

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0180]

### **Guidance for Industry and Food and Drug Administration: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA or agency) is announcing the availability of a revised guidance 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.” The guidance 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 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 (e.g., injunction or seizure) or a pending warning letter. 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 revised guidance document describes the recommended process for U.S. manufacturers to follow to be included on the list and explains FDA’s request, on Chile’s behalf, that this information be updated every 2 years.

**DATES:** This revised guidance is final upon the date of publication. Submit written or electronic comments on the revised guidance document at any time.

**ADDRESSES:** Submit written requests for single copies of the revised guidance document to the Office of Plant and Dairy Foods and Beverages, Division of Dairy and Egg Safety (HFS-306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent.

Submit written comments on the revised guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised guidance document.

**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](mailto:elazar@cfstan.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

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, FDA has established

a list, which is provided to the government of Chile and posted on FDA's Internet site, identifying 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 a pending 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 revised guidance document states that FDA has established 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 a pending warning letter. Inclusion of U.S. dairy product manufacturers/processors on this list is voluntary. However, Chile has advised that dairy products from firms not on this list could be refused entry at the Chilean port of entry. The revised 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 revised 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).

This is a revision of the guidance that FDA issued in May 2003 (68 FR 28237, May 23, 2003). This revised guidance adds to the information that FDA intends to post on its Web site and share with Chile, and it explains the actions that FDA intends to take to update the list every 2 years.

FDA is issuing this revised guidance as a level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the revised guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. This revised guidance represents the agency's current thinking on how FDA intends to comply with Chile's request for a list of U.S. manufacturers or processors that 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.

### **III. Paperwork Reduction Act of 1995**

This revised final guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0509. The approval expires on December 31, 2006. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

### **IV. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this revised 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 revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Persons with access to the Internet may obtain the revised guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: June 13, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**