Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile

0910-0509

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

As a direct result of discussions that have been adjunct to the United States-Chile Free Trade Agreement, Chile has recognized FDA as the competent U.S. food safety authority and has accepted the U.S. regulatory system for dairy inspections. Chile has concluded that it will not require individual inspections of U.S. firms by Chile as a prerequisite for trade, but will accept firms identified by FDA as eligible to export to Chile. Therefore, in the Federal Register of June 22, 2005 (70 FR 36190), FDA 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.

The guidance document is 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 document explains that FDA has established a list that is provided to the government of Chile and posted at http://www.fda.gov/Food/InternationalActivities/Exports/ucm120245.htm, which identifies U.S. dairy product manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. The term "dairy products," for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. Application for inclusion on the list is voluntary. However, Chile has advised that dairy products from firms not on 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 website 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 this 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 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. FDA requests that this information be updated every 2 years. FDA shares this information with Chile pursuant to 21 CFR 20.89, under our authority to share with foreign government officials, among other types of information, investigatory records compiled for law enforcement purposes as well as any information voluntarily submitted to FDA.

FDA requests the extension of OMB approval of the information collection provisions of the guidance document entitled, "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile."

2. Purpose and Use of the Information Collection

FDA uses the information submitted by firms to determine their eligibility for placement on the list, which is published on the agency's website. The purpose of the list is to assist the government of Chile in its determination of which U.S. dairy product manufacturers are eligible to export to Chile.

Description of Respondents: Respondents to this information collection include U.S. dairy product manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile. Respondents are from the private sector (for profit businesses).

3. Use of Improved Information Technology and Burden Reduction

FDA continually seeks 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. FDA estimates 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

The information collection is a unique collection for the purpose of assisting the government of Chile in its determination of which U.S. dairy product manufacturers are eligible to export to Chile. This was one of several agricultural trade issues whose resolution was tied to the United States – Chile Free Trade Agreement. Some, but not all, of the necessary 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 government of Chile. These lists are product specific and may not include the products that the firms intend to export to Chile. 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). Approximately 60 firms were not listed on the IMS list and the USDA list.

In addition, documentation requirements require a unique collection of information. FDA believes 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

FDA estimates 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. FDA aids small businesses through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has 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

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, FDA requests that firms update their information biennially. If the information collection is not conducted, Chile has advised that dairy products from firms not on this list could be delayed or prevented by Chilean authorities from entering commerce in Chile.

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 November 15, 2012 (77 FR 68128). No comments were received.

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

As noted in the guidance, FDA considers the information contained in the List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile, which is given voluntarily with the understanding that it will be posted on FDA's website and communicated to Chile, to be information that is not protected from disclosure under 5 U.S.C. § 552(b)(4). The guidance explains how FDA intends to communicate any new information to Chile and what information FDA intends to post on its website. The information posted on the FDA website and the information shared with Chile, some or all of which may be posted on Chile's website, includes the plant numbers; names, telephone numbers, and e-mail addresses of the contact persons; and lists of products being exported to Chile, in addition to the names and addresses of the firms' manufacturing and processing plants.

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. dairy product manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile. 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	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 total estimated hour burden associated with this collection is 139 hours annually. 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 FDA's experience maintaining the list over the past 3 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.

To date, over 175 producers have sought to be included on the list. FDA estimates that, each year, approximately 25 new firms will apply to be added to the list. 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 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 (175 firms x 0.5 = 87.5, rounded to 88 firms), will resubmit the information to remain on the list. We estimate that a firm already on the list will require 1.0 hours to biennially 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.

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $10,639.06. 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 2013, which is $38.27 per hour. To account for overhead, this cost is increased by 100 percent, which is $76.54 per hour. Thus, the annual wage cost for completion and submission of these requests and updates is approximately $10,639.06 (139 hours x $76.54 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

The annualized cost to the Federal government for the review and evaluation of requests and updates submitted by U.S. dairy product manufacturers is approximately $2,965.93. FDA bases its estimate on the salary of one full-time employee at GS-12, Step 3, in the Washington-Baltimore Locality Pay Area for the year 2013, who spends an estimated 77.5 hours (77.5 hours x $38.27/hour

= $2,965.93).

15. Explanation for Program Changes or Adjustments

The burden has increased from 124 hours to 139 hours. This adjustment is a result of an increase in the estimated number of new firms that will apply to be added to the list, from 15 to 25 respondents.

Table 2—Summary of Change in Responses and Hour Burden		
IC Number	Change in Responses	Change in Hour Burden
IC#1	+10	+15
Total Change	+10	+15

16. Plans for Tabulation and Publication and Project Time Schedule

FDA publishes the List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile on its website and shares the information with Chile, which may post some or all of the information on its website.

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.