

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10325 Disclosure and Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care Act

Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 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 Collections

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Disclosure and Recordkeeping Requirements for Grandfathered Health Plans under the Affordable Care Act; *Use:* Section 1251 of the Affordable Care Act provides that certain plans and health insurance coverage in existence as of March 23, 2010, known as grandfathered health plans, are not required to comply with certain statutory provisions in the Act. The final regulations titled "Final Rules under the Affordable Care Act for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent

Coverage, Appeals, and Patient Protections" (80 FR 72192, November 18, 2015) require that, to maintain its status as a grandfathered health plan, a plan must maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents that are necessary to verify, explain, or clarify status as a grandfathered health plan. The plan must make such records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official. A grandfathered health plan is also required to include a statement in any summary of benefits under the plan or health insurance coverage that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Affordable Care Act and provide contact information for questions and complaints. In addition, a grandfathered group health plan that is changing health insurance issuers is required to provide the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph § 147.140(g)(1) of the 2015 final regulations are exceeded. It is also required that, for an insured group health plan (or a multiemployer plan) that is a grandfathered plan, the relevant policies, certificates, contracts of insurance, or plan documents must disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year. *Form Number:* CMS-10325 (OMB Control Number: 0938-1093); *Frequency:* On Occasion; *Affected Public:* Private Sector, State, Local or Tribal governments; *Number of Respondents:* 14,603; *Total Annual Responses:* 2,094,506; *Total Annual Hours:* 40. (For policy questions regarding this collection contact Adam Pellillo at 667-290-9621.)

William N. Parham, III,

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

[FR Doc. 2024-30202 Filed 12-18-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5338]

Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Interstate Shellfish Dealer's Certificate as well as the collection of other records related to participation in the National Shellfish Sanitation Program (NSSP).

DATES: Either electronic or written comments on the collection of information must be submitted by February 18, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 18, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-N-5338 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitation Program." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." The Agency will review this copy, including the claimed confidential information, in its 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.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the

validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitary Program

OMB Control Number 0910-0021—Revision

Under section 243 of the Public Health Service Act (PHS Act) (42 U.S.C. 243), FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the U.S. bivalve molluscan shellfish industry in the NSSP.

Molluscan shellfish consumed fresh (raw) and fresh frozen poses unique public health concerns. The safety of molluscan shellfish directly reflects the cleanliness of the waters where they are grown. Molluscan shellfish are sessile, filter-feeding organisms that pump large quantities of water through their bodies during their normal feeding process. The relationship between shellfish harvesting waters that are contaminated with sewage and other forms of pollution and food safety concerns has been demonstrated often. Additionally, bivalve molluscan shellfish must be held, packed, and shipped under sanitary conditions to prevent contamination subsequent to harvest and prior to delivery to the consumer.

The NSSP is a voluntary cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish dealers. Each participating State and foreign nation monitors its molluscan shellfish production and issues certificates for those dealers that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish dealers to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate" (available for download at <https://www.fda.gov/media/72094/download>). FDA uses this information to publish the "Interstate Certified Shellfish Shippers List (ICSSL)," a monthly comprehensive

listing of all molluscan shellfish dealers certified under the cooperative program (available at <https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list>). We also provide information on our website at <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/state-cooperative-programs/fda-national-shellfish-sanitation-program>, which may serve as a helpful resource to respondents.

Under the authority of section 243 of the PHS Act, we are revising this information collection to also collect from State regulatory agencies samples of shellfish, along with metadata (date collected, temperature, and location). If available, we are also collecting analytical results needed to classify growing area waters for existing and emerging food safety hazards and to ensure that shellfish products of dealers listed on the ICSSL are safe. Respondents will have already independently collected samples at a given location/time (our request is for an additional sample to be collected and sent to FDA for analysis) and, in some cases (for requested existing analytical results), conducted tests associated with information submitted as part of samples and analytical results. Regarding the collection of samples, FDA will provide shipping materials for transport and will bear any shipping costs.

The information collection also includes respondents providing to FDA documents demonstrating compliance with the NSSP. When a competent

authority in another country conducts an evaluation to determine whether the U.S. food safety control measures for bivalve molluscan shellfish are equivalent to its own system of controls, the competent authority may require FDA to provide information and records demonstrating compliance with the provisions of the NSSP. Only those firms that comply with the NSSP would be permitted to export bivalve molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. FDA uses the information collection to support the export of U.S. shellfish to countries whose competent authorities have determined the U.S. system of food safety controls to be equivalent to their own system of controls by demonstrating that the exporter follows the U.S. system of controls specified in the NSSP.

For example, to implement the European Commission’s (EC) determination that the U.S. system of food safety controls for raw bivalve molluscan shellfish is equivalent to the European Union’s (EU) system of controls, the EC requires FDA to provide documentation collected from NSSP-participating shellfish control authorities for firms seeking to export raw molluscan shellfish to the EU. This documentation includes, but is not limited to:

- a list of growing areas with an approved classification;
- the most recent sanitary survey for each growing area with an approved classification; and

- the most recent inspection report for each dealer seeking to export bivalve molluscan shellfish to the EU.

The examples above are illustrative. Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We provide respondents with information about the specific documentation that is required for each equivalence assessment. For those competent authorities that recognize the U.S. system as equivalent, additional documentation may be needed to implement that determination.

Form FDA 3038 may be submitted on paper or submitted electronically by State or international officials. These officials securely log into a shellfish shippers account to fill out Form FDA 3038 electronically. The information obtained from the form has been entirely automated. The forms transmitted by the States, after approval by an FDA official, are entered into an FDA computer database program that allows the addition, deletion, download, and generation of the Interstate Certified Shellfish Shippers List, published monthly in PDF format, and may be updated daily when new data is available.

Description of Respondents: Respondents to this collection are participating State regulatory agencies and foreign nations.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer’s Certificate.	3038	40	57	2,280	0.10 (6 minutes)	228
Submission of NSSP Compliance Documentation.	N/A	13	1	13	0.25 (15 minutes) ..	3
Submission of Samples and Analytical Results.	N/A	35	2	70	0.50 (30 minutes) ...	35
Total	266

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 35 hours and 70 responses due to the program change of collecting samples and analytical results. We attribute the burden change to an increase in responses. This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years.

Dated: December 12, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024-30228 Filed 12-18-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5234]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the regulation requiring the manufacturer, packer, or distributor of a dietary supplement to notify us that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Either electronic or written comments on the collection of information must be submitted by February 18, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of February 18, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-N-5234 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." The Agency will review this copy, including the claimed confidential information, in its 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.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.