

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-D-6501]

New Dietary Ingredient (NDI) Notifications and Related Issues; Identity and Safety Information About the NDI: Guidance for Industry; Availability

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 final guidance for industry entitled “New Dietary Ingredient (NDI) Notifications and Related Issues; Identity and Safety Information About the NDI: Guidance for Industry.” The guidance focuses on frequently asked questions about the new dietary ingredient notification (NDIN) submissions. This guidance is intended to help provide recommendations to manufacturers and distributors of NDIs and dietary supplements containing an NDI regarding the identity and safety information that should be included in an NDIN.

DATES: The announcement of the guidance is published in the **Federal Register** on October 20, 2026.

ADDRESSES: You may submit either electronic or written comments on FDA guidances 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-2025-D-6501 for “New Dietary Ingredient (NDI) Notifications and Related Issues; Safety Information About the NDI: Guidance for Industry.” 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 guidance to the Office of Dietary Supplement Programs, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, 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 guidance.

FOR FURTHER INFORMATION CONTACT:

Gerie Voss, Office of Dietary Supplement Programs, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-620-9744; or Lauren Kleinman, Division of Human Foods Regulations, Office of Regulations & International Programs, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled “New Dietary Ingredient (NDI) Notifications and Related Issues; Identity and Safety Information About the NDI: Guidance for Industry.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking 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 alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of July 5, 2011 (76 FR 39111), we announced the availability of a draft guidance for industry entitled “Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues” and gave interested parties an opportunity to submit comments by October 3, 2011. Among other topics, the July 2011 draft

guidance discussed FDA's views and recommendations on when an ingredient intended for use in a dietary supplement is an NDI, when the requirement to submit an NDIN to FDA applies, the types of data and information that manufacturers and distributors should consider when they evaluate the safety of a dietary supplement containing an NDI, what to include in an NDIN (including recommendations about identity and safety information), and the procedures for submitting an NDIN. We received significant comments and decided to issue a revised draft guidance.

In the **Federal Register** of August 12, 2016 (81 FR 53486), we announced the availability of a revised draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry" to replace the July 2011 draft guidance. We gave interested parties an opportunity to submit comments on the 2016 revised draft guidance by October 11, 2016. On October 4, 2016, we extended the comment period for the revised draft guidance to December 12, 2016 (81 FR 68434).

The final guidance, whose availability we are announcing through this document, finalizes in a stand-alone document the identity and safety recommendations that had been in sections VI.A, "Identity Information about the NDI and the Dietary Supplement," VI.B, "History of Use or Other Evidence of Safety," and VI.C, "Summary of the Basis for Your Conclusion of Safety," of the 2016 draft guidance. To help alleviate the burden of submitting separate documents regarding the safety data submitted in an NDIN, we eliminated the references to a "comprehensive safety profile" and, instead, recommend use of a single "safety narrative" for all NDINs. We made changes to provide additional clarity and description regarding what should be included in the NDIN safety narrative, when additional evidence of safety should be submitted, and what types of studies are recommended to support an NDIN. Finally, the guidance contains editorial changes to improve clarity.

FDA has also updated the 2016 revised draft guidance to indicate which portions have been finalized and which portions remain in draft status (see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-new-dietary-ingredient-notifications-and-related-issues>).

FDA considered the applicability of Executive Order 14192 and finds this

action to be neither an E.O. 14192 regulatory action nor an E.O. 14192 deregulatory action.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 190.6 and found in the guidance have been approved under OMB control number 0910–0330.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Program Forms—OMB No. 0915–0285—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 19, 2026.

ADDRESSES: Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to: www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Program Forms, OMB No. 0915–0285—Revision

Abstract: The Health Center Program, administered by HRSA, is authorized under Section 330 of the Public Health Service Act (42 U.S.C. 254b). Health centers are patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients and adjust fees based on income and family size. More than 1,400 health centers operate nearly 17,000 service delivery sites that provide primary health care to more than 32 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA uses forms for new and existing health centers and other entities to apply for various grant and non-grant opportunities, renew grant and non-grant designations, report progress, and change their scopes of project.

A 60-day notice published in the **Federal Register** on July 30, 2026, Vol. 91, No.145, pp. 48170–72. There were no public comments.

Need and Proposed Use of the Information: The information HRSA collects from health centers via the Health Center Program-specific forms is necessary for the agency's oversight of Health Center Program awards. HRSA uses the information for program monitoring and for evaluating award recipients' compliance with Health Center Program statutory and regulatory requirements. These forms were approved by OMB on May 31, 2026, following 60- and 30-day public comment periods. Eight forms that were previously approved are being updated and three forms are being added to facilitate monitoring, improve scope of project documentation and oversight, increase the efficiency of the change in scope process, and enhance the accuracy of change in scope requests.