

Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### Information Collection

#### 1. Type of Information Collection

*Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Application for Enrollment in Medicare Part A Internet Claim (iClaim) Application Screen Modernized Claims System and Consolidated Claim Experience Screens; *Use:* The Centers for Medicare and Medicaid Services (CMS) Form “Application for Hospital Insurance” supports sections 1818 and 1818A of the Social Security Act (the Act) and corresponding regulations at 42 CFR 406.6 and 406.7.

The CMS–18–F5 is used to establish entitlement to Part A and enrollment in Part B for claimants who must file an application. The application follows the questions and requirements used by SSA on the electronic application. This is done not only for consistency purposes but because certain requirements under titles II and XVIII of the act must be met in order to qualify for Part A and Part B; including insured status, relationship and residency. The form is owned by CMS but is not utilized by CMS staff. SSA uses the form to collect information and make Part A and Part B entitlement determinations on behalf of CMS. *Form Number:* CMS–18F5 (OMB control number: 0938–0251); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,042,263; *Total Annual Responses:* 1,042,263; *Total Annual Hours:* 260,566. (For policy questions regarding this collection contact Carla Patterson at 410–786–8911 or [Carla.Patterson@cms.hhs.gov](mailto:Carla.Patterson@cms.hhs.gov)).

#### 2. Type of Information Collection

*Request:* Revision of a currently approved collection; *Title of Information Collection:* CAHPS Hospice Survey; *Use:* CMS launched the development of the CAHPS Hospice Survey in 2012. Public reporting of the results on Hospice Compare started in 2018. The goal of the survey is to measure the experiences of patients and their caregivers with hospice care. The survey was developed to:

- Provide a source of information from which selected measures could be

publicly reported to beneficiaries and their family members as a decision aid for selection of a hospice program;

- Aid hospices with their internal quality improvement efforts and external benchmarking with other facilities; and
- Provide CMS with information for monitoring the care provided.

Surveys focusing on patients’ experience of care with their health care providers are an important part of the NQS. In addition to publicly reporting clinical quality measures, CMS is currently reporting measures from patient experience of care surveys in a variety of settings, including in-center hemodialysis (ICH) centers, hospitals, home health agencies, and hospices on the Medicare Care Compare website. (<https://www.medicare.gov/care-compare>). *Form Number:* CMS–10537 (OMB control number: 0938–1257); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,159,420; *Total Annual Responses:* 1,159,420; *Total Annual Hours:* 168,115.90. (For policy questions regarding this collection contact Lauren Fuentes at 410–786–2290 or 443–618–2123).

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120–01–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 June 3, 2024 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.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a