application (IND) became effective. However, FDA records indicate that the IND effective date was July 21, 2012, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 29, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for JOENJA (NDA 217759) was initially submitted on July 29, 2022.

3. *The date the application was approved:* March 24, 2023. FDA has verified the applicant's claim that NDA 217759 was approved on March 24, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,613 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11318 Filed 6–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5338]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 21, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0021. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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.

In the **Federal Register** of December 19, 2024 (89 FR 103832), we published a 60-day notice soliciting comment on the proposed collection of information. Although one comment was received offering support for FDA's efforts in ensuring the safety of shellfish, it referenced proposed rulemaking and therefore we are clarifying that this notice pertains to FDA information collection activities subject to OMB review and clearance under the PRA of 1995.

We estimate the burden of the 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: June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11328 Filed 6–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3370]

Post-Warning Letter Meetings Under Generic Drug User Fee Amendments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.