"REAL TIME" SURVEYS OF CONSUMERS' KNOWLEDGE, PERCEPTIONS, AND REPORTED BEHAVIOR CONCERNING FOODBORNE ILLNESS OUTBREAKS OR FOOD RECALLS
REQUEST FOR GENERIC CLEARANCE

OMB No. 0910-NEW

SUPPORTING STATEMENT

PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2)), the Food and Drug Administration (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.

FDA communicates with consumers about food recalls directly, at its own Web site, and through various mass media channels, such as television and newspapers, during a foodborne illness outbreak or food recall. In these communications, FDA typically identifies the implicated food, the symptoms of the foodborne illness at issue, any subpopulations at elevated risk of infection or illness, and protective measures individuals can or should take. The purpose of these communications is to provide consumers with information so they can protect themselves from potential health risks associated with an outbreak or food recall. Consumers also get information about an outbreak or recall from other sources, including other Federal and State agencies, industry, consumer groups, and the mass media, which may or may not relay FDA's public announcements.

FDA is proposing to survey U.S. consumers using a web-based panel of U.S. households to collect information on consumers' "real time" knowledge, perceptions, beliefs, and self-reported behaviors for up to five foodborne illness outbreaks or food recalls a year. Moreover, because the information environment during certain foodborne illness outbreaks or food recalls evolves as new information emerges, the Agency plans to field up to five waves of independent surveys per event (i.e., outbreak or recall). The surveys will query consumers on topics such as: (1) the products that are subject to the outbreak or recall; (2) the implicated pathogens; (3) the food vehicle of the outbreak or recall; (4) how consumers can protect themselves; and (5) whether they are aware of the "all clear" advisories, when applicable. FDA plans to conduct the surveys within a few days of the first notice to the public about the outbreak or food recall and whenever the agency suspects that (1) messages are not reaching consumers; and/or (2) consumers do not understand the messages; and/or (3) consumers are not taking appropriate actions in response to the messaging.

Collecting information quickly during a foodborne illness outbreak or food recall is important because erroneous perceptions or misinterpreted information about an outbreak or recall can impede

consumer adoption of recommended protective behaviors. Six fully identified surveys are included with this request, along with two "open" surveys (contain blanks to be filled with the appropriate pathogen/problem and food product when none of the fully identified surveys meet current information needs). Prior to administering the "open" surveys, FDA will send a memorandum, with the survey attached, to OMB for its signoff. FDA requests that OMB sign-off be obtained within 24 hours of receipt.

2. Purpose and Use of the Information Collection

FDA is proposing to survey U.S. consumers using a web-based panel of U.S. households to collect information on consumers' "real time" knowledge, perceptions, beliefs, and self-reported behaviors for up to five foodborne illness outbreaks or food recalls a year. In order for FDA to protect the public health during foodborne illness outbreaks or food recalls, the agency needs timely information collected from consumers as the events unfold to ensure that consumers understand the extent of the incident and that they are taking appropriate actions. Results from the information collections will indicate to FDA whether the agency should adjust its communications strategies and messages for foodborne illness outbreaks or food recalls when needed to help consumers react appropriately. The results will not be used to develop population estimates.

3. Use of Improved Information Technology and Burden Reduction

The study will use web-based surveys. Web-based surveys not only reduce the burden on respondents, but also minimize possible administration errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, Web-based surveys are less intrusive, less costly, and quicker.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is aware of nongovernment organizations that have collected information from consumers soon after the onset of foodborne illness outbreaks or food recalls. The Food Policy Institute at Rutgers University reported results of a telephone survey of Americans about the public reaction to the 2006 bagged, fresh spinach recall at the organization's website on February 2007 (Cuite, Condry, Nucci, and Hallman 2007). Also, the Harvard School of Public Health (2009) issued a press release on consumer knowledge about the January 2009 peanut and peanut product recall associated with the Peanut Corporation of America. The FDA's proposed surveys focus on the Agency's mandate to provide the public with timely information on foodborne illness outbreaks or food recalls. To *ensure* that the FDA has timely information, it needs to collect the information itself. It is unknown whether a duplicative collection of this information will exist when the FDA needs it.

5. Impact on Small Businesses or Other Small Entities

This collection of information will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

If this information is not collected, FDA may not know whether consumers have the information to protect themselves from potential health risks associate with an outbreak or food recall. This lack of information would impede FDA's ability to be responsive to the public's need for information in case of an outbreak or food recall.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus two copies of the information; or retain records for more than 3 years. The design of the surveys will not produce results that cannot be generalized to the response universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of March 6, 2009 (74 FR 9822), FDA published a 60-day notice requesting public comment on the proposed information collection. No comments were submitted.

FDA consulted with Christine Prue, MSPH, Ph.D., Associate Director for Behavioral Science at the National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC), on its proposal, data collection and analyses plans, and question inventory. Dr. Prue brings a strong background in health communication theory and research and has worked with FDA on communication and outreach during food-related crises. Dr. Prue's suggestions include: (1) additional questions for the inventory, (2) an increase from three waves per incident to a potential five waves, (3) methods for a faster clearance process, (4) a higher number of respondents for the pre-test, and (4) the administration of additional pre-tests. FDA agrees with Dr. Prue's suggestion for additional questions, survey waves per incident, guidance for improving the time involved in the clearance process, and increasing the number of pre-test respondents from 40 to 200. FDA has plans to conduct a single pre-test of the question inventory and disagrees with Dr. Prue about the value or necessity of pre-testing each time we administer a survey.

9. Explanation of Any Payment or Gift to Respondents

Respondents will be recruited from members of Synovate's Consumer Opinion Panel. Members have voluntarily agreed to join the panel and participate in regular online surveys conducted by Synovate. Synovate offers panelists two main incentive programs: Sweepstakes and a Points Rewards Program. The sweepstakes draw is conducted quarterly or monthly, depending on the market. Panel members receive an entry into the draw for registering for the panel, and for each

survey they complete during this time period. Each time a member completes a survey, the individual is automatically entered into the current month's drawing to win one of the following cash prizes: one cash prize of $1,000, 10 prizes of $100, 15 prizes of $50, 30 prizes of $25, and 150 prizes of $10." In the Points Rewards Program, panelists earn points for every survey they complete and can redeem these points for cash in their native currency. Panelists receive 50 points for every survey minute anticipated. One thousand points = $1.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study instrument will contain a statement that responses will be kept confidential. Confidential information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). Identifying information will not be included in the data files delivered by contractors to the agency. FDA will keep the study data confidential to the extent permitted by law.

Confidentiality will be assured by using an independent contractor, Synovate, Inc., to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. The terms of the research proposal restrict Synovate from providing FDA with raw or other data that has identifiers that would permit the association of specific responses to a given respondent. Synovate will assure confidentiality by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. Synovate has a privacy policy that precludes them from sharing personal information on participants with any third party without the participant's express permission unless it is required by law or necessary to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in data files that may be delivered to the agency. Details of Synovate's privacy policy can be found at https://www.globalopinionpanels.com/privacy_popup.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The survey does not include any questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The following burden estimates are based on FDA's projected use of the "Real Time" Food Recall Surveys. FDA anticipates needing to administer the surveys for up to five incidences per year. Furthermore, FDA estimates the need to administer up to five survey waves per incident.

Approximately 50,000 respondents of a web-based consumer panel will be screened (five waves (independent surveys) for each of five incidents; 2,000 respondents screened per wave). We estimate that it will take a respondent 20 seconds (0.0055 hours) to complete the screening questions, for a total of 275 hours. We will conduct a pre-test of the first survey with 200 respondents; we estimate that it will take a respondent 10 minutes (0.167 hours) to complete the pre-test, for a total of 33 hours. Twenty-five thousand (25,000) respondents will complete the surveys (five waves (independent surveys) for each of five incidents; 1,000 survey respondents per wave). We estimate that it will take a respondent 10 minutes (0.167 hours) to complete the survey, for a total of 4,175 hours. Thus, the total estimated burden is 4,758 hours. FDA's burden estimate is based on prior experience with consumer surveys that are similar to these.

Table 1.--Estimated Annual Reporting Burden[1]

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	50,000	1	50,000	.0055	275
Pre-test	200	1	200	.167	33
Survey	25,000	1	25,000	.167	4,175
Total					4,758

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

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $76,128. (4,758 x 16) at $16 per hour (the 2009 median wage rate in the U.S.). [1]

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital, operating, or maintenance costs associated with this collection.

14. Annualized Cost to Federal Government

The total estimated annualized cost of this data collection is $159,000. This includes $150,000 paid to the contractor to program the study, draw the sample, collect the data, create a database of the results, deliver oral and written preliminary summaries, and deliver a written final report of summaries and analytical findings. In addition, FDA estimates the cost of salaries for the FDA staff

[1] http://www.bls.gov/oes/2009/may/oes_nat.htm#b00-0000.

involved in the project development, implementation and monitoring to be $9,000, for a total estimated cost of $159,000.

15. Explanation for Program Changes or Adjustments

This is a new data collection. The new burden hours are due to a one-time data collection and its related pre-test and screener.

16. Plans for Tabulation and Publication and Project Time Schedule

The "Real Time" Food Recall Surveys can provide information on consumer reaction and response to a current foodborn illness outbreak or food recall but they will not yield quantitative data that can be generalized.

The Agency anticipates disseminating the data collection results to interested stakeholders after the final analyses of the data are completed, reviewed, and cleared. The planned schedule for project activities is shown in Table 2.

Table 2. *Project Schedule*

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of generic clearance for collection of information	Notification to the contractor to proceed with programming the survey for pre-test administration to their consumer panel.	Not applicable
Within 1 day after the public announcement of the onset of a major foodborne illness outbreak or food recall	a. Submit request to OMB for questionnaire approval if preapproved, fully completed surveys not applicable.	Not applicable
Within 1 day of OMB sign-off (when needed)	Survey administration (and subsequent administrations)	Not applicable
Within 3 days after administration of the surveys	Delivery by the contractor of data files	Not applicable
Within 3 days of receiving data files from contractor	Presentation of analyzed data in written and oral format	Agency management
Within 30 days of presentation of analyzed data to Agency management	Post results of data analysis on FDA's website.	FDA and public

Activities associated with the outcomes of the surveys will primarily consist of written and oral presentations to FDA management as well as written final reports to be posted to the FDA website.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.

References

Cuite, C.L., Condry, S.C. Nucci, M.L & Hallman, W.K. (2007. Public Response to the Contaminated Spinach Recall of 2006. (Publication number RR-0107-013). New Brunswick, New Jersey: Rutgers, The State University of New Jersey, Food Policy Institute.

Harvard School of Public Health, Press Release 2-13-09. "Following Peanut Product Recall, Six in Ten Americans Taking Steps to Reduce Their Risk of Getting Sick." www.hsph.harvard.edu.