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

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You may submit written comments regarding this guidance at any time. Submit written comments on the guidance to Dockets Management Staff (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 III of this guidance

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Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile: Guidance for Industry and FDA [1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance document is being published to notify the public of FDA's efforts to assist U.S. manufacturers/processors (hereinafter referred to as "firms") that wish to export dairy products to Chile. FDA took this action in response to discussions with Chile that were adjunct to the negotiations of the United States-Chile Free Trade Agreement. As a result of those discussions, Chile recognized FDA as the competent food safety authority in the United States to identify U.S. dairy product manufacturers and processors eligible to export to Chile and concluded that it will not conduct individual inspections of U.S. firms identified on a list established by the FDA as eligible to export to Chile. The list identifies U.S. firms that have expressed interest to FDA in exporting dairy products to Chile, 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. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile established by FDA is posted on FDA's Internet site and shared with Chile. Every two years, Chile passes an authorizing resolution accepting this list and provides the list to their ports of entry to facilitate the importation of U.S. dairy products. Chile has requested that this list be updated every two years at the expiration of the current authorizing resolution. Therefore, 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 Chile so that Chile can reauthorize its resolution for another two-year period.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be

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

viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

This is a revision of the second edition of this guidance, which FDA issued in June 2005. This guidance revises the procedures firms should use to be included on FDA's list of dairy exporters to Chile.

II. Discussion

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

FDA has established and is maintaining a list identifying U.S. firms 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 (e.g., an injunction or seizure) or a pending warning letter. The list is sent to responsible authorities in Chile, and is posted on FDA's Internet site at: https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm120245.htm. Subsequent to the publication of the second edition of the guidance, FDA launched an electronic system for receiving and processing requests for inclusion on this list. Consequently, FDA is revising the guidance to explain how firms should request to be listed and how to update current listing information. Application for inclusion on this list is voluntary. However, Chile has advised that dairy products from firms not on this list could be prevented by Chilean authorities from entering commerce in Chile. The term "dairy products" for purposes of this list is not intended to cover the raw agricultural commodity raw milk.

FDA requests that all firms wishing to be included on the Chile dairy export list or to update their listing information indicate their interest by submitting an application to be listed via the FDA Unified Registration and Listing Systems (FURLS) Export Listing Module (ELM) found at https://www.access.fda.gov/. The ELM facilitates the collection of firm and product information that FDA will use to determine eligibility for placement on the export lists. Respondents who need help completing applications online or who need to submit applications through other means may contact the Center for Food Safety and Applied Nutrition (CFSAN) directly by mail using the address on the cover page of this guidance, by email (CFSANExportCertification@fda.hhs.gov) or telephone (240-402-2307).

The list on FDA's Internet site and the information shared with Chile, some or all of which may be posted on Chile's website, includes the plant numbers; names, telephone numbers, and e-mail addresses of the contact persons; and lists of products being exported to Chile, in addition to the names and addresses of the firms' manufacturing and processing plants. The information identified above for submission to FDA is intended to assist FDA in establishing and maintaining the list. We consider the information on this list, which is provided voluntarily with the understanding that it will be communicated to Chile 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 firm 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. FDA intends to deny listing a firm if the firm is the subject of a pending judicial enforcement action or a pending warning letter.

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 firms 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 Chilean authorities with an updated list of firms on a quarterly 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 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 Chile. 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 quarterly update schedule along with the two-year request for updated information is intended to provide FDA and dairy firms with a structured and predictable schedule for updating the list and to provide FDA 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 Chilean 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 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.

III. 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 60 minutes per response and 30 minutes per update every two years, 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:

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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 11/30/2020).