collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 23, 2014:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New Collection (Request for a new control number); *Title of Information Collection:* Marketplace Quality Standards; *Use:* Section 1311(c)(3) of the Affordable Care Act directs the Secretary to develop a rating system for qualified health plans (QHPs) on the relative basis of quality and price and requires Marketplaces to display this quality rating information on their Web sites. Section 1311(c)(4) of the Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system (ESS) that assesses consumer experience with QHPs (with more than 500 enrollees in the previous year) offered through a Marketplace and requires Marketplaces to display enrollee satisfaction information to allow individuals to easily compare enrollee satisfaction levels between comparable plans. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards beginning January 1, 2015. The collection of information from QHP issuers is necessary to implement these quality standards and to provide adequate and timely health care quality information to consumers, regulators and Marketplaces. Specifically, for implementation and reporting for the Federal Quality Rating System (QRS) and for the ESS, the collection, validation and submission of validated data is required as outlined in § 156.1120 and § 156.1125. In addition, QHP issuers must demonstrate compliance with the patient safety standards outlined in § 156.1110 which involves associated information collection, recordkeeping and disclosure requirements. It is also necessary to collect information per § 156.1105 to appropriately monitor and provide a process for survey vendors to appeal HHS' decision to not approve ESS vendor applications.

Form Number: CMS–10520 (OMB control number: 0938-New); *Frequency:* Annual; *Affected Public:* Individuals; Private Sector—Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 620; *Total Annual Responses:* 620; *Total Annual Hours:* 980,995. (For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.)

Dated: May 20, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–11948 Filed 5–22–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0192]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining a List of United States Dairy Product Manufacturers/Processors With Interest in Exporting

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 June 23, 2014.

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 0910–0509. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/ Processors With Interest in Exporting (OMB Control Number 0910–0509)—Extension

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food that the processor of the food is in compliance with applicable country of origin regulatory requirements. With regard to U.S. milk products, FDA is the competent U.S. food safety authority to provide this information to foreign governments. We provide the requested information about processors in the form of lists. The lists are provided to the foreign governments and also posted online at *http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm.* The term ''milk product'', for purposes of this information collection, includes products defined in 21 CFR 1240.3(j) and any product requested by foreign governments to be included in this list process.

We currently provide Chile a list of U.S. milk product manufacturers/ processors that have expressed interest in exporting their products to Chile, are subject to our jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. In the **Federal Register** of June 22, 2005 (70 FR 36190), we announced the availability of a revised guidance document entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile.'' The guidance can be found at *http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm078936.htm.*

FDA was asked to provide a list to China in response to China's State General Administration of the People's Republic of China for Quality Supervision and Inspection and Quarantine (AQSIQ) issuance of Administrative Measures for Registration of Overseas Manufacturers, known as AQSIQ Decree 145. Accordingly, we established and maintain for China a list that identifies U.S. milk product manufacturers/ processors that have expressed interest to us in exporting milk products to China, are subject to our jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. On January 9, 2014, we issued a guidance document entitled ''Establishing and Maintaining a List of U.S. Milk Product Manufacturers/ Processors with Interest in Exporting to China.'' The guidance can be found at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/ucm378777.htm.*

As noted, we provided the new list to China in response to AQSIQ Decree 145. In accordance with 5 CFR 1320.13, FDA requested emergency OMB review and approval of the collections of information found in the guidance document. The routine course of OMB approval would not have been in the best interest of the public health because it would have delayed our ability to collect the information from firms and, thus, would have been disruptive in our efforts to facilitate services that have been requested by China in AQSIQ Decree 145. OMB granted the approval under the emergency clearance procedures on November 7, 2013.

The guidance documents are published under the authority of section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)), which authorizes the Secretary to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA.

The guidance documents explain what information firms should submit to us in order to be considered for inclusion on the lists and what criteria we intend to use to determine eligibility for placement on the lists. The guidance documents also explain how we intend to update the list and how we intend to communicate any new information to the government that requested the list. Finally, the guidance documents note that the information is provided voluntarily by firms with the understanding that it will be posted on our Web site and communicated to, and possibly further disseminated by, the government that requested the list; thus, we consider the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4).

Application for inclusion on each list is voluntary. In the guidance documents, we recommend that U.S. firms that want to be placed on either list send the following information to us: 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. We request that this information be updated every 2 years.

We use the information submitted by firms to determine their eligibility for placement on the list, which is published on our Web site. The purpose of the list is to help the governments of Chile and China in their determination of which U.S. milk product manufacturers are eligible to export to their respective countries.

Description of Respondents: Respondents to this information collection include U.S. food product manufacturers/processors subject to our jurisdiction that wish to export products requested by foreign governments to be included in this list process.

In the **Federal Register** of February 18, 2014 (79 FR 9221) FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, they were not responsive to the information collection topics solicited in the notice.

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	125	1	125	1.5	188
Biennial update	125	1	125	1	125
Occasional updates	50	1	50	[2]0.5	25

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					338

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

The estimate of the number of firms that will submit new written requests to be placed on the list, biennial updates, and occasional updates is based on the FDA's experience maintaining the list over the past 8 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.

Based on submissions received for the Chile list over the past 3 years and the China list over the past 3 months, we estimate that, annually, an average of 100 new firms will submit written requests to be placed on the China list and 25 new firms will seek to be placed on the Chile list, reported as 125 total respondents on line 1 of table 1. We estimate that a firm will require 1.5 hours to read the guidance, to 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 187.5 burden hours, rounded to 188, as reported on line 1 of table 1. Under the guidance, every 2 years each firm on the list must provide updated information in order to remain on the list.

There are approximately 250 firms on the 2 lists combined. We estimate that, each year, approximately half of the firms on the list, 125 firms, will resubmit the information to remain on the list. We estimate that a firm already on the list will require 1 hour to biennially update and resubmit the information to us, including time reviewing the information and corresponding with us, for a total of 125 hours. In addition, we expect that, each year, approximately 50 firms will need to submit an occasional update and each firm will require 0.5 hour to prepare a communication to us reporting the change, for a total of 125 hours.

Dated: May 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11927 Filed 5–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0485]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

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 June 23, 2014.

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 title ''Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health.'' Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health—(OMB Control Number 0910–NEW)

This information collection request collects information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because there has been no established guidelines or instructions on how to submit an allegation to CDRH, allegations often contain minimal information and are received via phone calls, emails, or conversationally from any CDRH staff. CDRH seeks to establish a consistent format and process for the submission of device allegations that will enhance our timeliness in receiving, assessing and evaluating voluntary allegations. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

In the **Federal Register** of May 6, 2013 (78 FR 26373), 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: