SUPPORTING STATEMENT

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

OMB No. 0910-0509

A. JUSTIFICATION

1. Necessity of the Information Collection

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.cfsan.fda.gov/guidance.html. The guidance document explains that FDA has established a list that is provided to the government of Chile and posted on FDA's Internet site, 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 document is published under the authority of Section 701(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(h)) (Attachment A), 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.

2. How, by Whom, and for What Purpose Information is Used

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. 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 Internet site 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 (Attachment B), 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 the FDA.

3. Use of Improved Information Technology

The FDA continually seeks ways to reduce reporting burden. Presently, the U.S. firms may submit information by letter, facsimile, diskette, or electronic e-mail.

4. Identification of Duplication and Similar Information Already Available

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. Small Business

This information collection may include 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. CFSAN aids small businesses in complying with its requirements through its administrative and scientific staffs.

6. Consequences if Data Were Collected Less Frequently

The data in original submissions are submitted only once and therefore cannot be collected less frequently. A business may be required to submit updates if the submitted information changes.

7. Special Circumstances

There are no special circumstances involving this information collection.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), on July 31, 2006 (71 FR 43202), a 60-day notice for public comment was published in the Federal Register. No comments were received.

9. Gifts

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

As noted in the guidance, FDA considers the information on 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 Internet site 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. The other information requested will assist FDA in maintaining the list.

11. Sensitive Information

This information collection does not involve any questions of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Cost Estimates

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

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

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
New written requests to be placed on the list	15	1	15	1.5	23
Biennial update	55	1	55	1.0	55.0
Occasional updates	25	1	25	0.5	13
Total					91

[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 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 110 producers have sought to be included on the list. FDA estimates that, each year, approximately 15 new firms will apply to be added to the list. We estimate that a firm will require 1.5 hours to read the guidance, 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. 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, 55 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. 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.

Estimated Annualized Cost for Burden Hours

The total estimated annualized hour burden cost for this collection is $2,970. FDA estimates that new written requests to be placed on the list, biennial updates and occasional updates will be prepared by an employee making $33/hour or ($33/hr x 90 total hours = $2,970).

13. Annual Cost Burden to Respondent

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The annualized cost to the Federal government for the review and evaluation of letters submitted by U.S. dairy product manufacturers is $2,577. This is based on the salary of one (1) full-time employee (FTE) at GS-12, Step 3, in the Washington-Baltimore Locality Pay Area, who spends an estimated 77.5 hours (77.5 hours x $33.25/hour = $2,576.88).

15. Changes or Adjustments in Burden

The decrease in burden is due to the decrease in the number of U.S. firms that submitted new requests to be placed on the list.

16. Statistical Analysis, Publication Plans, and Schedule

Not applicable.

17. Approval Not to Display Expiration Date

N/A

18. Exceptions to the Certification Statement Identified in Item 19

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.