

Dated: September 7, 2005.

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Assistant Commissioner for Policy.

[FR Doc. 05-18163 Filed 9-13-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0349]

Agency Information Collection Activities: Proposed Collection; Comment Request; Food and Drug Administration Survey of Current Manufacturing Practices in the Food Industry

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 a 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 a proposed survey of current manufacturing practices in the food industry. The purpose of the proposed survey is to improve FDA's understanding of current food industry manufacturing practices. The information will be used to assess what impact, if any, new manufacturing requirements would make on the food industry.

DATES: Submit written or electronic comments on the collection of information by November 14, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

FDA Survey of Current Manufacturing Practices in the Food Industry

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

FDA's regulations in part 110 of Title 21 of the Code of Federal Regulations (21 CFR part 110) describe the methods, equipment, facilities and controls for producing processed food, hereafter referred to as food CGMPs. As the minimum sanitary and processing requirements for producing safe and wholesome food, CGMPs are an important part of regulatory control of the nation's food supply. FDA believes that it is necessary to revisit and modernize the food CGMPs. Since the food CGMPs were last revised in 1986, there have been significant changes in food production technology and important advances in the understanding of foodborne illnesses.

Accordingly, the agency will rigorously assess the impacts of any modernization policies on food facilities. To assess the impacts of the modernization policy, information is needed to help understand baseline or current industry practice. At present, however, FDA lacks baseline information on the nature of current manufacturing practices that would serve as part of a regulatory impact analysis.

FDA plans to conduct an Internet survey of all domestic FDA-registered facilities that primarily manufacture or process food and all foreign FDA-registered facilities that primarily manufacture or process food, which are located in those countries that are the largest food exporters to the United States: Japan, Canada, China, France, Italy and Mexico. The Internet survey will be supplemented by extended case study interviews with selected respondents from the survey. The survey and extended case studies will solicit detailed information about six key topics relevant to the food CGMPs modernization effort: employee training, sanitation and personal hygiene, allergen controls, process controls, post-production processing, and recordkeeping. Additionally, FDA will collect information on establishment characteristics, such as facility size and industry, which are expected to correlate with the presence or absence of various manufacturing practices, such as electronic recordkeeping, ongoing employee training in food safety, and product-to-label conformance procedures. The case study interviews will provide qualitative, in-depth information about various factors that influence decisions to implement these types of manufacturing practices, as well as about the circumstances that underlie the cost and effectiveness of such programs. The survey will be sent to every FDA-registered facility in the United States, Japan, Canada, China, France, Italy and Mexico that primarily manufactures or processes food products and that included an e-mail address with their registration. Participation will be voluntary and the respondent identifiers that would permit an association of specific responses to specific respondents will not be accessible to FDA.

The proposed Internet survey will collect the information from respondents electronically. With a custom-designed online survey system, responses will be entered directly into a computer database, eliminating the need for additional coding and data entry operations. Also, the system will ensure that conditional questions are asked in proper order, freeing the

respondent from the need to keep track of the question order and skip patterns. The data quality will also be higher because the instrument will contain built-in edits, prompts, and data validation features.

The Internet survey method was selected due to the following considerations: (1) E-mail addresses of the respondents are available from the FDA Food Facility Registration database and are continuously validated by FDA; (2) the Internet survey method is the least costly to the agency when compared with other modes of collection and generates the timeliest responses; (3) the Internet survey will impose a relatively modest reporting burden on small entities; and (4) the Internet survey method is the only feasible method by which FDA may survey foreign facilities that export food products to the United States.

The Internet survey includes a pledge of confidentiality regarding the contractor's use of the data provided by

the respondents. All data will be collected and compiled by Eastern Research Group, Inc. (ERG), an independent consulting firm contracted by FDA. ERG will provide FDA personnel with data compiled in the course of the study. In keeping with longstanding FDA practice, however, ERG will not provide FDA with identifiers that would permit the association of specific responses with a given respondent. Under its contract with FDA, ERG is precluded from releasing to the public any study data or findings without FDA's prior approval.

The key information to be collected includes responses to questions about the following: (1) Training procedures and practices for food production managers, production supervisors, quality control personnel, sanitation and cleaning supervisors and production line employees on the topics of food safety, basic cleaning, sanitizing, sanitation, personal hygiene, specific product and equipment training and

allergen control; (2) pest control and sanitation procedures and practices for food contact surfaces, non-food contact surfaces, production areas and warehouses; (3) allergen control procedures and practices for soybean or soybean-based ingredients, peanuts or peanut-based ingredients, finfish and crustacea, tree nuts, milk and other dairy products, eggs, and wheat or wheat-based products; (4) process controls, including written procedures for handling incoming raw materials, approving vendors, the calibration of operating equipment, pathogen control, and a Hazard Analysis and Critical Control Point system; (5) recordkeeping practices; (6) the primary operation characteristics conducted at the facility, such as the type of food manufactured or processed for human consumption; and (7) fresh produce and ready to eat packing practice and post harvest operations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Domestic Facilities					
Screener	10,241	1	10,241	.67	683
Completed Survey	15,361	1	15,361	.75	11,520
Total Domestic Facilities					36,355
Foreign Facilities					
Screener	17,565	1	17,565	.67	1,171
Completed Survey	17,565	1	17,565	.75	13,174
Total Foreign Facilities					14,345
Total					50,700

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

These estimates are based on FDA's registration database and FDA and the contractor's experience with previous surveys. The respondents are divided into two groups: domestic and foreign. We estimate the number of domestic facilities at 45,747 based on information in the registration database. However, we do not expect that all of these firms will participate in the survey. It is possible that the database will contain wrong e-mail addresses or out-of-business facilities, which we estimate will reduce the number of respondents by 20 percent, or 9,149. We estimate that an additional 22 percent, or 10,972, will simply not respond to the survey. Therefore, the number of domestic facilities expected to participate in the

survey is 25,602. Among the 54,806 foreign facilities in the registration database, 4,620 are expected to be out of business or have wrong e-mail addresses (or about 8 percent), and 15,056 (or about 27 percent) are not expected to respond at all. Therefore, it is expected that 35,130 foreign facilities will respond.

Prior to the administration of the survey, the agency plans to conduct a pretest of the final survey to identify and resolve potential problems. The pretest will be conducted with nine participants.

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