this list could be delayed or prevented by Chilean authorities from entering commerce in Chile. The guidance explains what information firms should submit to FDA in order to be considered for inclusion on the list and what criteria FDA intends to use to determine eligibility for placement on the list. The document also explains how FDA intends to update the list and how FDA intends to communicate any new information to Chile. Finally, the guidance notes that FDA considers the information on this list, which is provided voluntarily with the understanding that it will be posted on FDA's Web site and communicated to, and possibly further disseminated by, Chile, to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). Under the guidance, FDA recommends that U.S. firms that want to be placed on the list send the following information to FDA: Name and address of the firm and the manufacturing plant; name, telephone number, and email address (if available) of the contact person; a list of products presently shipped and expected to be shipped in the next 3 years; identities of Agencies that inspect the plant and the date of last inspection; plant number and copy of last inspection notice; and, if other than an FDA inspection, copy of last inspection report. FDA requests that this information be updated every 2 years.

In the **Federal Register** of November 15, 2012 (77 FR 68128), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New written requests to be placed on the list	25	1	25	1.5	38
Biannual update	88	1	88	1.0	88
Occasional updates	25	1	25	0.5	13
Total					139

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

The estimate of the number of firms that will submit new written requests to be placed on the list, biannual updates and occasional updates is based on the FDA's experience maintaining the list over the past 7 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms.

On average, over the last 3 years, the list contained approximately 176 firms. FDA estimates that, each year, approximately 25 new firms will apply to be added to the list. In any given year, some firms choose not to resubmit their information. These firms are removed from the list quarterly. This occurrence results in the number of firms to remain at approximately 176. We estimate that a firm will require 1.5 hours to read the guidance, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list for a total of 37.5 hours, rounded to 38. Under the guidance, every 2 years each producer on the list must provide updated information in order to remain on the list. FDA estimates that each year approximately half of the firms on the list, 88 firms ($176 \times 0.5 = 88$), will resubmit the information to remain on the list. We estimate that a firm already on the list will require 1.0 hours to biannually update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 88 hours. In addition, FDA expects that, each year, approximately 25 firms will need to submit an occasional update and each firm will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 12.5 hours, rounded to 13.

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06017 Filed 3–14–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1108]

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 April 15, 2013.

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: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400, Rockville, MD 20850, 301–796–5733, *domini.bean@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)—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 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.'' FDA uses 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 FDA 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.

In the **Federal Register** of November 15, 2012 (77 FR 68129), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. FDA received one letter in response to the notice, containing multiple comments on the testing methods used by certified shellfish processors in the NSSP. These comments were outside the scope of the four collection-of-information topics on which the notice requested comments, and will not be discussed in this document. 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	228

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

FDA estimates 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 FDA's experience and the number of certificates received in the past 3 years.

Dated: March 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05970 Filed 3–14–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Application of Advances in Nucleic Acid and Protein Based Detection Methods to Multiplex Detection of Transfusion-Transmissible Agents and Blood Cell Antigens in Blood Donations; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Application of Advances in Nucleic Acid and Protein Based Detection Methods to Multiplex Detection of Transfusion-Transmissible Agents and Blood Cell Antigens in Blood Donations.'' The purpose of this public workshop is to discuss research and development of multiplex assays and the use of these tests in blood donor screening and blood cell antigen typing. The public workshop has been planned in partnership with the AABB (formerly known as the American Association of Blood Banks), Advanced Medical Technology Association (AdvaMed), America's Blood Centers, Department of Defense, Department of Health and Human Services Office of the Assistant Secretary for Health, and the National Heart, Lung and Blood Institute, National Institutes of Health. The public workshop will include presentations and panel discussions by experts from academic institutions, blood establishments, industry, and government agencies.

Date and Time: The public workshop will be held on April 10, 2013, from 8 a.m. to 5:30 p.m., and April 11, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held in the Main Auditorium, Natcher Conference Center, National Institutes of Health, Bldg. 45, Bethesda, MD 20892.

Contact Person: Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6128, FAX: 301–827–2843, email: *CBEROBRRWorkshops@fda.hhs.gov*.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see *Contact Person*) by April 1, 2013. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Jennifer Scharpf (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The objectives of the workshop are to review the status of multiplex platforms and the technological advances in gene based and protein based pathogen and blood cell antigen detection methods and to discuss the scientific pathways to support the development of multiplex assays to screen blood donors for blood-borne pathogens and blood cell antigen typing.

The first day of this workshop will include presentations and panel discussions on the following topics: (1) Blood safety and infectious agents, (2) advances in blood-borne pathogen detection, and (3) molecular DNA-based typing of blood cell antigens.

The second day of the workshop will include presentations and discussion on the following topics: (1) Highly multiplexed technologies in blood donor screening; (2) bioinformatics, data