4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0430]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Submission of Food/Feed Facility Profile Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's program of voluntary submission of food facility profile information and new Form FDA 3797, which may be submitted electronically via the FDA Industry Systems Web site.

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: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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 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.

Voluntary Submission of Food/Feed Facility Profile Information (OMB Control Number 0910-New)

FDA has broad legal authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Public Health Service Act to protect the public health and the safety of the nation's food supply. In addition, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) (the "Bioterrorism Act") FDA was further authorized to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act added section 415 of 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. FDA regulations at 21 CFR 1.230 through 1.235 set forth the procedures for registration of food (including animal food/feed) facilities. Information provided to FDA under these regulations helps us notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. Furthermore, the FDA Food Safety Modernization Act (Public Law 11-353) (FSMA) added section 421 of the FD&C Act (21 U.S.C. 350j), which directed FDA to allocate resources to inspect facilities according to the known safety risks of the facilities. We propose to collect additional food/feed facility profile

information on a voluntary basis from firms that complete the FDA food facility registration process. Food facility profile information voluntarily provided to FDA will help us to determine whether a firm is high-risk or non-high-risk. We will use the profile information to assist us in determining the frequency at which we will inspect the firm. Facilities that voluntarily submit the food facility profile information would benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. The need for this collection of information derives from our objective to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)).

Firms will be offered the opportunity to voluntarily complete a food/feed facility profile after they register with FDA using the electronic system known as the Food Facility Registration Module, which is available at http://www.access.fda.gov, the FDA Industry Systems Web site. The use of an electronic form would enhance our ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that we could target inspections to facilities that manufacture, process, or pack foods that are at increased risk for a food safety problem. After completing their registration process, firms will see a popup screen by which they will be able to navigate to the food facility profile screens to provide the profile information. Food and feed facility profile information will only be collected electronically in English.

Information we propose to request in the voluntary food and feed facility profile includes, among other things:

- The facility type (e.g., manufacturer/processor, repacker/packer, or warehouse/holding facility);
- the products, and hazards (e.g., biological, physical, chemical) and preventive control measures associated with those products where either there is a regulation in place requiring identification of hazards and preventive control measures, e.g., seafood and juice, or the firm as a matter of its own business practices voluntarily identifies hazards and implements preventive control measures; and
- other facility information (e.g., food safety training, facility size, operational schedule, and number of employees).

Firms will be given the option of providing or updating their profile information whenever the firm accesses the Food Facility Registration Module (e.g., when completing their initial registration process or when updating their registration information). FDA will also provide a direct URL that a firm may use to submit the facility profile information at a time when they are not registering or updating their registration information.

Description of Respondents: The respondents to this information collection include 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]

Activity	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of New Domestic Food Facility Profile	FDA 3797	6,780	1	6,780	0.25 (15 minutes)	1,695
Submission of New Foreign Food Facility Profile	FDA 3797	11,685	1	11,685	0.75 (45 minutes)	8,764
Submission of Update to Existing Food Facility Profile	FDA 3797	59,265	1	59,265	0.0833 (5 minutes)	4,937
Total						15,396

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

This estimate is based on our experience and the average number of new facility registrations and updates estimated in the notice published in the Federal Register of May 28, 2010 (75 FR 30033) (the May 2010 notice) during the most recent request for extension of OMB approval under the PRA for the FDA food facility registration process (approved under OMB control number 0910-0502). In the May 2010 notice, we estimated that the annual number of new domestic facility registrations will be 13,560. Assuming that approximately half of these firms will also choose to provide the food facility profile information, we estimate that 6,780 domestic firms will voluntarily submit Form FDA 3797 annually. We estimate that submitting the food facility profile information will require a burden of approximately 0.25 hour (15 minutes) per average domestic facility. Thus, the total annual burden for the submission of new domestic food facility profiles is estimated to be 1,695 hours (6,780 x 0.25 hour = 1,695 hours).

In the May 2010 notice, we estimated that the annual number of new foreign facility registrations will be 23,370. Assuming that approximately half of these firms will also choose to provide the food facility profile information, we estimate that 11,685 foreign firms will voluntarily submit Form FDA 3797 annually. We estimate that submitting the food facility

profile information will require a burden of approximately 0.75 hour (45 minutes) per average foreign facility, taking into account that for some foreign facilities the respondent completing the registration may not be fluent in English. The information must be submitted electronically in the English language. Thus, the total annual burden for the submission of new foreign food facility profiles is estimated to be 8,764 hours (11,685 x 0.75 hour = 8,763.75 rounded to 8,764 hours).

In the May 2010 notice, we estimated that we will receive 118,530 registration updates annually. Assuming that approximately half of these firms will also choose to update their food facility profile information, we estimate that 59,265 firms will voluntarily submit Form FDA 3797 for that purpose annually. FDA estimates that updating food facility profile information will require a burden of approximately 0.0833 hour (5 minutes) per average facility, taking into account fluency in English. Thus, we estimate the total annual burden for updating food facility profiles to be 4,937 hours (59,265 x 0.0833 hour = 4,936.77 rounded to 4,937 hours).

We recognize that the May 2010 notice was issued prior to the passage of FSMA, which was signed into law on January 4, 2011. Section 102(a) of FSMA amended section 415 of the FD&C Act to create section 415(a)(3) (21 U.S.C. 350d(a)(3)), which requires that during the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has previously registered shall submit a renewal registration. We anticipate that this provision will impact the number of firms that access the Food Facility Registration Module and that are therefore given the option of providing or updating their profile information. Estimates regarding the impact of section 415(a)(3) will be provided in our next request for extension of OMB approval under the PRA for the FDA food facility registration process (approved under OMB control number 0910-0502).

Dated: May 8, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012-11457 Filed 05/10/2012 at 8:45 am; Publication Date: 05/11/2012]