entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents. Disclaimer entries are not FDA commodities.

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

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801 for FY 2002 Updated	3,406	652	2,955,595	.14	413,833

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

Dated: May 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12921 Filed 5–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0198]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information for medicated feed mill licensing requirements.

DATES: Submit written or electronic comments on the collection of information by July 22, 2003.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. Submit written comments on 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.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medicated Feed Mill License Application—21 CFR Part 515 (OMB Control Number 0910–0337)—Extension

In the **Federal Register** of November 19, 1999 (64 FR 63195), FDA published a final rule implementing the feed mill licensing provisions of the Animal Drug Availability Act (the ADAA) of 1966 (Public Law 104–250). The rule added a new part 515 to title 21 CFR to provide the requirements for medicated feed mill licensing.

The rule set forth the information to be included in medicated feed mill license applications and supplemental applications. Also, it set forth criteria for, among other things, the approval and refusal to approve a medicated feed mill license application, as well as the criteria for the revocation and/or suspension of a license.

Respondents to this collection of information are individuals or firms that manufacture medicated animal feed.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10(b)	7	1	7	0.25	1.75
515.11(b)	100	1	100	0.25	25.00

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—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 BURDEN [1]

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.

[FR Doc. 03–12922 Filed 5–22–03; 8:45 am]

BILLING CODE 4160–01–S

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@cfsan.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