Contains Nonbinding Recommendations

Guidance for Industry

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

Additional copies are available from:
Office of Food Safety
Division of Dairy and Egg Safety HFS-306
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-1485
http://www.fda.gov/FoodGuidances

You may submit written comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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*See additional PRA statements in Section IV of this guidance

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance document is being published to notify the public of FDA's efforts to assist U.S. firms that wish to export dairy products to China. FDA took this action in response to China's State General Administration of the People's Republic of China for Quality Supervision and Inspection and Quarantine (AQSIQ) issuance of Administrative Measures for Registration of Overseas Manufacturers, known as AQSIQ Decree 145. AQSIQ Decree 145, among other requirements, mandates that foreign competent authorities including FDA provide the Certification and Accreditation Administration of China (CNCA) with a "name list of overseas manufacturers of imported food applying for registration" with CNCA for commodities that CNCA has deemed to require registration. Subsequently, CNCA has added milk products to the commodities requiring registration of overseas manufacturers under Decree 145. China has recognized FDA as the competent food safety authority in the United States to establish and maintain the list of U.S. milk product manufacturers and processors eligible to export to China. The list identifies U.S. firms that have expressed interest to FDA in exporting milk products to China, that are subject to FDA jurisdiction, and that are not the subject of a pending judicial enforcement action (e.g., an injunction or seizure) or a pending warning letter. The List of U.S. Milk Product Manufacturers/Processors with Interest in Exporting to China established by FDA is posted on FDA's Internet site and shared with China's CNCA. FDA intends to contact the U.S. firms that are on the list every two years to verify that the information they have provided to FDA is still valid. FDA intends to report this updated list to China on a quarterly basis.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

[1] This guidance has been prepared by the Division of Dairy and Egg Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Discussion

A. Establishment of a List of U.S. Dairy Product Manufacturers/Processors

FDA is establishing a list identifying U.S. firms that have expressed to FDA their interest in exporting milk products to China, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (e.g., an injunction or seizure) or a pending warning letter. The list is sent to responsible authorities in China, and is posted on FDA's Internet site at: [INSERT URL]. FDA is establishing the list so that it will include the plant numbers, and the names and addresses of the firms' manufacturing and processing plants. Application for inclusion on this list is voluntary. However, China has advised that milk products from firms not on this list could be prevented by Chinese authorities from entering commerce in China. The term "milk products" for purposes of this list is not intended to cover the raw agricultural commodity raw milk. The term “milk product” is defined in 21 CFR 1240.3(j).

FDA has requested that U.S. dairy product manufacturers and processors provide certain information, as discussed below, if they currently export, or intend in the future to export, their milk products to China and wish to be included on the list. FDA is asking that this information be updated every two years in order to maintain the accuracy of the list. In order to either update the information included on the list or to be initially included on the list, the following information should be submitted to Ms. Esther Lazar, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, or e-mail Esther.Lazar@fda.hhs.gov:

1. Business name and address;
2. Name, telephone number, and e-mail (if available) of contact person;
3. List of products presently shipped to China and those intended to be shipped;
4. Name and address of the manufacturing plant for each product;
5. Name of any Federal, State, or local governmental agencies that inspect the plant, along with the government assigned plant identifier (e.g., plant number) and date of last inspection; and
6. Copy of last inspection notice and, if other than an FDA inspection, copy of last inspection report.

The list on FDA's Internet site and the information shared with China, some or all of which may be posted on China's website, includes the plant numbers; and the names and addresses of the firms' manufacturing and processing plants. The other information identified above for submission to FDA is intended to assist FDA in establishing and maintaining the list. FDA considers the information on this list, which is provided voluntarily with the understanding that it

will be communicated to China and posted on the Internet, to be information that is not protected from disclosure under 5 U.S.C. § 552(b)(4).

B. Inclusion on the List

For each manufacturer or processor that submits an application, FDA intends to review the applicant's recent inspection history, including FDA or other Federal or State agency inspections. FDA intends to place the names and addresses of firms that are not the subject of a pending judicial enforcement action (e.g., injunction or seizure) or a pending warning letter on the list. Firms must have a FDA inspection within 3 years or be on the Interstate Milk Shippers List and/or be on the U.S. Department of Agriculture (USDA) list, Dairy Plants Surveyed and Approved for USDA Grading Service for the products intended to ship. FDA intends to deny listing a firm if the firm is the subject of a pending judicial enforcement action or a pending warning letter or does not have one of the above mentioned inspection requirements.

FDA intends to send a confirmation e-mail or letter to the applicants to notify them of FDA's decision with respect to their eligibility or ineligibility for inclusion on the list. Every two years, FDA also intends to send a letter to manufacturers that are currently listed, requesting that they update the information they initially provided and indicate whether they wish to continue being listed.

C. Updating the List

FDA intends to provide Chinese authorities with an updated list of firms on a quarter annual basis. The quarterly update will list any additional firms that have applied to FDA within the previous three-month period and have been determined by FDA to meet the criteria for inclusion on the list. FDA also intends to delete from the list on a quarter annual basis those firms that FDA has determined (either by notice from the firm or by FDA inspection) have gone out of business or have indicated to FDA in writing that they no longer intend to export milk products to China. FDA also intends to remove from the list any firms that do not respond to FDA's request every two years for updated information. The quarter annual update schedule along with the two-year request for updated information is intended to provide FDA and milk product manufacturers/processors with a structured and predictable schedule for updating the list and to provide the agency with sufficient time to determine the eligibility or ineligibility of firms applying for placement on the list.

If a listed firm subsequently becomes the subject of a pending judicial enforcement action or a pending warning letter, FDA intends to remove that firm from the list posted on the Internet and to send a revised list to Chinese authorities as soon as possible after the firm becomes the subject of the pending judicial enforcement action or pending warning letter, usually within 48-72 hours after the relevant FDA action. Since a pending judicial enforcement action or a pending warning letter, if associated with a food safety concern, necessitates a more expedient process to protect public health, FDA intends to remove such a firm from the list as soon as possible, rather than to wait for the quarter annual update described above.

FDA intends for each issuance of the list, whether issued as a result of a scheduled quarter annual update or as a result of removal of a firm due to a pending judicial enforcement action or a pending warning letter, to be dated to indicate the date of the most recent update.

IV. Paperwork Reduction Act of 1995

This guidance contains information collections 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 time required to complete this information collection is estimated to average 90 minutes per initial request for inclusion on the list, 60 minutes per biennial update and 30 minutes per occasional update, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Department of Health and Human Services,
Food and Drug Administration,
Office of Chief Information Officer,
1350 Piccard Drive, Room 400,
Rockville, MD 20850.
(Please do NOT submit to this address your request for inclusion on the list or any updates to your firm's information. See section II.A. of the guidance.)

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. The OMB control number for this information collection is 0910-0509 (Expires 05/31/2016).