4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. 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 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 collection of information that FDA uses to establish and maintain lists of U.S. manufacturers and processors with an interest in exporting products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) to countries that require such lists to be maintained. The notice also solicits comments on changes to the electronic registry that will allow manufacturers and processors of CFSAN-regulated products to electronically request inclusion on the export lists.

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 11:59 p.m. 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-2018-N-4042 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of Manufacturers/Processors With Interest in Exporting CFSAN-regulated Products." 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 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, 10A-12M, 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

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 requested 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. FDA plans 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-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 very 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 of CFSAN's 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/GuidanceRegulation/ImportsExports/Exporting/ucm496929.htm. If a firm is unable to submit an application via the ELM, it may contact CFSAN and request assistance.

Description of Respondents: Respondents to this collection of information include U.S. manufacturers/processors subject to FDA/CFSAN jurisdiction that wish to export to certain foreign countries that require inclusion on export lists.

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 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 in order 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: November 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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