Agency Information Collection Activities; Proposed Collection; Comment Request; Comment Request; Interstate Shellfish Dealers Certificate

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2009–N–0232]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Comment Request; Interstate Shellfish Dealers Certificate**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 Dealers Certificate.

**DATES:** Submit either electronic or written comments on the collection of information by October 19, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to Division of Dockets Management (HFA–205), Food and Drug Administration, 8333-38th Street, Bldg. 56, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@ fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** 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. “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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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**

**OMB Control Number 0910–0021—Extension**

Under 42 U.S.C. 243, we are required to cooperate with and aid State and local authorities in the enforcement of their health regulations and are 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 participating State and foreign nation monitors its molluscan shellfish processors and 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 commerce, and its effectiveness would be nullified.

We estimate the burden of this collection of information as follows:
We estimate that 40 respondents will submit 2,280 Interstate Shellfish Dealer’s Certificates annually, for a total burden of 228 hours (2,280 submissions × 0.10 hours = 228 hours). This estimate is based on our experience with this information collection and the number of certificates received in past 3 years, which has remained constant.

Dated: August 14, 2015.

Leslie Kux,
Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Paris Watson, Senior Advisor, NIH Office of Disease Prevention, 6100 Executive Blvd., Room 2B03, Bethesda, MD 20892 or call (301) 496–1508 or email your request, including your address to prevention@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Identifying Experts in Prevention Science Methods To Include on NIH Review Panels (ODP)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), Office of Disease Prevention (ODP) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on April 7, 2015, page 18641 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to: the Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, Attn: NIH Desk Officer.

DATES: Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30- days of the date of this publication.

Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Activity</th>
<th>FDA Form No.</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission of Interstate Shellfish Dealer’s Certificate.</td>
<td>3038</td>
<td>40</td>
<td>57</td>
<td>2,280</td>
<td>0.10 (6 minutes)</td>
<td>228</td>
</tr>
</tbody>
</table>

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

Estimation process:
We estimate that 40 respondents will submit 2,280 Interstate Shellfish Dealer’s Certificates annually, for a total burden of 228 hours (2,280 submissions × 0.10 hours = 228 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.

We estimate that 3,120 investigators will respond to an online software in 2040, for a total burden of 1,040 hours (3,120 responses × 0.32 hours = 1,040 hours). This estimate is based on our experience with this information collection and the number of responses received in the past 3 years, which has remained constant.

This proposed information collection, we are now seeking OMB approval. This PRA clearance request is for the deployment of the new online software and the collection of data.

ODM approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,040.