

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.

#### **Mental Models Study of Farmers' Understanding and Implementation of Good Agricultural Practices**

The proposed information collection will help FDA protect the public from foodborne illness by increasing the agency's understanding of how farmers

and growers use Good Agricultural Practices (GAPs) to address common risk factors in their operations and thereby minimize food safety hazards potentially associated with fresh produce. Fresh fruits and vegetables are those that are likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form and that are reasonably likely to be consumed raw. 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 Title 42 of the Public Health Service Act (1944), FDA has authority to act to protect the public health.

In 1998, FDA issued a guidance document entitled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," available at <http://www.cfsan.fda.gov/~dms/prodguid.html>. The guidance addresses microbial food safety hazards and good agricultural and good management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form.

There is evidence that growers have not fully implemented the GAPs to

reduce production risks, despite intensive GAPS training programs. FDA is planning to conduct a study to determine growers' decision-making processes with regard to understanding and implementing GAPs on the farm, to more fully understand the barriers and constraints associated with GAPs implementation.

The project will use "mental modeling," a qualitative research method wherein the decision-making processes of a group of respondents (described below) concerning the implementation of GAPs on the farm are modeled and compared to a model based on expert knowledge and experience in the implementation of GAPs. The information will be collected via a telephone interview concerning the factors that influence the perceptions and motivations related to the implementation of GAPs. A comparison between expert and consumer models based on the collected information may identify "consequential knowledge gaps" that can be redressed through information campaigns designed by FDA.

#### *Description of respondents:*

Respondents will be farmers or growers, GAPs trainers, and retail buyer and/or grower association representatives.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pre-tests/ Cognitive Interviews	9	1	9	.75	6.75
Study	60	1	60	.75	45
Total					51.75

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

The study will involve approximately 60 respondents, including 24 farmers or growers of fruits and vegetables, 24 GAPs trainers, and 12 retail buyer or grower association representatives. FDA will also conduct a pretest using 9 respondents. FDA estimates that each respondent will take 45 minutes (0.75 hours) to complete the interview for the study (60 respondents x 0.75 hours = 45 hours). Thus, the total annual burden for this one-time collection of information is 51.75 hours (6.75 hours + 45 hours = 51.75 hours). These estimates are based on FDA's experience with consumer research.

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: June 24, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2008-N-0146]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey**

**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 July 31, 2008

**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, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0548. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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.

**Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities—Survey—(OMB Control Number 0910-0548)—Extension**

FDA has received four reports of medical gas mix-ups occurring during the past 9 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15

injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mix-ups, to determine if further steps are warranted to ensure the safety of patients.

In the **Federal Register** of March 7, 2008 (73 FR 12452), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
210 and 211	285	1	285	.25	71.25
Total	285	1	285	.25	71.25

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

Dated: June 24, 2008.  
**Jeffrey Shuren,**  
*Associate Commissioner for Policy and Planning.*  
 [FR Doc. E8-14888 Filed 6-30-08; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Innovative Food Defense Projects; New Limited Competition Cooperative Agreement U13; Request for Application Number: RFA-FDA-08-010**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) is announcing the availability of grant funds for the support of innovative food defense projects. These grants are available to State, local, and tribal levels and must have national implication or application that can enhance Federal, State, and local food regulatory programs and are likely to impact preparedness, response and/or recovery. FDA anticipates providing

approximately \$240,000 in direct plus indirect costs in support of this program in fiscal year 2008. It is anticipated that 6 awards will be made for up to \$40,000 per award/per year for up to 1 year.

**DATES:** The application receipt date is July 30, 2008.

**I. Background/Funding Opportunity Description**

Food defense is a term used to describe activities associated with protecting the nation's food supply from intentional contamination. FDA (agency) has adopted 3 broad strategies that encompass its food defense activities:

- (1) Awareness: Prevention/Preparedness: Increase awareness among Federal, state, local, and tribal governments and the private sector to better understand where the greatest vulnerabilities lie and develop effective protection/mitigation strategies to shield the food supply from intentional contamination;
- (2) Response: Develop the capacity for a rapid coordinated response to a foodborne terrorist attack;
- and (3) Recovery: Develop the capacity for a rapid coordinated recovery from a foodborne terrorist attack.

In the aftermath of 9/11, the agency utilized an approach known as Operational Risk Management (ORM). ORM involves a determination of which

combinations of foods and agents, and where on the farm-to-table continuum, constitute the highest risks of being targeted for attack that may result in a large number of casualties. It is recognized that any food could potentially be contaminated and thus zero-risk foods do not exist. However, based on ORM analysis it was discovered that higher-risk foods do share several common vulnerability factors: Large batch size, which implies a large number of servings; short shelf life, which implies rapid turnaround at retail and rapid consumption; uniform mixing, which would maximize the potential number of contaminated units; and accessibility of a so-called critical node, defined as a process or activity in the farm-to-table chain during which the agent could be added and go undetected.

Currently, there is a joint program led by FDA, U.S. Department of Agriculture, Federal Bureau of Investigations, and the Department of Homeland Security, in collaboration with private industry and the states known as the Strategic Partnership Program Agroterrorism (SPPA) Initiative. The SPPA was launched in July 2005 and through industry and state volunteers vulnerability assessments are conducted locally in different states on a variety of food commodities in coordination with