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Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China: Guidance for Industry

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<http://www.fda.gov/FoodGuidances>*

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 docket number FDA-2016-D-4484 and 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. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China: Guidance for Industry

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 intended to notify the public of FDA's efforts to help U.S. manufacturers/processors (hereinafter referred to as "establishments") that wish to export milk and milk products, seafood, infant formula, and formula for young children to China. FDA is taking 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. Milk and milk products, seafood, infant formula, and formula for young children are among the commodities for which registration of overseas manufacturers is required under AQSIQ Decree 145. China has recognized FDA as the competent food safety authority in the United States to establish and maintain the lists of U.S. establishments that intend to export U.S. milk and milk product, seafood, infant formula, and/or formula for young children to China, and the corresponding products for each establishment intended for export to China.

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This guidance document revises a guidance document issued in June 2017 entitled “Guidance for Industry: Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China.” It revises the procedures establishments should use to be included on FDA’s list of exporters to China for each type of product. This revised guidance document explains how establishments should apply to be included on FDA’s lists of exporters to China, how FDA intends to determine whether the establishment should be recommended for inclusion for specific products, and how FDA intends to update this information.

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 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.

II. Discussion

A. Applications for Inclusion on FDA’s Lists of Establishments Applying to Register with China

For the purpose of identifying U.S. food product establishments wishing to apply to register with China, we are establishing and maintaining lists identifying U.S. milk and milk product, seafood, infant formula, and formula for young children establishments that:

1. Have expressed to FDA their interest in exporting one or more of these types of products to China;
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 to China; and
3. Have been certified by an acknowledged third-party certification body to meet the relevant standards, laws, and regulations of China for the identified food products for export to China.

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

1. Expressing interest in exporting products to China

Establishments wishing to be included on the China export lists or to update their listing information should 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 establishment and product

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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).

a. Milk and milk products

For purposes of this guidance, we consider the terms “milk product” and “milk products” to include any “milk product” as defined in 21 CFR 1240.3(j), or products which are considered milk products under AQSIQ Decree 145.¹ Also note that CNCA requires that U.S. dairy establishments exporting milk products that CNCA considers to be high-risk (pasteurized milk, sterilized milk, modified milk, other disinfection milk, fermented milk, or flavored fermented milk) provide a registration application directly to CNCA.²

b. Infant formula and formula for young children

For purposes of this guidance, the term “infant” refers to persons 0 to 12 months of age,³ and the term “young children” refers to children 12 to 36 months of age.⁴ Note that, depending on the intended use of the product, a formula could satisfy the definition of both infant formula and formula for young children. Also note that CNCA requires that U.S. infant formula and formula for young children establishments provide a registration application directly to CNCA.⁵

2. Evaluating good regulatory standing with FDA, including substantial compliance with applicable FDA regulations

In evaluating good regulatory standing with FDA, we intend to review regulatory information relating to each establishment that has expressed interest in exporting milk and milk products, seafood, infant formula, and/or formula for young children to China. We consider good regulatory standing to mean that the establishment is not the subject of a pending judicial enforcement action (e.g., an injunction or seizure) or a pending administrative action (e.g., warning letter).

¹ For further information about the type of products covered under AQSIQ Decree 145, see http://www.cnca.gov.cn/bsdt/ywzl/jkspjwscpqzc/tzgg/201604/t20160401_50869.html.

² CNCA accepts online applications at <http://cifer.cnca.cn/cifer/>. To facilitate FDA processing of applications that include these products, you may provide a copy of the CIFER application confirmation page via the ELM. Paper applications are available at <http://www.cnca.gov.cn/bsdt/ywzl/jkspjwscpqzc/wjxz/> and may be submitted to CNCA through USDA. Completed paper applications should be sent to DairyExportsQuestions@ams.usda.gov.

³ See “National Standards on Food Safety of P.R. China: National food safety standard, Infant formula,” issued by the Ministry of Health of the People’s Republic of China, March 26, 2010, available at http://www.agrichina.org/admin/kindeditor-4.1.2/attached/file/20131009/20131009171710_2198.doc.

⁴ See “National Standards of People’s Republic of China: National food safety standard, Older infants and young children formula,” issued by the Ministry of Health of the People’s Republic of China, March 26, 2010, available at http://www.agrichina.org/admin/kindeditor-4.1.2/attached/file/20131009/20131009171754_7042.doc.

⁵ CNCA accepts online applications at <http://cifer.cnca.cn/cifer/>. To facilitate FDA processing of applications that include these products, you may provide a copy of the CIFER application confirmation page via the ELM. Paper applications are available at <http://www.cnca.gov.cn/bsdt/ywzl/jkspjwscpqzc/wjxz/> and may be submitted to CNCA through USDA. Completed paper applications should be sent to DairyExportsQuestions@ams.usda.gov.

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Establishments that are in good regulatory standing will be considered for inclusion on the list. FDA intends to deny listing a firm if the firm is not in good regulatory standing.

In evaluating good regulatory standing, we further intend to evaluate each establishment interested in exporting products to China to ensure substantial compliance with applicable FDA regulations. In evaluating substantial compliance with applicable FDA regulations, we intend to ensure that, during the most recent facility inspection by FDA, or by another federal agency, or by state or local government regulatory agency acting under contract with FDA, the firm has been found to be in substantial compliance with all applicable FDA regulations, including, but not limited to, all applicable current good manufacturing practice requirements.

We consider substantial compliance to mean that the most recent inspection identified no significant violations or, if such violations were identified, that the establishment has rectified such violations and provided evidence, to FDA's satisfaction, to prevent the recurrence of any violations. In the alternative, for milk and milk products as defined in 21 CFR 1240.3(j), we consider substantial compliance to include milk and milk product establishments that are on the Interstate Milk Shippers List or the U.S. Department of Agriculture list, Dairy Plants Surveyed and Approved for USDA Grading Service, for the products intended to ship.

Additionally, for establishments that have expressed interest in exporting infant formula products to China that are subject to the requirements in section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), we consider substantial compliance to mean that the establishment has satisfied the requirements for new infant formula registration in accordance with 21 CFR 106.110 and new infant formula submission in accordance with 21 CFR 106.120.

Establishments that are determined to be in substantial compliance with applicable FDA regulations will be considered for inclusion on the list. We intend to deny listing an establishment if the establishment is not in substantial compliance with applicable FDA regulations.

3. Third-party certification

Pursuant to a Memorandum of Understanding between the Food and Drug Administration, Department of Health and Human Services of the United States of America and the Certification and Accreditation Administration of the People's Republic of China regarding Third-Party Certification Procedures under AQSIQ Decree 145, FDA and China have expressed a mutual goal to establish a registration process that provides assurances to CNCA that U.S. food manufacturers subject to AQSIQ Decree 145, and the food products subject to AQSIQ Decree 145 that the manufacturers offer for entry into China, are in compliance with the relevant standards, laws and regulations of China, as specified in AQSIQ Decree 145. To facilitate the goal set forth in the agreement, CNCA has established a list of third-party certification bodies for milk and milk product, seafood, infant formula, and formula for young children establishments for which CNCA intends to accept a facility certification from a third-party certification body regarding an establishment's compliance with the relevant standards, laws and regulations of China. This list is available at

<https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm56336>

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[1.htm](#). Establishments that wish to register with CNCA and be added to FDA's lists of exporters should provide FDA with a copy of this certification from a third-party certification body that has been identified for this purpose. Establishments should submit third-party certification of compliance with Chinese standards, law and regulations via the ELM.

B. Establishing and Maintaining the Lists of Establishments and Products for Which Registration with China Has Been Requested

The information identified above for submission to FDA is intended to help FDA establish and maintain the lists. For each product category, FDA provides China with the names and addresses of establishments that have applied and are eligible to be listed and products manufactured by those establishments intended for export to China. We consider the information on the lists, 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).

Application for inclusion on these lists is voluntary. China has advised that milk and milk products, seafood, infant formula, and formula for young children from establishments not on this list could be prevented by Chinese authorities from entering commerce in China. To the extent we determine that an establishment no longer meets the criteria for inclusion on the list, we intend to notify the establishment of FDA's findings and, as appropriate, FDA's intent to remove the establishment from the FDA list.

FDA intends to send a confirmation e-mail or letter to the applicants to notify them of FDA's decision with respect to whether the firm will be included on the list.

C. Updating the Lists of Establishments and Products for Which Registration with China Has Been Requested

We intend to provide Chinese authorities with updated lists of establishments and products four times per year. The quarterly updates will list any additional establishments that have applied to FDA within the previous three-month period that have been determined by FDA to meet the criteria for inclusion on the lists. We also intend to delete from the list on a quarterly basis those establishments that we have determined (either by notice from the establishment or by FDA inspection) have gone out of business or have indicated to FDA in writing that they no longer intend to export milk and milk products, seafood, infant formula, or formula for young children, generally, or to delete specific products within each category that an establishment indicates it no longer intends to export, to China. Every two years, we intend to send a letter to establishments that are currently listed, requesting that they update the information they initially provided and indicate whether they wish to continue being listed and, if so, if they have any changes to the list of products. We intend to remove from the lists any establishments and their products that do not respond to this request for updated information. The quarterly update schedule along with the two-year request for updated information is intended to provide FDA and milk and milk products, seafood, infant formula, and formula for young children establishments with a structured and predictable schedule for updating the lists and to give FDA sufficient time to determine the eligibility or ineligibility of establishments applying for placement on the lists.

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If, after an establishment is listed, we determine the establishment is no longer in good regulatory standing, we intend to remove that establishment from the list and to send a revised list to Chinese authorities as soon as possible, usually within 48-72 hours after the relevant FDA action or finding. Because a lack of good regulatory standing, if associated with a food safety concern, necessitates a more expedient process to protect public health, we intend to remove such an establishment from the list as soon as possible, rather than to wait for the quarterly update described above.

We intend for each issuance of lists, whether issued as a result of a scheduled quarterly update or as a result of removal of an establishment due to a change in regulatory standing, to be 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 15 minutes per response, 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:

FDA PRA Staff, Office of Operations
Food and Drug Administration
Three White Flint North, 10A-12M
11601 Landsdown St.
North Bethesda, MD 20852
PRStaff@fda.hhs.gov

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 1.101 have been approved under OMB Control No. 0910-0482. The collections of information in 21 CFR parts 106 and 107 have been approved under OMB Control No. 0910-0256. The collections of information in 21 CFR part 123 have been approved under OMB Control No. 0910-0354. The collections of information in 15 CFR part 30 have been approved under OMB Control No. 0607-0152. Other collections of information have been approved under OMB Control No. 0910-0509.

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 0910-0839 (expires 01/31/2021).

IV. References

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We have placed the following references on display in the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of November 13, 2018, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after November 13, 2018.

1. For further information about the type of products covered under AQSIQ Decree 145, see http://www.cnca.gov.cn/bsdt/ywzl/jkspjwscpqzc/tzgg/201604/t20160401_50869.html
2. CNCA registration applications are available online at <http://cifer.cnca.cn/cifer/>. Paper applications are available at <http://www.cnca.gov.cn/bsdt/ywzl/jkspjwscpqzc/wjxz/>.
3. See “National Standards on Food Safety of P.R. China: National food safety standard, Infant formula,” issued by the Ministry of Health of the People’s Republic of China, March 26, 2010, available at http://www.agrichina.org/admin/kindeditor-4.1.2/attached/file/20131009/20131009171710_2198.doc.
4. See “National Standards of People’s Republic of China: National food safety standard, Older infants and young children formula,” issued by the Ministry of Health of the People’s Republic of China, March 26, 2010, available at http://www.agrichina.org/admin/kindeditor-4.1.2/attached/file/20131009/20131009171754_7042.doc.
5. CNCA registration applications are available online at <http://cifer.cnca.cn/cifer/>. Paper applications are available at <http://www.cnca.gov.cn/bsdt/ywzl/jkspjwscpqzc/wjxz/>.