4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

# Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions found in the guidance 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: Guidance for Industry."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions*: All submissions received must include the Docket No. FDA-2014-N-0192 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products to China." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff Office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made

publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

*Docket*: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before

submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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, 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%2

0Food%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/Center for Food Safety and Applied Nutrition (CFSAN) 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. In order 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: Guidance for Industry" which can be found at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm378777.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 that may ship food products to China, which we maintain. Updates to the FDA lists are sent to CNCA, which publishes quarterly its version of the information in the FDA lists on China's website (http://english.cnca.gov.cn/). 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.

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

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

| Activity | 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.

The burden for this information collection has not changed since the last OMB approval. 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, gather the information needed, and 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 in order to remain on the lists. FDA estimates that each year approximately half of the manufacturers/processors on the lists, or 555 manufacturers/processors (1,110 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 (1,110 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: September 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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