4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4042]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining Lists of U.S. Establishments with Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0509. 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. Establishments with Interest in Exporting CFSAN-Regulated Products

OMB Control Number 0910-0509--Extension

The United States exports a large volume and variety of foods in international trade. Foreign governments often require official certification from the responsible authority of the country of origin about imported foods and establishments involved in their production, storage, or distribution. Some foreign governments establish additional requirements with which exporters are required to comply and ask for additional assurances from the responsible authority. Importing countries may require, and FDA may provide, official certification or assurances for food products in different forms, including certificates that accompany specific products or lists of establishments and products that comply with certain requirements.

To facilitate exports of food subject to importing country listing requirements, FDA has historically provided official certification in the form of country- and product-specific export lists that include establishments and their products when: (1) the establishment has expressed interest in exporting their products to these countries; (2) the establishment and the products are subject to FDA's jurisdiction; and (3) the establishment can demonstrate that it is in good regulatory standing for the products it intends to export and the products are expected to comply with applicable FDA requirements. As we advise in the guidance document "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," (November 2018), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-establishing-and-maintaining-list-us-milk-and-milk-product-seafood-infant-formula, FDA considers "good regulatory standing" as meaning that an establishment is in substantial compliance with applicable FDA requirements and is not the subject of a pending enforcement action (e.g., an injunction or seizure) or pending administrative action (e.g., a warning letter).

FDA has generally published guidance documents for these country- and product-specific lists under the authority of section 701(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)), which authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA. The guidance documents generally explain what information establishments should submit to FDA to be considered for inclusion on the lists and what criteria FDA intends to use to determine eligibility for placement on the lists. The guidance documents also explain how FDA intends to update the lists and communicate any new information to the governments that requested the lists. Finally, the guidance documents note that the information is provided voluntarily by establishments with the understanding that it may be posted on FDA's external website and that it will be communicated to, and possibly further disseminated by, the government that requested the list; thus, FDA considers the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). The guidance documents include "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile" and "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." Additional information about FDA's Food Export Lists program is available at https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists. FDA has also published a guidance document on export certification that contains useful information that applies to export lists entitled, "FDA Export Certification," (August 2021) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certification.

Foreign governments are increasingly relying on certification as a strategy for ensuring the safety of imported food products, and many countries have announced new requirements for lists of establishments and products certified to comply with certain food safety requirements. FDA is committed to facilitating compliance with new listing requirements for U.S.

establishments that export FDA-regulated food products. We also understand that complying with multiple country- and product-specific listing requirements can be burdensome to U.S. establishments. For this reason, we plan to create a new list of establishments and products certified for export that would be offered to importing countries in lieu of country-specific lists.

Application for inclusion on all export lists will continue to be voluntary. However, some foreign governments may require inclusion on export lists as a precondition for market access or to satisfy other importing country registration or approval requirements. FDA uses the Export Listing Module (ELM), an electronic system (Form FDA 3972), to receive and process applications for inclusion on export lists for Center for Food Safety and Applied Nutrition (CFSAN)-regulated products. The ELM allows applicants to provide information about the products intended for export, the establishment that produces those products, evidence of the establishment's compliance with applicable requirements for the products intended for export, and any additional data or information (such as third-party certifications) that foreign governments may require. We request that this information be updated every 2 years. Additional information and screenshots of the ELM are available at https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists. If an establishment is unable to apply via the ELM, it may contact CFSAN and request assistance.

We use the information submitted by establishments to determine eligibility for certification and inclusion on the export lists, which may be published on our website or the websites of foreign governments. The purpose of the lists is to help CFSAN-regulated industries meet the import requirements of foreign governments. This collection of information is intended to cover all of CFSAN's existing export lists, as well as any additional export lists established by the center.

FDA notes that section 801 of the FD&C Act (21 U.S.C. 381) also provides that FDA may charge a fee of up to $175 if the Agency issues an export certification within 20 days of receipt of a complete request for such certification.

Description of Respondents: Respondents to this collection of information include U.S. establishments subject to FDA/CFSAN jurisdiction that wish to be included on export lists.

In the *Federal Register* of January 25, 2022 (87 FR 3814), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received offering general support for the information collection and offered points FDA might consider as it develops and maintains such lists. FDA appreciates this comment and continuously works to provide interested persons with useful information as its limited resources permit. The comment did not suggest alternative estimates.

We estimate 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 request	167	5	835	1	835
New request + third-party certification	85	2	170	22	3,740
Biennial update	132	4	528	0.5 (30 minutes)	264
Biennial update + third-party certification	58	2	116	22	2,552
Occasional updates	60	2	120	0.5 (30 minutes)	60
Total			1,769		7,451

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

Based on a review of the information collection since our last request for OMB approval, the estimated burden for this information collection has decreased. The number of respondents has declined dramatically since we transitioned to using the ELM, which also allows us to collect more precise data. These changes resulted in overall decreases of 3,421 responses and 14,837 burden hours.

Dated: June 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-13074 Filed: 6/16/2022 8:45 am; Publication Date: 6/17/2022]