4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0192]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining Lists of United States Manufacturers/Processors with Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products to China

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0839. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products to China--21 U.S.C. 371

OMB Control Number 0910-0839--Extension

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food product that the manufacturer/processor of the food product is in compliance with applicable country of origin regulatory requirements. Some foreign governments establish additional requirements with which exporters are required to comply.

In August 2011, China's State General Administration of the People's Republic of China for Quality Supervision and Inspection and Quarantine (AQSIQ) published the Administrative Measures for Registration of Overseas Manufacturers, known as AQSIQ Decree 145 (https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Registration%20of%20Overseas%20Food%20Manufacturing%20Facilities%20_Beijing_China%20-%20Peoples%20Republic%20of_6-27-2012.pdf), which became effective May 1, 2012. AQSIQ Decree 145, among other requirements, mandates that foreign competent authorities 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 each commodity that

CNCA has deemed to require registration. As of June 2017, milk and milk products, seafood, infant formula, and formula for young children are among the commodities for which CNCA requires registration of overseas manufacturers under AQSIQ Decree 145. CNCA has recognized FDA/CFSAN (Center for Food Safety and Applied Nutrition) as the competent food safety authority in the United States to establish and maintain lists of U.S. establishments that intend to export U.S. milk and milk products, seafood, infant formula, and/or formula for young children to China, including the corresponding products manufactured by each establishment and intended for export to China. To implement AQSIQ Decree 145, FDA and CNCA entered into a Memorandum of Understanding (China MOU) on June 15, 2017, which sets out the two Agencies' intent to facilitate the conditions under which U.S. manufacturers/processors can export to China milk and milk products, seafood, infant formula, and/or formula for young children.

Under the China MOU, FDA intends to establish and maintain lists that identify U.S. manufacturers/processors that have expressed interest to FDA in exporting milk and milk products, seafood, infant formula, and/or formula for young children to China; are subject to our jurisdiction; and have been found by FDA to be in good regulatory standing with FDA, including a finding by FDA that, during the most recent facility inspection, the manufacturers/processors have 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. Further, the China MOU provides for FDA to receive evidence that the manufacturer/processor has been certified by a third-party certification body--as acknowledged by CNCA--to meet the relevant standards, laws, and regulations of China for the identified food products for export to China. On June 28, 2017, FDA issued a guidance document entitled

"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" which can be found at https://www.fda.gov/Food/GuidanceRegulation/default.htm. The guidance informs industry of information that FDA and CNCA will collect to manage the listing of these manufacturers/processors and foods for export to China pursuant to AQSIQ Decree 145 and the China MOU.

In accordance with 5 CFR 1320.13, FDA requested emergency review and approval of the collections of information found in the guidance document. The routine course of approval would have delayed our ability to collect the information from firms and, thus, would have been disruptive in our efforts to facilitate exports of food in compliance with requirements established by China in AQSIQ Decree 145. OMB granted the approval under emergency clearance procedures on June 27, 2017.

FDA uses the information submitted by manufacturers/processors to consider them for inclusion on FDA's lists of eligible manufacturers/processors who may ship food products to China, which we maintain. Updates to the FDA lists are sent to CNCA, which publishes its version of the information in the FDA lists on China's website (http://english.cnca.gov.cn/) on a quarterly basis. The purpose of the lists is to assist China in its determination of which U.S. milk and milk product, seafood, infant formula, or formula for young children manufacturers/processors are eligible to import these products into China under applicable Chinese law. Currently FDA maintains lists for milk and milk product, seafood, infant formula, and formula for young children but FDA wants to be prepared if CNCA requires listing of manufacturers/processors of other CFSAN-regulated products in the future. As such, the

information collection request is not limited to milk and milk product, seafood, infant formula, and formula for young children but also may include other CFSAN-regulated products.

In the *Federal Register* of September 19, 2017 (82 FR 43761), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment was received but was not responsive to the four information collection topics solicited in the notice and therefore is not addressed.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Guidance Recommendations	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
New written requests to be placed on the lists	370	1	370	1	370
Third-party certification	370	1	370	21	7,770
Biennial update	555	1	555	1	555
Third-party certification biennial update	555	1	555	21	11,655
Occasional updates	100	1	100	0.5	50
Total					20,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This is a newly established information collection. Based on our experience maintaining other export lists, we estimate that, annually, an average of 370 new manufacturers/processors will submit written requests to be placed on the China lists. The estimate of the number of hours that it will take a manufacturer/processor to gather the information needed to be placed on a list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily

available to manufacturers/processors. We estimate that a firm will require 1 hour to read the guidance, to gather the information needed, and to prepare a communication to FDA that contains the information needed to request that the manufacturer/processor be placed on a list.

To be placed on a list, manufacturers/processors should provide FDA with evidence that they have obtained third-party certification from a CNCA-acknowledged certifier that the manufacturer/processor complies with the standards, laws and regulations of China according to relevant requirements specified in AQSIQ Decree 145. Based on our experience with other certification programs, FDA estimates that it will take each new manufacturer/processor about 21 hours to complete the third-party certification process for a total of 7,770 burden hours (370 manufacturers/processors x 21 hours).

Under the guidance, every 2 years each manufacturer/processor on the lists must provide updated information to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, or 555 manufacturers/processors (1110 manufacturers/processors x 0.5 = 555), will resubmit the information to remain on the lists. We estimate that a manufacturer/processor already on the lists will require 1 hour to biennially update and resubmit the information to FDA, including time reviewing the information and corresponding with FDA, for a total of 555 hours.

During the biennial update, manufacturers/processors also need to be recertified by a third-party certifier to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, 555 manufacturers/processors (1110 manufacturers/processors x 0.5 = 555), will get recertified. We estimate that it will take each manufacturer/processor about 21 hours to complete the certification process for a total of 11,655 burden hours (555 manufacturers/processors x 21 hours).

FDA expects that, each year, approximately 100 manufacturers/processors will need to submit an occasional update and each manufacturer/processor will require 0.5 hours to prepare a communication to FDA reporting the change, for a total of 50 hours.

Dated: November 29, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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