Updates
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Dietary Supplements: FDA Issues Final Guidance for NDIN Procedures and Timeframes

On March 5, FDA published its long-awaited Final Guidance on New Dietary Ingredient Notification (NDIN) Procedures and Timeframes (Final Guidance).

This new guidance updates and finalizes Section V of FDA's revised 2016 Draft Guidance. More specifically, it explains who should submit the NDIN, the information it should and should not contain, and addresses the option to meet with FDA to ask questions and obtain preliminary and nonbinding feedback from the agency regarding planned or potential NDINs, among other topics.

What Are New Dietary Ingredient Notifications?

Manufacturers must submit an NDIN to FDA 75 days before marketing a new dietary ingredient (NDI). *See* Federal Food, Drug, and Cosmetic Act (FD&C Act) § 413(a)(2) (codified at 21 U.S.C. § 350b(a)(2)). Under the FD&C Act, NDIs are dietary ingredients (i.e., vitamins, minerals, botanicals, amino acids, and substances used to supplement the diet) that were not marketed in the United States before October 15, 1994. 21 U.S.C. 350b(d)).

Key Aspects of the Final Guidance

- **Who must submit?** FDA explains that either the manufacturer or distributor of the NDI must submit an NDIN. FDA also clarifies that, in its view, manufacturers or distributors of dietary supplements containing an NDI must submit an NDIN unless the NDI manufacturer's NDIN included information about the dietary supplement at issue. In particular, FDA requires the NDI manufacturer's NDIN to include a description of the dietary supplement together with the history of use or other evidence of safety that formed the basis of the conclusion that the dietary supplement would reasonably be expected to be safe under its labeled conditions of use.

- **What information should and should not be in an NDIN?** The submission should only contain data or information that identifies the subject NDI or the dietary supplement containing the NDI, or that supports safety of the NDI or the dietary supplement. It should not contain general or extraneous information. For example, the NDIN should not include data or information primarily used to substantiate claims about the efficacy of the ingredient or supplement.
- **Submitting an NDIN.** The Final Guidance encourages electronic submissions (through the CFSAN Online Submission Module) over paper submissions, which FDA states will ensure a complete submission and allow the system to organize the NDIN for the applicant. The Final Guidance also explains that an NDIN may cover multiple dietary supplements, doses, intake levels, and other variations in which the NDI is used.
- **Post-submission issues.** The Final Guidance clarifies two points that are consistent with the agency's past practices. First, receiving a letter of acknowledgement without objection does not mean FDA determined "the NDI and the dietary supplement that contains the NDI are safe," but rather that FDA "did not find any reason to object" to the NDIN. Second, taking language from the background section of the Draft Guidance, the Final Guidance notes that FDA will publish the NDIN and the response letter 90 days after the NDIN's filing date at www.regulations.gov.
- **Meeting with FDA.** The Final Guidance adds a new discussion explaining that firms may voluntarily request meetings with FDA for nonbinding feedback on submitting NDINs. For example, a manufacturer concerned with how to describe its NDI may wish to meet with FDA about the expected detail before submitting its NDIN.

Takeaways

This new Final Guidance reinforces FDA's heightened interest in addressing safety concerns with NDIs and providing transparency for how dietary supplement manufacturers and distributors can comply with NDIN requirements.

For context, in 2022, FDA published draft guidance on limited enforcement discretion to encourage manufacturers of noncompliant dietary ingredients to correct past failures and submit appropriate NDINs to FDA for their products. Then, in 2023, FDA issued dozens of warning letters regarding noncompliant dietary supplement marketing. Now, this Final Guidance comes weeks after FDA launched an updated dietary supplement ingredient directory titled "Information on Select Dietary Supplement Ingredients and Other Substances," replacing FDA's "Dietary Supplement Ingredient Directory," released March 2023, as we discussed in this client Update.

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