This document is scheduled to be published in the
Federal Register on 06/12/2019 and available online at
https://federalregister.gov/d/2019-12321, and on **govinfo.gov**

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 United States Manufacturers/Processors 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) 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 0910-0509. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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

OMB Control Number 0910-0509--Revision

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 that the processor of the food is in compliance with applicable country of origin regulatory requirements. Some foreign governments establish additional requirements with which exporters are required to comply and ask for additional assurances from the responsible authority. When requested, FDA may provide this information in the form of lists which are provided to the foreign governments.

For products subject to importing country listing requirements, FDA has historically maintained certain export lists of manufacturers/processors that: (1) have expressed interest in exporting their products to these countries; (2) are subject to FDA's jurisdiction; and (3) are 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 lists under the authority of section 701(h) of the Federal, Food, Drug, and Cosmetic 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 manufacturers/processors 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 request the lists. Finally, the guidance documents note that the information is provided voluntarily by manufacturers/processors with the understanding that it may be posted on FDA's external web site 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).

Application for inclusion on each list is voluntary. However, some foreign governments may require inclusion on the list for acceptance of imported products. FDA recommends that U.S. manufacturers/processors that want to be placed on the export lists send FDA the following information: (1) country to which the food manufacturer/processor wants to export product; (2) type of food product facility; (3) the Food Facility Registration number (the information collected by this module is approved under OMB control number 0910-0502), FDA Establishment Identifier number or Dun & Bradstreet number for the facility; (4) name and address of the firm and the manufacturing plant; (5) name, telephone number, and email address of the contact person; (6) information on the products intended for export; (7) identities of agencies that inspected the plant; (8) date of last inspection, plant number, and copy of last inspection notice; and (9) if other than an FDA inspection, copy of last inspection report. We request that this information be updated every 2 years.

In addition to the information above, some countries may require additional information such as documentation that the firm has been certified by a third-party certification body that it meets the requirements of the importing country. Other information may need to be submitted to be included on the lists depending on the requirements of the importing country. We plan to provide exporters with information about any such additional information required by a foreign country as a condition for entry and collect the other information to accommodate the importing countries' requirements.

We use the information submitted by firms to determine their eligibility for placement on the export lists, which may be published on our web site. The purpose of the lists is to help CFSAN (Center for Food Safety and Applied Nutrition)-regulated industries meet the import requirements of foreign governments.

FDA currently maintains export lists for the European Community and China covered under OMB control numbers 0910-0320 and 0910-0839, respectively. These export lists also serve to assist firms to meet the import requirements of foreign governments. OMB control numbers 0910-0509, 0910-0320, and 0910-0839 are similar in that they allow FDA to collect information from firms for the purpose of establishing export lists for foreign governments that require these lists before allowing the subject goods to be imported. Thus, with this notice, FDA proposes to consolidate these collections of information for government efficiency and to allow the public to look to one OMB control number for all collections of information for CFSAN export lists. This collection of information is intended to cover all CFSAN existing export lists, as well as any additional export lists required by foreign countries.

In 2016, FDA launched the Dairy Listing Module, an electronic registry system (Form FDA 3972) to facilitate applications for inclusion on the dairy export lists. FDA has expanded

this system to accommodate applications for inclusion on export lists for CFSAN-regulated products, affording all firms the efficiencies of submitting information electronically. The expanded system is called the Export Listing Module (ELM). The ELM has data fields that allow firms to input the information identified above that FDA recommends providing. In addition, the ELM contains data fields such as "Additional Information" and "Additional Documents" that allow firms to submit any additional data or information (such as third-party certifications) that foreign governments may require. Screenshots of the ELM are available at https://www.fda.gov/food/food-export-lists/online-applications-export-lists. If a firm is unable to submit an application via the ELM, it may contact CFSAN and request assistance.

In the *Federal Register* of November 13, 2018 (83 FR 56350), we published a 60-day notice requesting public comment on the proposed collection of information. We received a number of comments. One letter cited a related public meeting docket (FDA-2016-D-4484) and included comments regarding topics covered in the subject guidance document. The comments did not address the information collection elements solicited in our notice; however, we will consider the comments consistent with our good guidance practice regulations at 21 CFR 10.115.

Another comment covered multiple topics suggesting that FDA clarify more specifically the utility of the information being collected, and that some of the information collection may be duplicative. The comment also appears to question both FDA's role in and authority for the information collection, however, this comment goes beyond the scope of the topics solicited in our 60-day notice, and is therefore not discussed in this notice.

Another comment suggested that the burden estimate associated with new requests to be placed on the list was too low. We appreciate feedback regarding user experience with reporting information. Although we believe that the new module will ultimately reduce the time necessary

for completing the application process, we have raised the estimate to 1 hour in deference to the comment.

Finally, other comments expressed encouragement for finding continued ways to improve the program, and we look forward to receiving continued feedback.

We estimate the burden of the information collection 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 requests to be placed on the lists	1,460	1	1,460	0.5 (30 minutes)	730
Third-party certification	370	1	370	21	7,770
Biennial update	2,505	1	2,505	0.5 (30 minutes)	1,253
Third-party certification biennial update	555	1	555	21	11,655
Occasional updates	300	1	300	0.5 (30 minutes)	150
Total					21,558

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

The information collection reflects an increase in burden by 18,458 hours due to the consolidation of the information collections covered by OMB control numbers 0910-0839 and 0910-0320. Also, our current estimate of the number of foreign countries that may require us to establish lists in the next 3 years and the type of information they may require us to collect to maintain such lists has also resulted in an increase. At the same time, we have developed an electronic reporting portal that is expected to reduce the overall reporting time per submission. The portal will enhance the ability of firms to more efficiently request inclusion on export lists.

We base our estimate on the number of manufacturers/processors that have submitted new written requests, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours it will take a manufacturer/processor to gather the information needed to be placed on the list or update its information is based on our experience with manufacturers/processors submitting similar requests. We believe that the information to

be submitted will be readily available to manufacturers/processors. This collection is incorporating additional information collected to maintain lists of eligible exporters of CFSAN-regulated products who wish to export to foreign markets, including the European Union, Chile and China under OMB control numbers 0910-0320, "Request for Information from U.S. Processors that Export to the European Community" and 0910-0839, "Establishing and Maintaining Lists of U.S. Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products to China."

We estimate that 1,460 firms will average 30 minutes (0.5 hour) to submit new requests for inclusion on the list, 2,505 firms will average 30 minutes (0.5 hour) to update their information every 2 years, and 300 firms will average 30 minutes (0.5 hour) to occasionally update their information in this system.

Some firms will need to provide documentation that they obtained third-party certification to certify that they have met the requirements of the importing country. Currently, only China has this requirement. Based on our experience with this program, 370 firms will spend about 21 hours to complete the third-party certification for a total of 7,770 burden hours. During the biennial update, we estimate that about half of the 1,110 manufacturers/processors for which the importing country requires third-party certification will be recertified, meaning that 555 manufacturers/processors (1110 manufacturers/processors × 0.5) will get recertified each year. We estimate that it will take each such manufacturer/processor about 21 hours to complete the certification process for a total of 11,655 burden hours (555 manufacturers/processors × 21 hours).

We calculate, therefore, that the total burden for this collection is 21,558 hours.

Dated: June 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-12321 Filed: 6/11/2019 8:45 am; Publication Date: 6/12/2019]