Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

OMB Control No. 0910-0502

Request for Emergency Clearance of the Paperwork Reduction Act Package for Revision of OMB Control Number 0910-0502 to Add Mandatory Fields to the Food Facility Registration Form and Make Other Changes to the Food Facility Registration System Under the FDA Food Safety Modernization Act

The Food and Drug Administration (FDA) is requesting that a Paperwork Reduction Act (PRA) package for the revision of OMB Control Number 0910-0502 to add mandatory fields to the food facility registration form and make other changes to FDA Food Facility Registration as provided by the FDA Food Safety Modernization Act (P.L. 111-353) (FSMA) be approved using the emergency clearance process under 5 C.F.R. § 1320.13(a)(2)(i). Public harm is reasonably likely to occur if the normal clearance procedures are followed.

Public Harm is Reasonably Likely to Occur if Normal Clearance Procedures are Followed

The FSMA amendments to section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350(d)) require several changes to FDA Food Facility Registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Section 415(a)(2) of the FD&C Act, as amended by FSMA, requires food facilities to submit additional registration information to FDA, including the e-mail address for the contact person of the facility (for a domestic facility) or the United States agent for the facility (for a foreign facility), and an assurance that FDA will be permitted to inspect the facility at the times and in manner permitted in the FD&C Act. 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. Section 415(a)(3) of the FD&C Act, as amended by FSMA, requires food facilities to submit registration renewals to FDA biennially. Finally, section 415(b), as added by FSMA, provides FDA with the authority to suspend a food facility's registration under certain circumstances, and section 801(l), as amended by FSMA, provides that food being imported or offered for import in the United States from a foreign facility with a suspended registration can be held at the port of arrival. Section 415(b)(2) requires FDA to provide a registrant subject to a suspension order with an opportunity to request an informal hearing on the actions required for reinstatement of registration and why the registration should be reinstated. Section 415(b)(3) provides that if FDA determines that a suspension of registration remains necessary, the registrant is required to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA. Additional details about these changes are provided in the Supporting Statement.

Registration information provided to FDA 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 (CBP), to target import inspections more effectively

and help protect the nation's food supply against terrorist acts and other food-related 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 consequence or death.

If FDA receives the additional data elements provided under FSMA and biennial registrations renewals, and is able to utilize the suspension of registration provisions, including the requirement that registrants subject to suspension orders submit to FDA corrective action plans, along with other FSMA changes to registration, it will be better able to respond in case of a known or potential threat to the food supply. In the absence of immediate approval of the collections of information based on these FSMA changes to food facility registration, FDA will be impaired in its ability to protect the nation's food supply against terrorist acts and other public health emergencies. The Agency will be at risk of not fulfilling its FSMA mandate and public harm is reasonably likely to occur.

FDA believes that public harm will occur if normal PRA clearance procedures are followed. In the six months or more it can take to obtain a full PRA clearance, FDA would not have access to information that may protect consumers in food-related emergencies. FDA believes that these circumstances can be mitigated or prevented through prompt communication with facilities that might be affected by a deliberate or accidental contamination of the food supply and through targeted import inspections. Accordingly, FDA is requesting that OMB use its emergency clearance process to **immediately approve** the PRA package requesting the revision of OMB Control Number 0910-0502 to add FSMA-required data elements, biennial renewal of registration, and additional food categories to be included in the food facility registration form. As discussed in Section 12 of the Supporting Statement, FDA believes that the collections of information in section 415(b) of the FD&C Act for the suspension of a food facility's registration, including the submission of informal hearing requests and corrective action plans by registrants, are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. If OMB disagrees with FDA's conclusion regarding the applicability of the exemption, FDA would like OMB to approve the collections of information provided in section 415(b) of the FD&C Act regarding the suspension of food facility registrations in this emergency request.

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