4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-0706]

New Dietary Ingredient Notification Master Files for Dietary Supplements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "New Dietary Ingredient Notification Master Files for Dietary Supplements." The draft guidance, when finalized, will provide recommendations to the dietary supplement industry on Master Files for new dietary ingredients. The purpose of this draft guidance, when finalized, will be to help industry comply more easily with the new dietary ingredient notification requirement by providing recommendations on the submission and use of Master Files that contain identity, manufacturing, or safety data that can be used to support a new dietary ingredient notification. New dietary ingredient Master Files are submitted solely at the discretion of the Master File owner and are not required by statute or regulation.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-D-0706 for "New Dietary Ingredient Notification Master Files for Dietary Supplements." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Lisa Bieniek, Office of Dietary Supplement Programs (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; or Lauren Kleinman, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry titled, "New Dietary Ingredient Notification Master Files for Dietary Supplements." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance, when finalized, will provide recommendations to industry on Master Files for new dietary ingredient notifications (NDINs). For purposes of the guidance, a new dietary ingredient notification Master File (NDIN Master File or Master File) is a file containing identity, manufacturing, and/or safety information relating to a new dietary ingredient (NDI) that the Master File owner submits to FDA for use in evaluating a potential future NDIN by the Master File owner or by another person designated by the Master File owner (e.g., business partner, supplement manufacturer). An NDIN Master File contains information about an NDI, a dietary supplement containing an NDI, or both. The Master File owner may refer to the Master File in an NDIN or may grant written authorization to other parties to incorporate information from the Master File by reference in NDINs. A written authorization granting a right of reference to a Master File in an NDIN does not include the right to see or copy the Master File.

The recommendations in this draft guidance expand upon and replace the recommendations related to Master Files in FDA's revised draft guidance, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," dated August 2016. The purpose of this draft guidance, when finalized, will be to help industry comply more easily with the NDIN requirement in the Federal Food, Drug, and Cosmetic Act (FD&C Act) by providing recommendations for the submission and use of NDIN Master Files (see section 413(a)(2) of the FD&C Act (21 U.S.C. 350b(a)(2))). The draft guidance contains information on establishing an NDIN Master File, updating or closing an NDIN Master File, the use of data from an NDIN Master File by the Master File owner and other parties authorized by the Master File owner, and FDA's role in reviewing and administering NDIN Master Files. Master Files benefit NDIN submitters with a right of reference by allowing them to refer to data already on file with FDA, instead of having to develop the data themselves and resubmit it in each NDIN for the same ingredient.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collection of information in 21 CFR 190.6 has been approved under OMB control number 0910-0330, and the collections of information in 21 CFR part 111 have been approved under OMB control number 0910-0606.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/regulatory-information/search-fda-guidance-documents or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: March 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-07095 Filed: 4/3/2024 8:45 am; Publication Date: 4/4/2024]