

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0286]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey to Evaluate FDA's Food Defense Awareness Initiative ALERT

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 a survey of food industry supervisory employees about their awareness and perceptions of FDA's Food Defense Awareness Initiative ALERT.

DATES: Submit written or electronic 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: 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: 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.

Survey to Evaluate FDA's Food Defense Awareness Initiative ALERT

In July 2006, FDA announced its Food Defense Awareness Initiative, called ALERT (the letters stand for the five key components of the initiative: (assure, look, employees, report, and threat). The ALERT initiative is intended to raise the awareness of State and local government agencies and the food industry regarding food defense issues. ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination at their facility. The ALERT Web-based training module and more information on ALERT are available at www.cfsan.fda.gov/~dms/defterr.html.

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393 (b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. Under this authority, FDA is planning to conduct a survey of first line supervisors working in a range of capacities in the food industry about their awareness and perceptions of the agency's ALERT initiative and the ALERT initiative informational materials. The purpose of the survey is to help FDA evaluate ALERT informational materials and to gauge whether the materials succeed in informing food industry supervisory employees about the risk of intentional food contamination and in motivating them to engage in protective behaviors. The survey results will be used to assess how knowledge and awareness, threat perceptions, attitudes, norms, benefits and barriers affect the implementation of the ALERT initiative.

The data will be collected using a Web-based questionnaire. The survey will employ a stratified, cluster sampling design. Using industry networks and listings, we will randomly sample from databases of eight industry groups (regulators, growers, packers, processors, warehouse, transporters, retailers,

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and food service operators). We will stratify within groups by organization size (small, medium, and large) based on number of employees on the payroll, for a total random sample of 200 organizations. Participation in the survey is voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Cognitive Interviews	10	10	10	1	10
Pre-tests	10	1	10	.4	4
Survey	200	1	200	.4	80
Total					94

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

FDA's burden estimate is based on prior experience with consumer surveys similar to this proposed survey.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: May 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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