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

21 U.S.C. 393(d)(2)(D)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Gatekeeper Reviews	400	1	400	0.50	200
Omnibus Surveys	2,400	1	2,400	0.17	408
Total (General Public)	16,448		16,448		2,860
Veterinarian/Scientific Expert Focus Group Interviews	288	1	288	0.75	216
Total (Veterinarians/Scientific Experts)	288	1	288		216
Total (Overall)	16,736	1	16,736		3,076

[1] There are no capital costs or operating or maintenance costs associated with this collection of information.
[2] These are brief interviews with callers to test message concepts and strategies following their call-in request to an FDA Center 1–800 number.

Annually, FDA projects about 30 studies with 16,736 respondents, using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08–1.5 hours).

Dated: October 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26141 Filed 11–3–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 December 4, 2014.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0345. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road, COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Food Safety Survey—(OMB Control Number 0910–0345)—Reinstatement

I. Background

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), we are 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. The Food Safety Survey measures consumers' knowledge, attitudes, and beliefs about food safety. Previous versions of the survey were collected in 1988, 1993, 1998, 2001, 2006, and 2010. Data from the previous Food Safety Surveys and from this proposed survey will be used to evaluate two Healthy People 2020 objectives: (1) Increase the proportion of consumers who follow key food safety practices (Objective FS–5) and (2) reduce severe allergic reactions to food among adults with a food allergy diagnosis (Objective FS–4) (Ref. 1). Data from this survey will also be used to measure progress toward the United States Department of Agriculture's Food Safety Inspection Service's Fiscal Year 2011-Fiscal Year 2016 Strategic Plan goal of ensuring that, ''Consumers, including vulnerable and underserved populations, adopt food safety best practices'' (Ref. 2). Additionally, Food Safety Survey data are used to measure trends in consumer food safety habits including hand and cutting board washing, cooking practices, and use of food thermometers. Finally, data are used to evaluate educational messages and to inform policymakers about consumer attitudes about technologies such as food irradiation and biotechnology.

The proposed Food Safety Survey will contain many of the same questions and topics as previous Food Safety Surveys to facilitate measuring trends in food safety knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to explore emerging consumer food safety topics and expand understanding of previously asked topics. For example, recent papers in both the United States (Ref. 3) and Europe (Refs. 4 and 5) have pointed to changing epidemiology of listeriosis where adults over 60 years old have the highest rates of the illness. One reason for the increase in listeriosis rates among those over 60 years old could be increasing host susceptibility due to widened use of immunocompromising medications. We plan to include questions on the proposed survey to document the proportion of those over 60 years old who self-report taking a defined list of major immunocompromising medications. In conjunction with our established questions about safe food handling and eating potentially risky foods, the additional questions will expand our understanding of listeriosis among those over 60. Other new topics planned to be covered on the survey include: Consumer understanding of mechanically tenderized beef, awareness of foodborne pathogens such as *Toxoplasma gondii,* and awareness of the risks associated with eating raw sprouts.

The methods for the proposed Food Safety Survey will be largely the same as those used with the previous Food Safety Surveys. One major difference is that, unlike the data collection mode for previous Food Safety Surveys that used only land telephone lines, the proposed survey will include cell phones in addition to landlines. A nationally representative sample of 4,000 adults

(2,400 landline and 1,600 cell phone) will be selected at random for the telephone interviews. The survey will also include an oversample of Hispanics and Blacks to ensure a minimum of 400 each. Additionally, 50 non-respondents will be asked to participate in a short version of the survey from which we will conduct a non-response analysis. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

In the **Federal Register** of November 1, 2013 (78 FR 65661), we published a 60-day notice requesting public comment on the proposed collection of information. We received two letters in response to the notice, each containing one comment. The comments, and our responses, are discussed in the following paragraphs. For ease of reading, we preface each comment with a numbered ''Comment''; and each response by a corresponding numbered ''Response.'' We have numbered each comment to help distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, or importance, or the order in which it was received.

(Comment 1) One comment asked if a sample size of 4,000 was sufficient for this study, and suggested that FDA work with the Centers for Disease Control (CDC) on questions related to *Toxoplasma gondii.*

(Response 1) We believe that a sample size of 4,000 adults is sufficient for this study since this study evaluates consumer knowledge, attitudes, and perceptions related to food safety. It is not a clinical study looking at the effects of *Toxoplasma gondii* in the U.S. population. We consult with our Federal partners, including the CDC and the U.S. Department of Agriculture to make sure this survey meets their needs.

(Comment 2) One comment suggested that we add questions to the survey about preparing offals at home, washing raw poultry and meat, and cooking turkeys in the oven overnight.

(Response 2) We agree that these are interesting additional topics and have added questions about washing raw poultry and cooking turkeys to the survey. Due to space constraints, we are unable to add questions about preparing offals at home to the survey questionnaire. This topic will be considered for future research.

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 screener	75	1	75	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1	9
Pretest screener	45	1	45	0.0167 (1 minute)	1
Pretest	18	1	18	0.33 (20 minutes)	6
Survey screener	10,000	1	10,000	0.0167 (1 minute)	167
Survey	4,000	1	4,000	0.33 (20 minutes)	1,320
Non-response survey screener	125	1	125	0.0167 (1 minute)	2
Non-response survey	50	1	50	0.167 (10 minutes)	8
Total					1,519

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

We base our estimate of the number of respondents and the average burden per response on our experience with previous Food Safety Surveys. We will use a cognitive interview screener with 75 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 6 hours, rounded down from 6.225 hours. We will conduct cognitive interviews with nine participants. We estimate that it will take a participant approximately 1 hour to complete the interview, for a total of 9 hours. Prior to the administration of the Food Safety Survey, we plan to conduct a pretest to identify and resolve potential survey administration problems. We will use a pretest screener with 45 individuals; we estimate that it will take a respondent approximately 1 minute (0.0167 hours) to complete the pretest screener, for a total of 1 hour, rounded up from 0.7515 hours. The pretest will be conducted with 18 participants; we estimate that it will take a participant 20 minutes (0.33 hours) to complete the pretest, for a total of 6 hours, rounded up from 5.94 hours. We will use a survey screener to select an eligible adult respondent in each household reached by landline and cell phone telephone numbers to participate in the survey. A total of 10,000 individuals in the 50 states and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 1 minute (0.0167 hours) to complete the screening, for a total of 167 hours. We estimate that 4,000 eligible adults will participate in the survey, each taking 20 minutes (0.33 hours), for a total of 1,320 hours. Additionally, we will administer a non-response survey using a short version of the survey from which we will conduct a non-response analysis. We will use a non-response survey screener with 125 individuals; we estimate that it will take a respondent approximately 1 minute (0.0167 hours) to complete the non-response survey screener, for a total of 2 hours, rounded down from 2.0875 hours. The non-response survey will be conducted with 50 participants; we estimate that it will take a participant 10 minutes (0.167 hours) to complete the non-response survey, for a total of 8 hours, rounded down from 8.35 hours. This is a correction to our previous estimate of 5 hours to complete the non-response survey. Thus, the total estimated burden is 1,519 hours, which incorporates the correction of the estimate to complete the non-response survey.

II. References

1. U.S. Department of Health and Human Services, ''Healthy People 2020—Improving the Lives of Americans,'' July 30, 2013. Available at *http://www.healthypeople.gov/2020/default.aspx.*
2. U.S. Department of Agriculture, Food Safety Inspection Service, ''Strategic Plan FY 2011–2016,'' April 6, 2012. Available at *http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/strategic-planning/fy-2011-2016-strategic-plan/ct_index.*
3. Pouillot, R., K. Hoelzer, K. A. Jackson, et al. ''Relative Risk of Listeriosis in Foodborne Diseases Active Surveillance

Network (FoodNet) Sites According to Age, Pregnancy, and Ethnicity,'' *Clinical Infectious Diseases,* 54(S5): S401–410, 2012.
4. Goulet, V., C. Hedberg, A. Le Monnier, et al. ''Increasing Incidence of Listeriosis in France and other European Countries,'' *Emerging Infectious Diseases,* 14(5): 734–740, 2008.
5. Muñoz, P., L. Rojas, E. Bunsow, et al. ''Listeriosis: An Emerging Public Health Problem Especially Among the Elderly,'' *Journal of Infection,* 64: 19–33, 2012.

Dated: October 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26144 Filed 11–3–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0312]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements associated with extralabel drug use in animals.

DATES: Submit electronic or written comments on the collection of information by January 5, 2015.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

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, including each proposed extension of an existing 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.

Extralabel Drug Use in Animals—21 CFR 530 (OMB Control Number—0910–0325)—Extension

The Animal Medicinal Drug Use Clarification Act of 1994 allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. Although to date we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal Agencies, academia, or individuals.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b)	2	1	2	4,160	8,320

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