DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0192]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of United States Milk Product Manufacturers/Processors With Interest in Exporting

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 the 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 entitled, ''Establishing and Maintaining Lists of United States (U.S.) Milk Product Manufacturers/Processors with Interest in Exporting.''

DATES: Submit either electronic or written comments on the collection of information by April 21, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites 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.

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

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/ImportsExports/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 the 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.

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 updates	125	1	125	1.0	125
Occasional updates	50	1	50	0.5	25
Total					338

[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, 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 hours to prepare a communication to us reporting the change, for a total of 125 hours.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0444]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the 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 focus groups as used by FDA to gauge public opinion on all FDA-regulated products.