Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors with Interest in Exporting

OMB Control No. 0910-0509

SUPPORTING STATEMENT, Part A

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The United States (U.S.) 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, the Food and Drug Administration (FDA or we) 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/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/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.

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 website 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 e-mail 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.

As noted, we provided the new list to China in response to AQSIQ Decree 145. In accordance with 5 CFR 1320.13, we requested emergency review and approval of the collections of information found in the guidance document entitled, "Establishing and Maintaining a List of U.S. Milk Product Manufacturers/Processors with Interest in Exporting to China." The routine course of 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.

2. Purpose and Use of the Information Collection

We use the information submitted by firms to determine their eligibility for placement on the list, which is published on our website. The purpose of the list is to assist 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. milk product manufacturers/processors subject to our jurisdiction that wish to export products requested by foreign governments to be included in this list process. Respondents are from the private sector (for profit businesses).

3. Use of Improved Information Technology and Burden Reduction

We continually seek ways to reduce the reporting burden. Presently, U.S. firms may submit information by letter sent via the U.S. Postal Service or overnight delivery, facsimile, or e-mail. We estimate that fifty percent (50%) of the respondents will use electronic means to submit their information.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is a unique collection for the purpose of assisting the governments of Chile and China in their determination of which U.S. milk product manufacturers are eligible to export to their respective countries. Some, but not all, of the same information is collected by FDA or the U.S. Department of Agriculture (USDA) for other purposes, for example, the *"The Interstate Milk Shippers (IMS) List for Grade 'A' Dairy Plants"* and *"The List of Dairy Plants Surveyed and Approved for USDA Grading Service."* However, it is not practical to use the information on these lists for the purpose of assisting the governments of Chile or China with their requests. These lists are product specific and may not include the products that the firms intend to export to Chile or China. The USDA list is a voluntary listing with a fee for those firms who wish to have their products graded. The IMS list is only for Grade A milk products and does not include non-Grade A products (e.g., cheese or ice cream).

In addition, documentation requirements require a unique collection of information. We believe that it is necessary for the agency to create a complete and unique file corresponding to each initial request for placement on the list. The documentation contained in this file would include all relevant information necessary to demonstrate satisfaction of the minimum conditions for listing of a firm, including a copy of the most current inspection report, whether that inspection was conducted by FDA or by another regulatory entity, i.e., USDA or a state regulatory agency. A firm's presence on any other list would not be sufficient to document satisfaction of the listing criteria.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ten percent (10%) of the respondents are small businesses._ However, because the collection gathers the minimum information that a business is required to submit to qualify to be placed on the list, there is no way to reduce the burden on small businesses. We aid small businesses through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We have provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The data in new requests to be placed on the list are submitted only once. A business is requested to submit occasional updates if the previously submitted information changes. In addition, we request that firms update their information biennially. If the information collection is not conducted, milk products from firms not on this list could be delayed or prevented by the government authorities of Chile or China from entering commerce in their respective countries.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of February 18, 2014 (79 FR 9221). We received two letters in response to the February 18, 2014 notice. However, the comments were outside the scope of the four collection of information topics on which the February 18, 2014 notice sought comments and will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality is provided. As noted in the guidance documents, FDA considers the information contained in the lists, which is given voluntarily with the understanding that it will be posted on FDA's website and communicated to Chile or China, to be information that is not protected from disclosure under 5 U.S.C. § 552(b)(4).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents to this information collection include U.S. milk product manufacturers/processors subject to our jurisdiction that wish to export products requested by foreign governments to be included in this list process. Respondents are from the private sector (for profit businesses).

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. 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	1.0	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 5 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 25 hours.

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $26,127.40. FDA estimates that the new written requests, biennial updates and occasional updates will be prepared by an employee making an average wage similar that of a Federal government employee at the GS-12/Step-3 rate for the Washington-Baltimore Locality Pay Area for the year 2014, which is $38.65 per hour. To account for overhead, this cost is increased by 100 percent, which is $77.30 per hour. Thus, the annual wage cost for completion and submission of these requests and updates is approximately $26,127.40 (338 hours x $77.30 per hour).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that, on average, the annualized cost to the Federal government for the review and evaluation of requests and updates submitted by U.S. milk product manufacturers is approximately $2,995.38. FDA bases its estimate on the hourly rate of one full-time employee at the GS-12/Step 3 level, in the Washington-Baltimore Locality Pay Area for the year 2014, which is $38.65 per hour.

To account for overhead, this cost is increased by 100 percent, which is $77.30 per hour. The employee spends an estimated 77.5 hours reviewing and evaluating the submissions. Thus, FDA estimates that the annual cost to the Federal Government would be $2,995.38 (77.5 hours x $38.65/hour).

15. Explanation for Program Changes or Adjustments

This is an extension request in which both the total annual number of responses and the total annual hour burden are being increased. The total annual number of responses increased from 163 to 300 responses (an increase of 137) and the total annual hour burden has increased from 176 to 338 hours (an increase of 162). The increase is due to industry growth, resulting in an increased number of respondents. Thus, we are characterizing the increase as an adjustment.

For IC#1, we estimate that the number of respondents will increase from 50 to 125, causing the annual number of responses to increase from 50 to 125 (an increase of 75) and the annual hour burden to increase from 75 to 188 hours (an increase of 113). We also are characterizing this increase as an adjustment because it is based on the increase in the number of requests received by FDA.

For IC#2, we estimate that the number of respondents will increase from 88 to 125, causing the annual number of responses to increase from 88 to 125 (an increase of 37) and the annual hour burden to increase from 88 to 125 hours (an increase of 37). We also are characterizing this increase as an adjustment because it is based on the increase in the number of updates received by FDA.

For IC#3, we estimate that the number of respondents will increase from 25 to 50, causing the annual number of responses to increase from 25 to 50 (an increase of 25) and the annual hour burden to increase from 13 to 25 hours (an increase of 12). We also are characterizing this increase as an adjustment because it is based on the increase in the number of occasional updates received by FDA.

Table 2—Summary of Change in Responses and Hour Burden

IC Number	Change in Responses	Change in Hour Burden
IC#1	+75	+113
IC#2	+37	+37
IC#3	+25	+12
Total Change	+137	+162

16. Plans for Tabulation and Publication and Project Time Schedule

We publish the lists on our website and share the information with Chile and China, which may post some or all of the information on their websites.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.