Updates

On April 3, 2024, FDA published Draft Guidance titled *New Dietary Ingredient Notification Master Files for Dietary Supplements* (the Draft Guidance).

The Draft Guidance provides recommendations on how stakeholders can establish, update, and close New Dietary Ingredient Notification (NDIN) Master Files. These Master Files can be used to facilitate the submission of identity, manufacturing, and/or safety information regarding a New Dietary Ingredient (NDI) to the FDA for use in evaluating potential future NDINs.

These latest recommendations build upon the agency's Final Guidance issued last month—the subject of a prior Update—regarding procedures and timeframes for industry stakeholders to submit NDINs.

About NDIN Master Files

FDA's Draft Guidance describes an NDIN Master File as a document containing identity, manufacturing, and/or safety information relating to an NDI that the Master File owner submits to FDA for the agency's use in evaluating a potential future NDIN by the Master File owner or by another person (i.e., business partner or supplement manufacturer) designated by the Master File owner.

An NDIN Master File may contain information about an NDI, a dietary supplement containing an NDI, or both. The advantage of a Master File in the NDIN context is that an NDIN submitter may refer to data already on file with FDA (in the Master File), so they would not necessarily be required to develop such data and resubmit it in each NDIN for the same ingredient.

What To Submit

FDA's Draft Guidance sets out a number of key features that should be included in a NDIN Master File, including:

- A cover letter that includes (1) a brief description of the content of the Master File, (2) a statement that the information is being submitted as an NDIN Master File, and (3) contact information for the NDIN Master File owner, as well as contact information for any authorized representative.
- Table of contents.
- The information that the submitter wishes to comprise the Master File.
- A list of persons authorized to reference the NDIN Master File.
- For each person authorized to reference the NDIN Master File, any limitations on the authorization (i.e., if the Master File owner grants a right of reference to only specific sections of the Master File, then this fact should be made clear in the submission).

Where To Submit

Submissions are accepted either by mail to FDA's Center for Food Safety and Applied Nutrition (CFSAN) or electronically via the CFSAN Online Submission Module (COSM).

Trade Secrets and Confidential Commercial Information (CCI)

FDA does not presume information in an NDIN Master File contains trade secrets or CCI. As a result, FDA recommends that the Master File owner identify information believed to be trade secret or CCI by marking it where it appears in the Master File or by identifying it in a separate document that accompanies the Master File. If the Master File contains no trade secrets or CCI, FDA recommends the Master File owner state the absence of such information.

Additional Notes

The Draft Guidance also covers how to update or close an NDIN Master File and how an NDIN Master File owner can authorize others to reference the Master File.

With regard to FDA's review of NDIN Master Files, FDA intends to perform a substantive review of an NDIN Master File when it receives an NDIN that incorporates information from the NDIN Master File by reference. When FDA receives an NDIN that relies on information in an NDIN Master File to which the notifier has a right

of reference, the agency will review the referenced information in the

NDIN Master File as part of its standard review of the NDIN. FDA does not intend to conduct a scientific review of an NDIN Master File without a corresponding NDIN.

Takeaways

This latest Draft Guidance reinforces FDA's heightened interest in addressing safety concerns regarding NDIs and dietary supplements more broadly.

FDA is accepting comments on the Draft Guidance until June 3, 2024.

Authors

Brian P. Sylvester

Partner
BSylvester@perkinscoie.com 202.434.1669

Thomas (Tommy) Tobin

Counsel
TTobin@perkinscoie.com 206.359.3157

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