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

injunction or seizure) or an unresolved warning letter. Inclusion of U.S. dairy product manufacturers/processors on this list is voluntary. However, dairy products from firms not on this list could be refused entry at the Chilean port of entry. 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 will consider the information on this list, which 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).

This guidance represents the agency's current thinking on the procedures for assisting Chile in determining which U.S. manufacturers or processors are eligible to export dairy products to Chile. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This guidance document is being issued as a level 1 guidance consistent with FDA's good guidance practices (GGPs) regulation (§ 10.115 (21 CFR 10.115)). Consistent with GGPs, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. The guidance document presents a less burdensome policy that is consistent with the public health.

III. Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

The Office of Management and Budget (OMB) has approved this collection of information under the emergency processing provision of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j) and 5 CFR 1320.13) and has assigned OMB control number 0910–0509. As discussed in the **Federal Register** of April 10, 2003 (68 FR 17655), public reporting burden for this collection of information is estimated to be 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

V. Electronic Access

Interested persons also may access the guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: May 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12975 Filed 5–22–03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

List of Foreign Entities Violating Textile Transshipment and Country of Origin Rules

AGENCY: Bureau of Customs and Border Protection, Homeland Security.

ACTION: General notice.

SUMMARY: This document notifies the public of foreign entities which have been issued a penalty claim under section 592 of the Tariff Act of 1930, for certain violations of the customs laws. This list is authorized to be published by section 333 of the Uruguay Round Agreements Act.

DATES: This document notifies the public of the semiannual list for the 6-month period starting March 31, 2003, and ending September 30, 2003.

FOR FURTHER INFORMATION CONTACT: For information regarding any of the operational aspects, contact Gregory Olavsky, Fines, Penalties and Forfeitures Branch, Office of Field Operations, (202) 927–3119. For information regarding any of the legal aspects, contact Willem A. Daman, Office of Chief Counsel, (202) 927–6900.

SUPPLEMENTARY INFORMATION:

Background

Section 333 of the Uruguay Round Agreements Act (URAA) (Pub. L. 103–465, 108 Stat. 4809)(signed December 8, 1994), entitled Textile Transshipments, amended Part V of title IV of the Tariff Act of 1930 by creating a section 592A (19 U.S.C. 1592a), which authorizes the Secretary of the Treasury (and this authority has been delegated to the Secretary of Homeland Security and to the Commissioner of the Bureau of Customs and Border Protection) to publish in the **Federal Register**, on a semiannual basis, a list of the names of any producers, manufacturers, suppliers, sellers, exporters, or other persons located outside the Customs territory of the United States, when these entities and/or persons have been issued a penalty claim under section 592 of the Tariff Act, for certain violations of the customs laws, provided that certain conditions are satisfied.

The violations of the customs laws referred to above are the following: (1) Using documentation, or providing documentation subsequently used by the importer of record, which indicates a false or fraudulent country of origin or source of textile or apparel products; (2) Using counterfeit visas, licenses, permits, bills of lading, or similar documentation, or providing counterfeit visas, licenses, permits, bills of lading, or similar documentation that is subsequently used by the importer of record, with respect to the entry into the Customs territory of the United States of textile or apparel products; (3) Manufacturing, producing, supplying, or selling textile or apparel products which are falsely or fraudulently labeled as to country of origin or source and (4) Engaging in practices which aid or abet the transshipment, through a country other than the country of origin, of textile or apparel products in a manner which conceals the true origin of the textile or apparel products or permits the evasion of quotas on, or voluntary restraint agreements with respect to imports of textile or apparel products.

If a penalty claim has been issued with respect to any of the above violations, and no petition in response to the claim has been filed, the name of the party to whom the penalty claim was issued will appear on the list. If a petition or supplemental petition for relief from the penalty claim is submitted under 19 U.S.C. 1618, in accord with the time periods established by sections 171.2 and 171.61, Customs Regulations (19 CFR 171.2, 171.61) and the petition is subsequently denied or the penalty is mitigated, and no further petition, if allowed, is received within 60 days of the denial or allowance of mitigation, then the administrative action shall be deemed to be final and administrative remedies will be deemed to be exhausted. Consequently, the