

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.23	25	1	25	0.25	6.25
515.30(c)	0.15	1	0.15	24	3.60
Total Burden Hours					36.6

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	1,160	1	1,160	0.03	34.80

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

The estimated number of respondents is derived from agency data on the number of medicated feed manufacturers entering the market each year, changing ownership or address, requesting voluntary revocation of a medicated feed mill license, and those involved in revocation and/or suspension of a license. The estimate of the time required for this reporting requirement is based on the agency communication with industry.

Dated: May 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0180]

Guidance for Industry and FDA; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile; Availability and a Request for Information From Such Manufacturers/Processors

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry and FDA; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile." This guidance explains that FDA intends to establish and maintain a list, which will be sent to Chile and posted

on FDA's Internet site, identifying the names and addresses of U.S. manufacturers 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., injunction or seizure) or an unresolved warning letter.

DATES: This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit electronic or written information for inclusion on the Chilean dairy list to Esther Z. Lazar, Center for Food Safety and Applied Nutrition (HFS-306) (*see FOR FURTHER INFORMATION CONTACT*). Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Submit written comments on the guidance document or the collection of information to the Dockets Management Branch (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. Submit electronic comments on the guidance document or the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. *See the SUPPLEMENTARY INFORMATION* section for electronic access to this guidance document.

Submit written requests for single copies of this guidance to the Office of Plant and Dairy Foods and Beverages, Division of Dairy and Egg Safety, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT:

Esther Z. Lazar, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1485, or e-mail: elazar@cfstan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

As a direct result of trade 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, FDA intends to establish and maintain a list, which will be sent to Chile and posted on FDA's Internet site, identifying the names and addresses of U.S. dairy product manufacturers/processors that have expressed to FDA their interest 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 an unresolved warning letter. The term "dairy products," for purposes of this list, is not intended to cover the raw agricultural commodity raw milk.

II. Discussion

The guidance document states that FDA intends to establish and maintain a list identifying U.S. 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