4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2013-N-0065]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 of the Agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

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:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2013-N-0065 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002--21 CFR 1.230 to 1.235

OMB Control Number 0910-0502--Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 415 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230 to 1.235 of FDA's regulations (21 CFR 1.230 to 1.235) set forth the procedures for registration of food facilities. Information provided to FDA under these regulations helps the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support FDA enforcement activities and to screen imported food shipments. Advance notice of imported food allows FDA, with the support of the Bureau of Customs and Border Protection, to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. If a facility is not registered or the registration for a facility is not updated when necessary, FDA may not be able to contact the facility and may not be able to target import inspections effectively in case of a known or potential threat to the food supply or other food-related emergency, putting consumers at risk of consuming hazardous food products that could cause serious adverse health consequences or death.

FDA's regulations require that each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States register with FDA using Form FDA 3537 (§ 1.231), unless exempt under 21 CFR 1.226 from the requirement to register. The term "Form FDA 3537" refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at http://www.access.fda.gov. Domestic facilities are required to register whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture/process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility outside the United States. However, if the further manufacturing/processing conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature, the former facility is required to register.

Information FDA requires on the registration form includes the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, facilities are encouraged to submit their preferred mailing address; type of activity conducted at the facility; type of storage, if the facility is primarily a holding facility; and approximate dates of operation if the facility's business is seasonal.

In addition to registering, a facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to manufacture/process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, and to require facilities required to register with FDA to renew such registrations biennially. Section 415(a)(2) of the FD&C Act, as amended by FSMA, also provides that, when determined necessary by FDA "through guidance," a food facility is required to submit to FDA information about the general food category of a food manufactured, processed, packed or held at such facility, as determined appropriate by FDA, including by guidance. The modified food facility registration forms includes the following mandatory fields: (1) The email address for the contact person of a domestic facility and the e-mail address of the United States agent for a foreign facility; (2) an assurance that FDA will be permitted to inspect the facility; and (3) specific food categories as identified in the guidance document entitled, "Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories" (section 415(a)(2) of the FD&C Act 21 U.S.C. 350d(a)(2)).

Food Facility Registration, in conjunction with advance notice of imported food, helps FDA act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Food Facility Registration provides FDA with information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information helps FDA and other authorities determine the source and cause of the event. In addition, the registration information enables FDA to notify more quickly the facilities that might be affected by the outbreak. See Interim Final Rule entitled, "Registration of Food Facilities Under the Public

Health Security and Bioterrorism Preparedness and Response Act of 2002" (68 FR 58894, at 58895; October 10, 2003).

Implementation of the FSMA requirements described previously helps enable FDA to quickly identify and remove from commerce an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA uses the information collected under these provisions to help ensure that such food products are quickly and efficiently removed from the market.

Description of Respondents: Respondents to this collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

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

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

21 CFR Section and/or Section of FD&C Act	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
New Facilities						
Domestic						
§§ 1.230 to 1.233 and section 415 of the FD&C Act	FDA 3537[2]	11,080	1	11,080	2.7	29,916
Foreign						
§§ 1.230 to 1.233 and section 415 of the FD&C Act	FDA 3537	19,900	1	19,900	8.9	177,110
New Facility Registration Subtotal						207,026
Previously Registered Facilities						
Updates under § 1.234 and section 415 of the FD&C Act	FDA 3537	118,530	1	118,530	1.2	142,236
Cancellations under § 1.235	FDA 3537a	6,390	1	6,390	1	6,390
Biennial renewal of registration required by section 415 of the FD&C Act	FDA 3537	104,786	1	104,786	0.50 (30 mins.)	52,393
Updates, Cancellations, or Biennial Renewals Subtotal						201,019
Total Hours Annually						408,045

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

[2]The term "Form FDA 3537" refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at http://www.access.fda.gov.

This estimate is based on FDA's experience and the average number of new facility registrations, updates and cancellations received in the past 3 years. Based on this experience, we estimate the annual number of new domestic facility registrations will be 11,080. We estimate that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 2.5 hours per average domestic facility registration. We estimate that the FSMA-required additional information for new facility registrations will require an additional 12 minutes (0.2 hour) per response for domestic facilities. The average domestic facility burden hour estimate of 2.7 hours takes into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new domestic facility registrations is calculated to be 29,916 hours (11,080 × 2.7 hours).

Based on FDA's experience, we estimate the annual number of new foreign facility registrations will be 19,900. We estimate that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 8.5 hours per average foreign facility registration. We estimate that the FSMA-required additional information for new facility registrations will require an additional 24 minutes (0.4 hour) per response for foreign facilities. The average foreign facility burden hour estimate of 8.9 hours includes an estimate of the additional burden on a foreign facility to obtain a U.S. agent, and takes into account that for some foreign facilities the respondent completing the registration may not be fluent in English and/or not have readily available Internet access. Thus, the total annual burden for new foreign facility registrations is calculated to be 177,110 hours (19,900 × 8.9 hours).

Based on FDA's experience, we estimate that the average annual number of updates to facility registrations will remain unchanged at 118,530 updates annually over the next 3 years. We also estimate that updating a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. We estimate that the FSMA-required additional information for updates will require an additional 12 minutes (0.2 hour) per response. Thus, the total annual burden of submitting updates to facility registrations is calculated to be 142,236 hours (118,530 × 1.2 hours).

Based on FDA's experience, we estimate that the average annual number of cancellations of facility registrations will remain unchanged at 6,390 cancellations annually over the next 3 years. We also estimate that cancelling a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. FSMA did not change the required information for cancellations. Thus, the total annual burden for cancelling registrations is estimated to be 6,390 hours.

We estimate that the new biennial registration required by FSMA, which will require the submission of certain new data elements and the verification and possible updating of other information rather than re-entering all information, will require 30 minutes (0.5 hour) per response, including time for the new FSMA-required information. We estimate that, on an annualized basis, the number of biennial registrations submitted over the next 3 years will be 104,786. This estimate is based on the number of currently registered firms (209,573) divided by two. Thus, the total annual burden for biennial registration is calculated to be 52,393 hours (104,786 × 0.5 hours).

Dated: May 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.
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