

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
179.25(e), Large processors	3	300	900	1	900
179.25(e), Small processors	4	30	120	1	120
Total					1,020

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

FDA bases its estimate of burden for the recordkeeping provisions of § 179.25(e) on the Agency's experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. FDA estimates that there are three irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on three facilities devoting 100 percent of their business to food irradiation (3 × 300 hours = 900 hours for recordkeeping annually), and four facilities devoting 10 percent of their business to food irradiation (4 × 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: May 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0858]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys

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 18, 2012.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, 301-796-5733, domini.bean@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.

Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys—(OMB Control Number 0910-NEW)

I. Background

Since the early 1980s, the Center for Food Safety and Applied Nutrition at FDA has been commissioning several waves of two national consumer surveys, the Food Safety Survey (FSS) and the Health and Diet Survey (HDS), to gather data on consumer knowledge, perceptions, and behaviors regarding food safety and nutrition. The purposes of the surveys are threefold: (1) To generate nationally representative estimates of knowledge, perceptions, and practices of interest at a given point in time; (2) to track trends of the estimates over time; and (3) to understand the relationships among knowledge, perceptions, and practices regarding food safety and nutrition, and how these relate to demographic characteristics.

Traditionally, all waves of the surveys have been administered via landline telephones and have used the random digit dialing (RDD) technique to recruit national samples of adults (18 years old or above) from households with landline telephone numbers. A noticeable phenomenon that has appeared in our recent surveys is a precipitous decline of younger respondents in completed interviews. For example, the proportion of respondents in the 18 to 29 age group for the FSS has dropped from 17 percent in 2001, to 11 percent in 2006, to only 4 percent in 2010; the corresponding proportion for the HDS has gone from 14 percent in 2002, to 15 percent in 2004, to only 6 percent in 2008.

One possible reason for the decline is the rapid adoption of cell phones in recent years. During the second half of 2010, 28 percent of American adults lived in households with only wireless service ("wireless-only households" or "cell-phone only households"), compared to 15 percent in the second half of 2007 and 5 percent in the second half of 2004 (Ref. 1). During the second half of 2010, 17 percent of adults lived

in households that received all or almost all calls on cell phones despite having a landline phone ("wireless-mostly households" or "cell-phone mostly households"), an increase of 3 percentage points from the first half of 2008 (Ref. 1). Thus, the number of adults reachable by landline phone calls has decreased in recent years. The rate of cell phone adoption, however, has been uneven among adults with different demographic characteristics. In 2010, adults living in wireless-only households were more likely to be 18 to 34 year olds, living in poorer households, without a college or higher educational degree, or Hispanics or Latinos (Ref. 1). Meanwhile, adults who live in landline households differ from those who live in wireless-only households as well those in wireless-mostly households (Ref. 2), and the demographic characteristics of adults living in wireless-mostly households are much less diverse than that of adults living in wireless-only households (Ref. 1).

The underrepresentation of wireless-only or wireless-mostly adults, especially those in younger age groups, in landline surveys can affect national estimates of the prevalence of certain consumer perceptions, knowledge or behaviors, and understanding of the relationships between certain survey responses and demographic characteristics. For example, previous research found different prevalence rates of drinking and smoking between respondents reached on a landline call versus respondents from wireless-only households (Ref. 1). Wireless-mostly adults were less likely than landline adults to say their health is fair or poor and were less likely to be a current smoker than wireless-only adults (Ref. 2). Voigt et al. (Ref. 3) reported that cell phone users were less likely to have fathered or given birth to a child than their landline telephone counterparts. The differences observed in these studies are pertinent and potentially problematic for the HDS and FSS because past surveys have shown that age variations were associated with, among other things, consumers' knowledge of dietary fats, and awareness and concern about pesticide and antibiotic residues (Refs. 4 and 5).

Thus, our recent surveys may have become vulnerable to a noncoverage problem due to the fact that many eligible respondents are not included in the survey samples because they do not own landline phones or because they receive calls only or mostly on cell phones. Adults living in wireless-only and wireless-mostly households are less likely to appear in landline telephone

samples and often possess characteristics that differ from those of adults in landline households. Thus, a telephone survey that still relies exclusively on landline phone calls to interview respondents may not produce results that are reliable and valid (Refs. 2 and 6), may not yield results that are comparable to results from past landline surveys when this noncoverage problem was absent, or both.

One common approach to addressing potential impacts of cell phone use on landline telephone survey results is to supplement a landline telephone survey with a cell phone survey to achieve a wider coverage of population in the sample of respondents. Existing evidence on the usefulness of this approach varies between national estimates and population subgroup estimates. Many studies conducted around the mid-2000s (for example, Ref. 7), when the use of cell phones was not as common as today, and a 2007 study (Ref. 2) suggested that general population estimates of certain social and political attitudes, voting behavior, and media use and attitudes did not always vary when a landline survey was supplemented or was not supplemented with a cell-phone only survey, especially when the response to a landline survey was weighted to reflect population characteristics. On the other hand, this research also suggested that among young adults and low-income adults, estimates of certain health-related behaviors, such as smoking and binge drinking, differ between those living in households with and without landlines (Ref. 8). In addition, young adults who had a landline phone were less likely to report drinking alcohol or to agree that marijuana smoking is acceptable (Ref. 9). We are, however, not aware of any research that has examined whether food safety or nutrition related perceptions, attitudes, and behaviors differ when landline telephone surveys miss respondents who are not reachable by landline telephone calls.

Therefore, we are concerned that the diminishing survey participation among consumers who are not easily reached by landline telephones may lead to unreliable or biased estimates of critical information and the relationships among knowledge, perceptions, and other food safety and nutrition-related variables. These concerns warrant a systematic examination of the impacts of cell phone use on the quality of the FSS and HDS data.

The objective of this data collection is to provide data for an experimental study that compares demographic distributions in and responses to selected FSS and HDS questions by

samples of respondents drawn from an overlapping dual frame (Ref. 6), i.e., two overlapping sampling frames: (1) a list-assisted landline telephone frame and (2) a cell-phone frame. Using this approach, we will not screen out any households or individuals because of their type(s) of telephone service (landline or cell phone). The study plans to interview 2,000 respondents in English, half of them (1,000) using a 10-minute HDS questionnaire and half of them (1,000) using a 10-minute FSS questionnaire. Each respondent will be randomly assigned to one of the questionnaires. The target distributions within each of the HDS and FSS samples are:

- 700 respondents who are drawn from the landline frame and complete the questionnaire on a landline telephone;
- 150 respondents who are drawn from the cell phone frame and complete the questionnaire on a cell phone, regardless whether they are wireless-only or wireless-mostly; and
- 150 respondents who are drawn from the cell phone frame, complete the questionnaire on a cell phone, and do not have a landline phone to receive personal calls.

The HDS questionnaire will focus on knowledge of dietary fats, use of food labels, awareness of diet-health relationships, and use and understanding of dietary supplements. The FSS questionnaire will focus on perceptions of general food safety risks, food handling practices, perceived personal vulnerability to food safety risks, consumption of risky foods, and awareness of mercury and fish. All questions have been asked in previous surveys.

The Agency will use the study to assess the impacts of cell phone use on population estimates of nutrition and food safety related perceptions, attitudes, and behaviors. The assessment will help the Agency determine whether and how future administrations of the FSS and HDS should be adjusted to produce reliable, valid, and historically comparable results in response to the growing prevalence of cell phone use.

In the **Federal Register** of December 7, 2011 (76 FR 76422), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received two comments in response to the notice. Both responses dealt with topics outside the scope of the proposed collection of information described in the 60-day notice and are therefore not addressed here.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	10	1	10	0.167 (10 minutes)	2
Survey	2,000	1	2,000	0.167 (10 minutes)	334
Total					336

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 (see **ADDRESSES**) 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 FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Blumberg, S.J. and J.V. Luke, "Wireless Substitution: Early Release of Estimates From the National Health Interview Survey, July-December 2010." National Center for Health Statistics, June 2011. Available at: <http://www.cdc.gov/nchs/nhis.htm>.
2. Lee, S., J.M. Brick, E.R. Brown, and D. Grant, "Growing Cell-Phone Population and Noncoverage Bias in Traditional Random Digit Dialing Telephone Health Surveys," *Health Services Research*, 45: 1121–1139, 2010.
3. Voigt, L.F., S.M. Schwartz, D.R. Doody, et al., "Feasibility of Including Cellular Telephone Numbers in Random Digit Dialing for Epidemiologic Case-Control studies," *American Journal of Epidemiology*, 173: 118–126, 2011.
4. Yen, S.T., K.L. Jensen, and C.-T.J. Lin, "Awareness and Perceived Risk of Pesticide and Antibiotic Residues in Food: Socioeconomic Variations Among United States' Consumers," *Food Protection Trends*, 26: 654–661, 2006.
5. Lin, C.-T.J. and S.T. Yen, "Knowledge of Dietary Facts Among U.S. Consumers," *Journal of the American Dietetic Association*, 110: 613–618, 2010.
6. American Association for Public Opinion Research (AAPOR), "New Considerations for Survey Researchers When Planning and Conducting RDD Telephone Surveys in the U.S. With Respondents Reached via Cell Phone Numbers," 2010. Available at: http://www.aapor.org/Cell_Phone_Task_Force_Report.htm.
7. Keeter, S., "The Impact of Cellular Phone Noncoverage Bias on Polling in the 2004 Presidential Election," *Public Opinion Quarterly*, 70: 88–98, 2006.
8. Blumberg, S.J. and J.V. Luke, "Reevaluating the Need for Concern Regarding Noncoverage Bias in Landline Surveys," *American Journal of Public Health*, 99: 1806–1810, 2009.

9. Keeter, S., C. Kennedy, A. Clark, et al., "What's Missing From National Landline RDD Surveys? The Impact of the Growing Cell-Only Population," *Public Opinion Quarterly*, 71: 772–792, 2007.

Dated: May 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Cross-Site Evaluation of the Minority Substance Abuse/HIV Prevention Program—(OMB No. 0930–0298)—Revision and Reinstatement

The Substance Abuse and Mental Health Services Administration Center for Substance Abuse Prevention (CSAP) is requesting from the Office of Management and Budget (OMB) approval for the revision of data collection activities for the cross-site study of the Minority HIV/AIDS Initiative (MAI), which includes both youth and adult questionnaires. This revision includes the addition of four cohorts, changes to the data collection procedures based on intervention duration, and the addition of two questions on binge drinking behavior. The instruments were also modified to include six items for adults and three items for youth on military families and deployment that were recently approved by OMB under the CSAP National Outcomes Measures (NOMs) (OMB # 0930–0230). The current approval for the full cross-site is under OMB No. 0930–0298, which expires on 4/30/12.

This cross-site study supports two of SAMHSA's eight Strategic Initiatives: Prevention of Substance Abuse and Mental Illness and Data, Outcomes, and Quality. The primary objectives of the cross-site study are to:

- Determine the success of the MAI in preventing, delaying, and/or reducing the use of alcohol, tobacco, and other drugs (ATOD) among the target populations.
- Measure the effectiveness of evidence-based programs and infrastructure development activities such as: outreach and training, mobilization of key stakeholders, substance abuse and HIV/AIDS counseling and education, referrals to appropriate medical treatment and/or other intervention strategies (i.e., cultural enrichment activities, educational and vocational resources, and computer-based curricula).
- Assess the process of adopting and implementing the Strategic Prevention