understandings. These roles and responsibilities are as follows:

1. *Sponsor/requester.* The sponsor/requester initiates consideration for parallel review by submitting a complete nomination as outlined previously under ''1. Nomination,'' of section II.C of this document entitled ''Procedures.''. Once a nomination has been submitted, the sponsor/requester should comply with all requirements necessary for FDA review of a PMA or de novo petition and CMS issuance of an NCD including the submission of a formal request for an NCD. The Agencies request that a sponsor/requester who wishes to withdraw from the parallel review process notify the FDA and CMS in writing before CMS' formal opening of an NCD by the posting of the NCD tracking sheet.

2. *The FDA.* FDA will provide a secure and confidential nomination and review process as outlined previously in section II.C of this document. FDA will initiate review of nominations for parallel review by retrieving applications from the secure mailbox, and coordinating with CMS, on the planning and implementation of the parallel review process. FDA will review PMAs and de novo petitions for products that have been selected by the Agencies for parallel review according to the usual timeframes, procedures, and review standards for PMA approval and de novo classification.

3. *The CMS.* In addition to the coverage review, CMS's parallel review roles include participating in the nomination process as well as coordinating with FDA regarding the planning and implementation of the parallel review process. During the parallel review, CMS is responsible for maintaining open communication channels with FDA and the sponsor/requester and for fulfilling its statutory obligations concerning the NCD process.

*E. Duration of the Pilot*

The Agencies intend to accept requests for participation in the pilot program for parallel review for 2 years. The Agencies may terminate the pilot program before the close of the 2-year period, or may extend the pilot program beyond 2 years. The decisions will be announced in the **Federal Register.**

*F. Evaluation*

The Agencies intend to use their experience with the pilot program to develop a parallel review program not only for devices but also for drugs and biological products. The Agencies anticipate their experience with the parallel review program for devices and feedback from participants in the program will inform guidance for a broader program applicable to all medical products. The Agencies may also determine that they should extend or modify the parallel review pilot program to continue their evaluation.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 21, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: September 21, 2011.

**Margaret A. Hamburg,**

*Commissioner of Food and Drugs.*

[FR Doc. 2011–25907 Filed 10–6–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0263]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak

**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 (the PRA).

**DATES:** Fax written comments on the collection of information by November 10, 2011.

**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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

**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.

### Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak—(OMB Control Number 0910—NEW)

#### I. Background

This proposed collection of information entitled ''Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak'' will be conducted under a cooperative agreement between the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the Center for Risk Communication Research (CRCR) at the University of Maryland. JIFSAN was established in 1996 and is a public and private partnership between FDA and the University of Maryland. The CRCR will design and administer the study.

FDA is requesting OMB approval under the PRA for the CRCR to conduct research with produce growers, food retailers, and consumers to gain information about these groups' risk perceptions associated with produce that has recently been subject to a food recall resulting from a foodborne illness outbreak. The purpose of this research is to help FDA better understand whether the magnitude and duration of the decline in commodity consumption following food recalls can be partly explained by grower and retailer speculations and projections about consumers' attitudes toward food recalls resulting from foodborne illness outbreaks. This research will be used to assess how grower, retailer, and consumer perceptions, attitudes, knowledge, and beliefs affect market recovery after a hypothetical fresh spinach recall.

Epidemiologists define foodborne illness outbreaks as two or more cases of a similar illness resulting from the ingestion of a common food (Ref. 1). Because many foodborne illness cases are mild, most outbreaks are never

recognized or brought to the attention of public health authorities. When the outbreaks are large in scale or cause hospitalization, serious illness, or death, public health officials will inform the public in order to try to stop the spread of disease. A food recall can occur when a particular food in the marketplace is found to have a known contaminant because either people have become sickened by it or pathogen testing has revealed contamination (Ref. 2). The purpose of a food recall is to rid retail establishments of the product and to inform consumers that they should discard the product if they have it in their homes. Although the purpose of a food recall is to keep consumers from becoming ill, food recalls can be costly to all sectors of the food distribution chain (Ref. 3). The goal of the proposed project is to test, by experimental study, whether the psychological tendency called ''attribution error,'' contributes to unnecessarily prolonging the economic effects of a food recall. ''Attribution error'' is the tendency people have of overestimating others' negative response to situations compared to their own response. If industry decisionmakers' measures of consumer response are biased by ''attribution error,'' industry could be contributing to its own slow recovery after a food recall.

When a widespread foodborne illness outbreak results in a food recall, the product can be out of the marketplace for an extended period of time; this occurred when fresh, bagged spinach was recalled in 2006 (Ref. 3). Tomatoes were also less available following the *Salmonella* Saintpaul outbreak in 2008 (Ref. 4). Although growers and retailers want to provide safe foods, decisions surrounding production, wholesale, and retail sales forecasting in response to a food recall affects how quickly the food is again available for consumption. We hypothesize that industry's overattribution of consumers' fear of the food after such a food recall would result in the food being kept off of the market longer than necessary.

The CRCR plans to conduct an experiment using a Web-based questionnaire. The center will use a convenience sample of 900 participants (180 growers, 180 retailers, 540 consumers) drawn from industry networks (for the growers and retailers), and a Web-based panel of U.S. households (for the consumers). Participation in the study is voluntary.

This study will help FDA better understand the reasons for the time between a food recall resulting from a foodborne illness outbreak and market recovery. In order to understand the complexities of market recovery process, the CRCR will compare understandings and reactions of growers, retailers, and consumers to a hypothetical food recall resulting from a hypothetical foodborne illness outbreak. To make this comparison, individuals in each group will be assigned to one of the following experimental conditions (consisting of vignettes in the form of news articles on a hypothetical food recall): An ''anger'' scenario, a ''fear'' scenario, or a ''control'' scenario. After reading the news article, participants will complete a questionnaire assessing their emotional response; appraisals; attribution of responsibility; perceptions about the safety of the affected produce; intentions to grow, sell, or buy the affected produce; perceived probability of a repeat event; and a measure of their innate ability to effectively respond to the information in the article.

To help design and refine the questionnaire, we will recruit 25 participants in order to conduct 10 cognitive interviews. We estimate cognitive interview recruitment will take 5 minutes (0.083 hours), for a total of 2 hours. The cognitive interviews are estimated at 1 hour per response for a total of 10 hours for the cognitive interview activities. We expect to send screeners to 800 members of a consumer panel, each taking 2 minutes (0.03 hours) to complete, for a total of 24 hours for the consumer panel screener activity. We also expect to administer 360 screeners to growers and retailers, each taking 2 minutes (0.03 hours) to complete, for a total of 22 hours (11 + 11 = 22). Twenty-four participants (20 consumers, 2 growers, 2 retailers) will complete the pretest. Each pretest will take 10 minutes (0.17 hours) for a total of 5 hours for the pretest activity. We estimate that 900 individuals (540 consumers, 180 growers, and 180 retailers) will complete the questionnaire for the experiment, each taking 10 minutes (0.17 hours) for a total of 153 hours for the experimental study activities. The estimated total hour burden of the collection of information is 216 hours.

In the **Federal Register** of April 15, 2011 (76 FR 21379), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received two comments. The comments, and the Agency's responses, are discussed in the following paragraphs.

(Comment 1) One comment suggested that FDA should include the foodservice distributor community in the study.

(Response) FDA disagrees. FDA is not including the foodservice distributor community as a study sample because the foodservice distributor community is responsive to retail's demands for product. The retail sector is included in the study.

(Comment 2) One comment questioned the need for FDA to apply government resources toward the research question, which was characterized in the comment as a survey of consumers' reactions to food recalls.

(Response) FDA disagrees that the research data are not needed. The proposed study utilizes an experimental design to assess how well industry predicts consumer reaction to a food recall. This information will help FDA in their risk management role during and following a food recall. Risk management involves communicating both with industry and consumers about the important health and economic consequences related to the recall.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Cognitive Interview Recruitment. | 25 | 1 | 25 | 0.08 (5 min.) | 2 |
| Cognitive Interviews | 10 | 1 | 10 | 1 (60 min.) | 10 |
| Consumer Panel Screener | 800 | 1 | 800 | 0.03 (2 min.) | 24 |
| Grower Screener | 360 | 1 | 360 | 0.03 (2 min.) | 11 |
| Retailer Screener | 360 | 1 | 360 | 0.03 (2 min.) | 11 |
| Pretests | 24 | 1 | 24 | 0.17 (10 min.) | 5 |

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

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Experiment | 900 | 1 | 900 | 0.17 (10 min.) | 153 |
| Total | | | | | 216 |

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

## II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Olsen, S., L. MacKinnon, J.S. Goulding, et al., ''Surveillance for Foodborne Disease Outbreaks—United States, 1993 to 1997,'' *Morbidity and Mortality Weekly Report,* vol. 49, pp. 1–51, 2000.

2. ''FDA 101: Product Recalls—From First Alert to Effectiveness Checks,'' (*http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm*).

3. Calvin, L., ''Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices,'' *Amber Waves,* vol. 5, pp. 24–31, 2007.

4. Lucier, G. and R. Dettmann, ''Vegetables and Melons Outlook: A Report From the United States Department of Agriculture, Economic Research Service,'' VGS–327, June 26, 2008.

Dated: October 4, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2011–26131 Filed 10–7–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0509]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

**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 November 10, 2011.

**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:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0566. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

**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.

### Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine—21 CFR Part 10.75 (OMB Control Number 0910–0566)—Extension

*Respondents:* Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

The Center for Veterinary Medicine's Guidance for Industry #79 ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine'' describes the process by which the Center for Veterinary Medicine (CVM) formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

In the **Federal Register** of July 13, 2011 (76 FR 41264), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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