master file guidance, we suggest FDA to provide clarity on how to submit a master file for an NDI that has been successfully notified in the past, to further encourage submission of NDI master files. Firms should have the ability to submit a "retroactive" NDI master file and to have the existence of that master file confirmed via public display to facilitate incorporation of the NDI master file into future NDI notifications.

New Dietary Ingredient Notification Enforcement Enhances Public Safety

We are disappointed the Draft Guidance was not accompanied with an announcement by FDA of its commitment to rigorously enforce the NDI notification requirement, as CRN recommended in a letter to the agency when we learned that a draft guidance on NDI master files was being planned.[4] We remain unconvinced that this added guidance on master files will have significant impact without robust FDA enforcement of the NDI requirement, despite the NDI master file's potential as a tool that could help facilitate proper NDIN submissions overall and thereby increase consumer safety.

It is an unfortunate reality that bad actors undermine the legitimate operations of responsible dietary supplement firms by blatantly breaking the law. These actors do not submit an NDI notification when required to, and some fail to do so claiming without evidence that their NDI is identical to another firm's successfully notified NDI. The FDA must be willing to allocate resources to identifying and prosecuting bad actors who ignore their obligation under the law.

In addition to facilitating appropriate NDIN submissions, which provide assurance of safety of NDIs in the market, the NDI master file provides a way to keep secured confidential information about NDIs; notifiers authorized to reference an NDI master file in their notifications can have their notifications reviewed by FDA while allowing the master file owner to protect confidential information including intellectual property. They offer a legitimate and efficient way for third parties to reference confidential information in NDI notifications, thereby encouraging NDI notifications broadly. More NDINs provide more data to inform FDA about NDIs that enter the market, which, in turn, facilitate agency actions to protect public safety.

Conclusion

CRN appreciates the inclusion in the Draft Guidance of many elements of the NDI master file framework we submitted to the agency in 2020. We recommend that FDA provide clarity in the final guidance on how to submit a master file for an NDI that has been successfully notified in the past, to further

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https://www.crnusa.org/sites/default/files/pdfs/CRN_CHPA%20Comments_NDI%20Notification%20Draft%20Guidance_Final_12_2_2011.pdf. Accessed 26 April 2024; and CRN comment on FDA's 2016 revised draft guidance. https://www.regulations.gov/comment/FDA-2011-D-0376-1994. Accessed 26 April 2024.

[4] CRN letter to Cara Welch, Ph.D. Planned FDA Draft Guidance for Industry on Dietary Supplement Master Files. https://www.crnusa.org/sites/default/files/pdfs/CRN%20Letter%20to%20FDA_Planned%20Draft%20Guidance_Dietary%20Supplement%20Master%20Files.pdf. 9 August 2023. Accessed 26 April 2024.

encourage submission of NDI master files. CRN believes the most effective action FDA should take to increase compliance with the NDI notification requirement is utilize all available tools to enforce against those who break the law. This would safeguard public health, which is a priority that CRN shares with FDA, and would also help to protect innovation.

Thank you for considering our comments.

Sincerely,

Haiuyen Nguyen

Vice President, Regulatory & Nutrition Policy