

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
Justification Submitted as General Correspondence and in the Annual Report	2	1	2	16	32

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

Dated: October 28, 2014.
Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0420]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Food and Drug Administration-Regulated Products Used in Animals

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 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 0910-0689. 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 Rd.; 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.

Testing Communications on FDA/Center for Veterinary Medicine (CVM)-Regulated Products Used in Animals (21 U.S.C. 393 (d)(2)(D))—OMB Control Number 0910-0689—Reinstatement

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of CVM-regulated products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. FDA expects that improving communications about the safety of regulated animal drugs, feed, food additives, and devices will involve many research methods, including individual indepth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about the use of FDA-regulated products for use in animals. Knowledge of consumer and veterinary professional decision-making processes

will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, labels, and labeling. These communications will aim to improve public understanding of the risks and benefits of using regulated animal drugs, feed, food additives, and devices by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

In the **Federal Register** of June 16, 2014 (79 FR 34312) FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was submitted; however, it was not responsive to the four collection of information topics solicited and therefore is not discussed in this document.

FDA estimates the burden of this collection of information based on recent prior experience with the various types of data collection methods described in this document:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

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
Individual Indepth Interviews	360	1	360	0.75	270
General Public Focus Group Interviews	288	1	288	1.5	432
Intercept Interviews: Central Location	600	1	600	0.25	150
Intercept Interviews: Telephone	² 10,000	1	10,000	0.08	800
Self-Administered Surveys	2,400	1	2,400	0.25	600

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—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.

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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