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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 0910-0502. Also include the FDA docket number found in brackets in the heading of this document.

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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.

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002--21 CFR 1.230–1.235 (OMB Control Number 0910–0502)--Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188) 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 the Food and Drug Administration (FDA). Sections 1.230 through 1.235 of FDA's regulations (21 CFR 1.230-1.235) 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). 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 before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are 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) (Public Law 111-353), enacted on January 4, 2011, 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. These amendments took effect October 1, 2012. To comply with this statutory deadline, FDA initially obtained OMB approval of the following additional collection of information requirements under the emergency processing provisions of the PRA:

- Modification of food facility registration forms to include the following mandatory fields: The email address for the contact person of a domestic facility and the email address of the United States agent for a foreign facility, an assurance that FDA will be permitted to inspect the facility, and 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)); and

- The requirement that registered facilities submit registration renewals to FDA biennially (section 415(a)(3) of the FD&C Act (21 U.S.C. 350d(a)(3)).

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 new 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.

In the Federal Register of January 22, 2013 (78 FR 4414), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments in response to the notice.

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						
§§ 1.230-1.233 and section 415 of the FD&C Act	FDA 3537[2]	11,080	1	11,080	2.7	29,916
Foreign						
§§ 1.230-1.233 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	224,930	1	224,930	0.5 (30 minutes)	112,465
Updates, Cancellations or Biennial Renewals Subtotal						261,091
Total Hours Annually						468,117

[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. FDA received 12,011 new domestic facility registrations during 2010; 10,646 during 2011; and 10,584 during 2012. Based on this experience, FDA estimates the annual number of new domestic facility registrations will

be 11,080. FDA estimates 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 estimated to be 29,916 hours (11,080 x 2.7 hours).

FDA received 20,598 new foreign facility registrations during 2010; 20,009 during 2011; and 19,092 during 2012. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 19,900. FDA estimates 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 estimated to be 177,110 hours (19,900 x 8.9 hours).

Based on its experience, FDA estimates that the average annual number of updates to facility registrations will remain unchanged at 118,530 updates annually over the next 3 years. FDA also estimates 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 estimated to be 142,236 hours (118,530 x 1.2 hours).

Based on its experience, FDA estimates that the average annual number of cancellations of facility registrations will remain unchanged at 6,390 cancellations annually over the next 3 years. FDA also estimates 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. FDA estimates that, on an annualized basis, the number of biennial registrations submitted over the next 3 years will be 224,930. This estimate is based on the number of currently registered firms (449,860) divided by 2. Thus, the total annual burden for biennial registration is estimated to be 112,465 hours (224,930 x 0.5 hours).

Dated: March 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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