

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-1112]

#### 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 or we) 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 June 8, 2022.

**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](mailto: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—Extension

Under section 243 of the Public Health Service 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. molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

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 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>). If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and prevent the distribution in the United States of shellfish processed by uncertified dealers. Consequently, the NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce. Without the ICSSL, the effectiveness of the NSSP would be nullified. The ICSSL is also used to identify U.S. shellfish dealers eligible to obtain health certificates and export to certain countries or regions.

FDA has been collecting information to construct the ICSSL since 2001. FDA is seeking to add one new data field to Form FDA 3038, the "FDA Establishment Identifier" (FEI number). The FEI number is a unique number assigned by FDA to identify FDA-regulated facilities. FDA will explore whether the FEI can be used to retrieve

data on shellfish dealers from existing FDA systems, which could reduce the number of required data elements that firms have to submit on Form FDA 3038.

The information collection also includes providing certain 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 molluscan shellfish are equivalent to their 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 molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. FDA uses this information 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 is in compliance with 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 is requiring FDA to provide documentation collected from NSSP-participating shellfish control authorities with 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 firm seeking to export shellfish to the EU.

Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We plan to 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.

#### Description of Respondents:

Respondents to this collection are participating State and local regulatory agencies and foreign nations.

In the **Federal Register** of November 4, 2022 (86 FR 60840), we published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Form FDA 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 Other Records Related to Participation in the NSSP.	N/A	13	1	13	0.25 (15 minutes) .....	3.25
Total .....	.....	.....	.....	.....	.....	231.25

<sup>1</sup> 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 made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

Dated: May 2, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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This rate is based on the Interest Rates for Specific Legislation, “National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))” and “National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).” This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

**David C. Horn,**

*Director, Office of Financial Policy and Reporting.*

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comments or requesting information, please include the document identifier 0937-0166 and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* 42 CFR Subpart B: Sterilization of Persons in Federally Assisted Family Planning Projects.

*Type of Collection:* Reinstatement without change.

OMB No. 0937-0166

*Abstract:* The Office of Population Affairs (OPA), Office of the Assistant Secretary for Health, requests a reinstatement without change of a currently approved collection for the disclosure and recordkeeping requirements codified at 42 CFR part 50, subpart B (“Sterilization of Persons in Federally Assisted Family Planning Projects”). The consent form solicits information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by federal financial assistance administered by the PHS. It provides additional procedural protection to the individual and the regulation requires that the consent form be a copy of the form that is appended to the PHS regulation. In 2003, the PHS sterilization consent form was revised to conform to OMB government-wide standards for the

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the “Schedule of Certified Interest Rates with Range of Maturities” unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 9<sup>3</sup>/<sub>8</sub>%, as fixed by the Secretary of the Treasury, is certified for the quarter ended March 31, 2022.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0937-0166]

#### Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 8, 2022.

**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](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

#### FOR FURTHER INFORMATION CONTACT:

Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting