Guidance for Industry and FDA: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile and the European Union

Contains Nonbinding Recommendations

May 2003; Revised September 18, 2017

GUIDANCE

Comments and suggestions regarding this document may be submitted at any time. Submit comments to 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 Docket Number 2014-N-0192 as listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact Ms. Esther Lazar at the Center for Food Safety and Applied Nutrition (CFSAN) at (Tel) 240-402-1485), (Fax) 301-436-2632, or e-mail **Esther.Lazar@fda.hhs.gov (mail-to:Esther.Lazar@fda.hhs.gov)**.

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

Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile and the European Union

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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 appropriate 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 Chile and the European Union. FDA is taking this action in response to the import requirements of these countries. FDA will establish and maintain lists of U.S. manufacturers/processors with interest in exporting to these countries, 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.

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

This is a revision of the guidance, which FDA first issued in May 2003.

II. DISCUSSION

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

FDA is establishing and maintaining lists identifying U.S. dairy establishments that:

1. Have expressed to FDA their interest in exporting dairy products to one of these countries; and

2. Are subject to the jurisdiction of the Federal Food, Drug, and Cosmetic Act and relevant FDA regulations, have been found by FDA to be in good regulatory standing with FDA, and have, during the most recent facility inspection, been found to be in substantial compliance with all applicable FDA regulations, including, but not limited to, current good manufacturing practice requirements for the identified products for export.

FDA provides the following guidance regarding the criteria FDA will evaluate in determining whether to add establishments to the applicable list of establishments.

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 dairy products to Chile or the European Union and wish to be included on the list.

To either update the information included on these lists or to be initially included on these lists, the following information should be submitted through the FDA Unified Registration and Listing Systems (FURLS) Dairy Listing Module (DLM) found at https://www.access.fda.gov:

1. Parent company name and address – the parent company name and physical address of the requesting establishment;
2. Name and address to be listed – the name and physical address that will be provided to the importing country (if different from the parent company name and address, this information must be part of a food facility's registration information);
3. Contact information – the name, mailing address, email, telephone number, and fax number (if available) of the designated contact person for the requesting establishment;
4. Food Establishment Identifier (FEI), Food Facility Registration (FFR) numbers and establishment type, or other government-assigned plant identifier (if applicable);
5. List of products – a list of products the establishment intends to export and/or currently exports;
6. Name of any governmental agencies that inspect the plant, date of last inspection, copy of last inspection notice, and, if other than an FDA inspection, copy of last inspection report; and
7. A written statement acknowledging that the firm or individual(s) representing the firm submitting the request to the FDA realize that they are subject to the provisions of Title 18 of the United States Code, Section 1001, which states that it is a criminal offense to knowingly and willfully make false statements of material fact to a United States government official in the performance of the official's duties.

The information identified above for submission to FDA is intended to assist FDA in establishing and maintaining the lists. For each list, FDA intends to provide the importing country authorities with the names and addresses of establishment that have applied and are eligible to be listed and products manufactured by those establishments intended for export. FDA considers the information on this list, which is provided voluntarily with the understanding that it will be communicated to importing country authorities 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 Lists

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 lists. FDA intends to deny listing a firm if the firm is the subject of a pending judicial enforcement action or a pending warning letter.

Application for inclusion on these lists is voluntary. However, officials from Chile and the European Union have advised that dairy products from firms not on these lists could be prevented by importing country authorities from entering commerce.

FDA intends to send a confirmation e-mail to the applicants to notify them of FDA's decision with respect to their eligibility or ineligibility for inclusion on the lists. Every two years, FDA also intends to contact 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 Lists

FDA intends to provide Chilean and European Union authorities with an updated list of firms four times a year. The quarterly updates 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 lists. FDA also intends to delete from the lists on a quarterly 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 dairy products to these countries. FDA also intends to remove from the lists any firms that do not respond to FDA's request every two years for updated information. The quarterly update schedule

along with the two-year request for updated information is intended to provide FDA and dairy 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 lists.

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 lists and to send a revised list to the relevant importing country 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 lists as soon as possible, rather than to wait for the quarterly update described above.

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

The above document supersedes the previous versions of this guidance document.

Current List Of U.S. Dairy Product Manufacturers/Processors With Interest In Exporting To Chile and the European Union. (/Food/GuidanceRegulation/ImportsExports/Export- ing/ucm120245.htm)
(Updated quarterly.)

More in Guidance Documents & Regulatory Information by Topic (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm)

Acidified and Low-Acid Canned Foods (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/default.htm)

Allergens (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/default.htm)

Biotechnology (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/default.htm)

Bottled Water & Carbonated Soft Drinks (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/BottledWaterCarbonatedSoftDrinks/default.h

Chemical Contaminants, Metals, Natural Toxins & Pesticides (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxins

Dietary Supplements (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/default.htm)

Eggs (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Eggs/default.htm)

Emergency Response (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/EmergencyResponse/default.htm)

Food Defense (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/default.htm)

Imports & Exports (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/default.htm)

Infant Formula (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/default.htm)

Ingredients, Additives, GRAS & Packaging (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/default.htm)

Juice (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/default.htm)

Labeling & Nutrition (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm)

Medical Foods (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/default.htm)

Milk (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/default.htm)

Produce & Plant Products (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/default.htm)

Reportable Food Registry (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/RFR/default.htm)

Retail Food Protection (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/RetailFoodProtection/default.htm)

Salmonella (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Salmonella/default.htm)

Sanitation & Transportation (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/default.htm)

Seafood (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/default.htm)

Small Businesses/Small Entity Compliance Guides (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SmallBusiness/default.htm)