DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0349]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 June 7, 2007.

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: 202–395–6974. All comments should be identified with the OMB control number, ''0910–NEW'' and title, ''FDA Survey of Current Manufacturing Practices in the Food Industry.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

FDA Survey of Current Manufacturing Practices in the Food Industry—(OMB Control Number 0910–NEW)

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 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 may 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, if conducted, 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 its 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 only with a summary of data (aggregated statistical data) compiled in the course of the study. No reports will have information about individual facility participation or lack of participation, or information that enables FDA to determine individual responses. In keeping with longstanding FDA practice, ERG will not provide FDA with identifiers that would permit the association of specific responses with a given respondent. Responses will not be the property of the Federal government. The raw data generated by the Internet survey will not be owned by FDA, will not be an FDA record, and will not be provided, or otherwise made available, to FDA.

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 diary 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.

In the **Federal Register** of September 14, 2005 (70 FR 54390), FDA published a 60-day notice requesting public comment on the information collection provisions. We received comments from three respondents on the 60-day notice regarding the collection entitled ''FDA Survey of Current Manufacturing Practices in the Food Industry.'' One of the respondents' comments was received after the 60-day comment period closed and is not addressed.

Respondents were asked to submit comments pertaining to 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. Comments outside the scope of these four questions are not addressed in this notice.

(Comment 1) One industry respondent wanted assurances from FDA that individual company information was not subject to release under the Freedom of Information Act (FOIA).

(Response 1) The Internet survey includes a pledge of confidentiality regarding the data provided by the respondent. All data will be collected, compiled, and owned by ERG, an independent consulting firm contracted by FDA. ERG is contractually obligated to retain the raw data and to not provide FDA with access to it. ERG will provide FDA personnel only with anonymous summary and aggregate statistical data compiled during the course of the study; ERG is contractually restricted from providing FDA with raw or other data that has identifiers that would permit the association of specific responses to a given respondent. Data that FDA does not own cannot be requested through the FOIA.

(Comment 2) The respondent requests that only one contact be made for each individual firm through the parent company contact listed on the firm's facility registration form and not to each location where the firm has a production facility.

(Response 2) We recognize the additional burden this places on a firm but because we need current information from each manufacturing plant we do not believe that we have an alternative approach. Not every facility processes the same types of foods with the same preventive controls even when the parent company is the same. We need to get an idea of CGMPs at each facility location. Having a parent company respond could give us inaccurate information.

(Comment 3) The respondent requests that each firm (facility) receive only one solicitation for information.

(Response 3) Response to this survey is voluntary. For the sake of statistical reliability, we must contact non-responders more than just initially or our survey data result could be subject to a non-response bias. Non-response bias is affected by both the proportion of non-responders and the extent to which non-respondents and respondents differ on key questions being measured in the survey. To reduce the bias, it is necessary to reduce the number of non-responders by contacting them multiple times. It also helps to obtain information about non-responders to assess whether their socio-demographic characteristics differ systematically from survey responders. Survey researchers should always try to follow up with individuals who do not consent to participate in a survey and ascertain their reasons for non-response. We do recognize that there should be an upper limit for the number of times a non-responder should be contacted before being dropped. From our experience, data quality will not be improved significantly by more than six contacts, so we will set our upper limit at six contacts.

(Comment 4) One respondent opposes investigating foreign manufacturers.

(Response 4) We are not investigating foreign manufacturers; we are surveying them to get an idea about their manufacturing practices. Nearly 20 percent of all imports into the United States are food and food products; imported fresh produce and seafood make up a large percentage of these imports. All food, including imported and domestic food, must follow the same manufacturing regulations, thus information on foreign manufacturing processes is necessary and relevant to help inform us about how to modernize our regulation on CGMPs for food facilities.

At the time of the 60-day notice, approximately 45,000 domestic and 55,000 foreign facilities were registered with FDA. Now approximately 126,000 domestic and 81,000 facilities from Japan, Canada, China, France, Italy, and Mexico are registered with FDA.

Recent experience with online surveys has shown that fewer respondents respond than estimated at the time of the 60-day notice. Estimates of public burden have been adjusted to account for the increase in respondents and our estimate of the decrease in response rate.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Domestic Facilities					
Screening questions only	17,000	1	17,000	.067	1,139

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Completed survey	44,500	1	44,500	.75	33,375
Total domestic	61,500		61,500		34,514
Foreign Facilities					
Screening questions only	14,000	1	14,000	.067	938
Completed survey	26,000	1	26,000	.75	19,500
Total foreign	40,000	1	40,000		20,438
Grand total	101,500				54,952

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

These estimates of the number of respondents and the burden hours per response 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 126,000 based on information in the registration database. However, we do not expect that all of these firms will participate in the survey. We anticipate that approximately 61,500 facilities will participate, which takes into account typical response rates to these types of surveys and inaccurate contact information that facilities have entered into the registration database (see *http://www.cfsan.fda.gov/~furls/ffregacc.html*). Similarly, among the 81,000 foreign facilities in the registration database, we expect that 40,000 foreign facilities will respond.

We estimate that it will take a respondent 4 minutes (.067 hours) to complete the screening questions and 45 minutes (0.75 hours) to complete the entire survey. 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.

Dated: May 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0363]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 7, 2007, the comment period for a draft guidance entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device.'' FDA published a notice of availability of the draft guidance in the **Federal Register** of October 31, 2006 (71 FR 63774). The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirement of special controls for class II devices, if the device is reclassified. Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on a proposed rule to reclassify the absorbable hemostatic device from class III (premarket approval) into class II (special controls)

DATES: Submit written or electronic comments on the draft guidance by June 7, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) into class II (special controls). In the same issue of the **Federal Register** (71 FR 63774), FDA published a notice of availability of a draft guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device.'' The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirement of special controls if they were reclassified. FDA invited interested persons to comment on the proposed