United States Food and Drug Administration

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

0910-0509

SUPPORTING STATEMENT

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 https://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, under a different OMB Control Number (OMB Control No. 0910-0839), 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.

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.

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 the European Union 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 the European Union 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 the European Union with their requests. These lists are product specific and may not include the products that the firms intend to export to Chile or the European Union. 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 the European Union 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 June 15, 2017 (82 FR 27485). FDA received 3 comments from one commenter which were not related to the PRA and will not be addressed here.

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 the European Union, 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

    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	2,000	1	2,000	1	2,000
Biennial update	2,000	1	2,000	0.5 (30 minutes)	1,000

Occasional updates	200	1	200	0.5 (30 minutes)	100
Total					3,100

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

FDA bases its estimate of the number of manufacturers/processors that have submitted new written requests to be placed on the list, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours that it will take a manufacturer/processor to gather the information needed to be placed on the list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to the manufacturers/processors. This collection is also incorporating information collected to maintain lists of eligible exporters of dairy products who export to the European Union from OMB control number 0910-0320, "Request for Information from U.S. Processors that Export to the European Community."

FDA estimates that 2,000 firms will average 1 hour to submit new requests for inclusion on the list, 2,000 firms will average 30 minutes to update their information every two years, and 200 firms will average 30 minutes to occasionally update their information in this system. FDA also believes that submission via the electronic registry will not affect the burden estimates. The electronic registry will enhance the ability of firms to more efficiently request inclusion on exports lists. FDA calculates, therefore, that the total burden for this collection is 3,100 hours ((2,000 x 1) plus (2,000 x 0.5) plus (200 x 0.5)).

12b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $252,650.00. 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 2017, which is $40.75 per hour. To account for overhead, this cost is increased by 100 percent, which is $81.50 per hour. Thus, the annual wage cost for completion and submission of these requests and updates is approximately $252,650 (3,100 hours x $81.50 per hour).

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Processing of new requests, biennial updates, and occasional updates.	3,100	$81.50	$252,650
Total			$252,650

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 $6,316.25. 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 2017, which is $40.75 per hour. To account for overhead, this cost is increased by 100 percent, which is $81.50 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 $6,316.25 (77.5 hours x $81.50/hour).

15. Explanation for Program Changes or Adjustments

The information collection reflects agency adjustments. The total annual number of responses and the total annual hour burden are expected to increase over the next three years. The total annual number of responses increased from 125 to 2,000 (an increase of 1,875 responses) and the total annual hour burden has increased from 338 to 3,100 hours (an increase of 2,762 hours). The increase is due to industry growth resulting in an increased number of respondents and additional total hours to complete reporting for these respondents.

FDA expects an increase in the number of respondents for both new requests to be placed on the export lists and biennial updates, from 125 to 2,000 respondents. The number of responses per respondent is expected to remain constant at 1, and the average burden per response is expected to decrease by one half hour for both new requests (from 1.5 to 1 hour) and biennial updates (from 1 hour to a half hour). The total number of hours, however, is expected to increase from 313 to 3,000, due primarily to expected increases expected using FDA's relatively new electronic Dairy Labeling Module System (DLM) for respondent reporting. With the increase in respondents for the collection, the number of occasional updates is also expected to increase from 25 to 100. These increases are expected primarily because of the use of FDA's relatively new Dairy Labeling Module electronic reporting system, which makes it much easier for respondents to request to be placed on the dairy export lists, update their existing records, or occasionally update other information for this collection of information. Increases are also expected because this collection is now incorporating information previously collected from manufacturers/producers who submitted information to maintain lists of eligible exporters of dairy products who export to the European Union under OMB control

number 0910-0320, “Request for Information from U.S. Processors that Export to the European Community.”

16. Plans for Tabulation and Publication and Project Time Schedule

We publish the lists on our website and share the information with Chile and the European Union, 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.