VII. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Kessler, D.A., ''Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems,'' *Journal of the American Medical Association,* 269: 2765–2768, 1993.

Dated: December 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31341 Filed 12–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0858]

Agency Information Collection Activities; Proposed Collection; 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 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 on a study entitled ''Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys.''

DATES: Submit either electronic or written comments on the collection of information by February 6, 2012.

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: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

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 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 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 three-fold: (1) To generate nationally representative estimates of knowledge, perception, and practice 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 under-representation 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 of 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.

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
Pretest	10	1	10	.167 (10 minutes)	2
Survey	2,000	1	2,000	.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,'' *(http://www.cdc.gov/nchs/nhis.htm),* National Center for Health Statistics, June 2011.
2. Lee, S., J.M. Brick, E.R. Brown, et al., ''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 U.S. 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 United States With Respondents Reached via Cell Phone Numbers,'' *(http://www.aapor.org/Cell_Phone_Task_Force_Report.htm),* 2010.
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: December 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31389 Filed 12–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0326]

Biologics Price Competition and Innovation Act of 2009; Proposed Recommendations for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the proposed recommendations for a user fee program for biosimilar biological products for fiscal years (FYs) 2013 through 2017.

DATES: The public meeting will be held on Friday, December 16, 2011, from 9 a.m. to 1 p.m. Registration to attend the meeting must be received by December 14, 2011. See section III.B of this document for information on how to register for the meeting. Submit either electronic or written comments by January 6, 2012.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993–0002. Please note that visitors to the White Oak Campus must enter through Building 1.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments 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.

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the public meeting (see section III.C of this document).

FOR FURTHER INFORMATION CONTACT: Rokhsana Safaai-Jazi, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1164, Silver Spring, MD 20993–0002, (301) 796–4463, *Fax:* (301) 847–8443, Email: *BiosimilarsUserFeeProgram@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a public meeting to discuss proposed recommendations for a user fee program for biosimilar biological products (biosimilars user fee program) for FYs 2013 through 2017. On March 23, 2010, President Obama signed into law the Affordable Care Act (Pub. L. 111–148). The Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. (See sections 7001 through 7003 of the Affordable Care Act.) Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product.

The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications in the definition of ''human drug application'' for the purposes of the prescription drug user fee provisions. (See section 7002(f)(3)(A) of the Affordable Care Act.) Accordingly, under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), the fee for a biologics license application (BLA) is currently the same regardless of whether the application is submitted under the new 351(k) approval pathway or the preexisting 351(a) approval pathway.

The authority conferred by the Federal Food, Drug, and Cosmetic Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a biosimilars user fee program for FYs 2013 through 2017. (See section 7002(f)(1) of the Affordable Care Act.) The BPCI Act provides that FDA must consult with a range of groups, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups (public stakeholders), and regulated industry (industry stakeholders), in developing the recommendations. As described in section II of this document, FDA consulted with public and industry stakeholders from June 2011 through September 2011.

The BPCI Act requires that FDA must publish the recommendations for a biosimilars user fee program in the **Federal Register** and provide a period of 30 days for the public to provide written comments on the recommendations.