(MCHB), which is implementing the Combating Autism Act Initiative (CAAI) in response to the legislative mandate. The purpose of this evaluation is to design and implement a three-year assessment of the effectiveness of MCHB's activities in meeting the goals and objectives of the CAAI, and to provide sufficient data to inform MCHB and the Congress as to the utility of the grant programs funded under the Initiative. To address the requirements for the Report to Congress, the evaluation will focus on short-term indicators related to: (1) Increasing awareness of ASD and other DD among health care providers, other MCH professionals and the general public; (2) reducing barriers to screening and diagnosis; (3) supporting research on evidence-based interventions; (4) promoting the development of evidence-based guidelines and tested/validated intervention tools; and (5) training professionals.

Respondents: Grantees funded by HRSA under the CAAI will be the respondents for this data collection activity. The programs to be evaluated are listed below.

1. Training Programs

- Leadership Education in Neurodevelopmental Disabilities (LEND) training programs with thirty nine grantees; and
- Developmental Behavioral Pediatrics (DBP) training programs with six grantees.

2. Research Programs

- Two Autism Intervention Research Networks that focus on intervention research, guideline development, and information dissemination;
- Five R40 Maternal and Child Health (MCH) Autism Intervention Research Program grantees that support research on evidence-based practices for interventions to improve the health and well-being of children and adolescents with ASD and other DD; and
- Two R40 MCH Autism Intervention Secondary Data Analysis Study (SDAS) Program grantees that support research on evidence-based practices for interventions to improve the health and well-being of children and adolescents with ASD and other DD, utilizing exclusively the analysis of existing secondary data.

3. State Implementation Program Grants for Improving Services for Children and Youth With Autism Spectrum Disorder (ASD) and Other Developmental Disabilities (DD)

- Nine grantees will implement state autism plans and develop models for improving the system of care for children and youth with ASD and other DD.

The data gathered through this evaluation will be used to:

- Evaluate the grantees' performance in achieving the objectives of the CAAI during the three year grant period;
- Assess the short- and intermediate-term impacts of the grant programs on children and
- families affected by ASD and other DD;
- Measure the CAAI outputs and outcomes for the Report to Congress; and
- Provide foundation data for future measurement of the initiative's long-term impact.

The estimated response burden is shown in Table 1.

TABLE 1—ESTIMATED HOUR AND COST BURDEN OF THE DATA COLLECTION

Grant program	No. of respondents	Responses per respondent	Total responses	Average hours per response	Total hour burden	Wage rate	Total hour cost
LEND	39	6	234	.75	175.5	$39.36	$6907.68
DBP	6	6	36	.75	27	39.36	1062.72
State Implementation Program	9	6	54	.75	40.5	38.22	1547.91
Research Program	9	6	54	.75	40.5	39.36	1594.08
Total	63		378		283.5		11,112.39

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated April 28, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–10450 Filed 5–3–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0535]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; "Real Time" Surveys of Consumers' Knowledge, Perceptions, and Reported Behavior Concerning Foodborne Illness Outbreaks or Food Recalls

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 3, 2010.

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 "'Real Time' Surveys of Consumers' Knowledge, Perceptions, and Reported Behavior Concerning Foodborne Illness Outbreaks or Food Recalls." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, 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.

"Real Time" Surveys of Consumers' Knowledge, Perceptions, and Reported Behavior Concerning Foodborne Illness Outbreaks or Food Recalls (OMB Control No. 0910–NEW)

I. Description

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.

Existing data show that many consumers do not take appropriate protective actions during a foodborne illness outbreak or food recall (Refs. 1 and 2). For example, 41 percent of U.S. consumers say they have never looked for any recalled product in their home (Ref. 2). Conversely, some consumers overreact to the announcement of a foodborne illness outbreak or food recall. In response to the 2006 fresh, bagged spinach recall which followed a multistate outbreak of *E. coli* O157: H7 infections (Ref. 3), 18 percent of consumers said they stopped buying other bagged, fresh produce because of the spinach recall (Ref. 1). Existing research also suggests that many consumers may not have correct knowledge about products subject to a given recall. For example, in a survey conducted 2 months after the onset of the 2006 spinach recall, one third of respondents did not know that, in addition to bagged spinach, fresh loose spinach was part of the recall, while 22 percent believed that frozen spinach was subject to the recall (it was not) (Refs. 1 and 3). 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 collection will indicate to FDA whether the Agency should adjust its communications to help consumers react appropriately.

FDA conducts research and educational and public information programs relating to food safety under its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393 (b)(2), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C) to conduct research relating to foods, drugs, cosmetics, and devices in carrying out the act.

FDA plans 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 three 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, and (4) how consumers can protect themselves. FDA plans to conduct the surveys soon after the onset of an outbreak or 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. Criteria for selecting a particular foodborne illness outbreak or food recall for a survey will include a qualitative assessment of the salience of some or all of the following: The geographical dispersion of the event, the number of illnesses or deaths associated with it, the relative familiarity of the food product, the complexity of consumer precaution instructions, and the presence of national media focus.

The Agency will use the survey results to help adjust its communication strategies and messages for foodborne illness outbreaks or food recalls, when needed. The results will not be used to develop population estimates.

In the **Federal Register** of November 18, 2009 (74 FR 59558), 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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	30,000	1	30,000	.0055	165
Pre-test	40	1	40	.167	7
Survey	15,000	1	15,000	.167	2,505
Total					2,677

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

Approximately 30,000 respondents of a Web-based consumer panel will be screened (3 waves (independent surveys)) for each of 5 incidents; 2,000 respondents per wave). We estimate that it will take a respondent 20 seconds (0.0055 hours) to complete the screening questions, for a total of 165 hours. We will conduct a pre-test of the first survey with 40 respondents; we estimate that it will take a respondent 10 minutes (0.167 hours) to complete the pre-test, for a total of 7 hours. Fifteen thousand (15,000) respondents will complete the surveys (3 waves (independent surveys)) for each of 5 incidents; 1,000 respondents per wave). We estimate that it will take a respondent 10 minutes (0.167 hours) to complete the survey, for a total of 2,505 hours. Thus, the total estimated burden is 2,677 hours. FDA's burden estimate is based on prior experience with consumer surveys that are similar to these.

II. References

1. Cuite, C., S. Condry, M. Nucci, et al., "Public Response to the Contaminated Spinach Recall of 2006," Publication no. RR–0107–013, New Brunswick, NJ: Rutgers, the State University of New Jersey, Food Policy Institute, 2007.

2. Hallman, W., C. Cuite, N. Hooker, "Consumer Responses to Food Recalls: 2009 National Survey Report," Publication no. RR–0109–018, New Brunswick, NJ: Rutgers, the State University of New Jersey, Food Policy Institute, 2009.

3. Acheson, D., "Outbreak of *Escherichia coli* 0157 Infections Associated With Fresh Spinach—United States, August-September 2006," 2007 (*http://first.fda.gov/cafdas/documents/Acheson_Spinach_Outbreak_2006_FDA_pres.ppt*).

Dated: April 28, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10357 Filed 5–3–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0184]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Patient Information Prototypes

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 for research entitled "Experimental Study of Patient Information Prototypes." This study is designed to determine based on different prototype testing whether consumers are able to comprehend serious warnings, directions for use, drug indications and uses, contraindications, and side effects in the material that is presented.

DATES: Submit written or electronic comments on the collection of information by July 6, 2010.

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: Elizabeth Berbakos, Office of Management Programs (HFA–250), Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

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.

Experimental Study of Patient Information Prototypes—New

In order to make informed decisions about health care and to use their medications correctly, consumers need easy access to up-to-date and accurate information about the risks, benefits and safe use of their prescription drugs. Consumers currently receive multiple pieces of paper with their prescription drugs from the pharmacy, containing information that is developed and distributed through various sources. Written prescription drug information is provided through a voluntary effort (Consumer Medication Information)[1] as well as through FDA mandated use of Medication Guides[2] and Patient Package Inserts (PPI).[3] Patients describe a wide range of experiences and varying degrees of satisfaction with information currently provided at the time medicines are received at the pharmacy. In some cases, the written documents are difficult to read and understand, duplicative and overlapping, incomplete or contradictory. FDA has held multiple public meetings to solicit feedback on providing balanced, comprehensive and up-to-date prescription drug information to consumers.

Since 1968, FDA regulations have required that PPIs written specifically for patients be distributed when certain prescription drugs or classes of prescription drugs are dispensed. PPIs are required for estrogens and oral contraceptives, are considered part of the product labeling, and are to be dispensed to the patient with the product. In the 1970s, FDA began evaluating the general usefulness of patient labeling for prescription drugs resulting in a series of regulatory steps to help ensure the availability of useful written consumer information. Other

[1] Public Law 104–180, August 6, 1996, Title VI. Effective Medication Guides.

[2] 21 CFR part 208.

[3] 21 CFR 310.501 and 310.515.