Authority: 42 U.S.C. 5106.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0232]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Interstate Shellfish Dealer's Certificate

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: Fax written comments on the collection of information by May 24, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0021. Also include the FDA docket number found in brackets in the heading of this document.

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: 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 OMB Control Number 0910–0021—Revision

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, we participate with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP). 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 processors.

Each NSSP-participating State and foreign nation monitors its molluscan shellfish processors and for purposes of interstate or international commerce issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' We use this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If we did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate and international commerce, and its effectiveness would be nullified.

In the **Federal Register** of March 9, 2018 (83 FR 10487), we published a notice seeking comment on a proposed determination that the European Union's (EU's) system of food safety control measures for raw bivalve molluscan shellfish intended for export into the United States, as adopted and implemented in Spain and the Netherlands, provides at least the same level of sanitary protection as the United States equivalent. If finalized, such a determination would permit the importation of shellfish harvested from certain European production areas and processed by European establishments that have been listed by FDA on the Interstate Certified Shellfish Shippers List.

The March 9, 2018, notice also described the European Commission's (EC's) determination that the United States' system is equivalent to its own, and as a result of that determination, its stated intent to accept shellfish from certain growing areas in the United States. On November 6, 2018, the EC published Commission Implementing Decision (EU) 2018/1668 which added the United States (MA and WA only) to the list of Third Countries from which molluscan shellfish imports are permitted. Shellfish harvested from growing areas with an Approved classification in those states are eligible for export to the EU.

As part of the equivalence determination, the EC identified the need for FDA to provide documentation collected from NSSP-participating shellfish control authorities seeking recognition under the EC's equivalence determination. This documentation includes:

- 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.

For NSSP-Participants that do not produce live/raw shellfish required documentation is limited to the most recent Plant and Shipping Element Program Evaluation Report and the most recent inspection report for each shellfish processing firm to be listed for export to the EU.

In the **Federal Register** of June 8, 2018 (83 FR 26699), 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 [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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of NSSP Compliance Documentation.	N/A	13	1	13	0.25 (15 minutes)	3.25
Total	.....	.....	.....	.....	.....	231.25

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

We estimate that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates (Form FDA 3038) annually, or an average of 57 responses per respondent. We estimate that it takes a respondent an average of 6 minutes or 0.1 hour to complete each form for a total burden of 228 hours (2,280 submissions × 0.10 hours). 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.

In order to gain equivalence recognition by the EC, we estimate that respondents will make a one-time submission of documents demonstrating NSSP compliance. We estimate that 13 respondents will each submit 1 response, for a total of 13 responses. We estimate that each response will take 15 minutes, or 0.25 hour, for an annual total of 3.25 hours (13 responses × 0.25 hour).

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08174 Filed 4–23–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3458]

Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for data and information; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period provided in the notice entitled ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information'' that appeared in the **Federal Register** of December 7, 2018. That notice announced the establishment of a docket to obtain data, information, and comments that will assist the Agency in assessing the safety and effectiveness of food handler antiseptic drug products (*i.e.,* antiseptic hand washes or rubs intended for use in food handling settings) for over-the-counter human use. The Agency is taking this action to allow interested persons additional time to submit comments, data, or information.

DATES: FDA is reopening the comment period on the notice published on December 7, 2018 (83 FR 63168). Submit either electronic or written comments by July 23, 2019.

ADDRESSES: You may submit comments, data, or information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 23, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 23, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2018–N–3458 for ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information; Reopening of Comment Period.'' 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.

- 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