NATIONAL CONSUMER SURVEYS ON UNDERSTANDING THE RISKS AND BENEFITS OF FDA-REGULATED MEDICAL PRODUCTS

REQUEST FOR OMB REVIEW
AND SUPPORTING STATEMENT

Food and Drug Administration
Office of the Commissioner
Office of Planning

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date May 20, 2011

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for Approval of FDA's "National Consumer Surveys on Understanding the Risks and Benefits of FDA-Regulated Medical Products"

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB

Through HHS Reports Clearance Officer_____

The Food and Drug Administration (FDA), Office of Planning, Office of the Commissioner, is seeking OMB approval to conduct National Consumer Surveys on Understanding the Risks and Benefits of FDA-Regulated Medical Products. The purpose of the study is to better inform the process by which FDA plans more effective risk communication strategies and messages.

FDA expects the survey results to provide insight as to how well the public understands and incorporates risk/benefit information into their belief structures, and how well the public understands the context within which FDA makes decisions on medical product recalls and warnings. Using this information, the agency will more effectively design messages and select formats and distribution channels that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way. Survey findings will be considered by FDA's Risk Communication Advisory Committee in its evaluation of the agency's campaign to provide consumers with the context they need to better understand new, and often uncertain, risk information. FDA plans to seek future OMB approval to conduct additional survey administrations to build upon the findings of this study, and to track the agency's communications-related performance over time.

FDA proposes to conduct parallel surveys of 1,500 noninstitutionalized U.S. adults; one survey of 1,500 subjects will be a telephone survey, and the second survey of another 1,500 subjects will be conducted with members from an Internet survey panel. Results from each survey will also be compared to provide insight into the best methodology for future studies. Total annual respondent burden is calculated at 1,428 hours. Thank you in advance for your consideration.

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SUPPORTING STATEMENT

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

FDA is responsible for ensuring that medical products it approves for marketing are safe and effective when used properly. Risks and benefits are inherent in all FDA-regulated medical products, including drugs, biologics, and medical devices (e.g., pacemakers, implantable cardiac defibrillators, contact lenses, infusion pumps). FDA plays a critical oversight role in managing and preventing injuries and deaths related to medical product use. However, the users of FDA-regulated products are ultimately the ones who determine which products are used and how they are potentially misused. For this reason, it is critical that the public understand the risks and benefits of FDA-regulated medical products to a degree that allows them to make rational decisions about product use.

FDA's responsibility includes communicating about medical products. This encompasses communications that FDA generates and those it oversees through regulation of product manufacturers' and distributors' communications. Activities include, but are not limited to, recall notices, warnings, public health advisories and notifications, press releases, and information made available on its Web site. FDA also regulates communications drafted and disseminated by manufacturers and distributors of many medical products, including all the communications (advertising and labeling) about prescription drugs, biologics, and restricted medical devices, and a subset of communications (omitting advertising) about nonprescription drugs and other medical devices. In order to conduct educational and public information programs relating to these responsibilities, as authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. Section 393) (Attachment 1), it is beneficial for FDA to conduct research and studies relating to health information as authorized by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) (Attachment 2).

Need for Public Feedback. Effective two-way communication with audiences who use FDA-regulated medical products is critical in preserving the overall balance between product benefits and risks. Besides communicating to the public, we also must effectively hear back from the public to determine whether the information being disseminated both by FDA and by the entities we regulate (manufacturers and distributors of medicines and devices) is appropriately reaching our targeted audiences in an understandable fashion. This is not just a matter of determining whether the public is satisfied with FDA's communications-related performance, but whether the public receives and understands the information and incorporates it into their belief structures. Unless the public is able to employ FDA communications to make appropriate choices, FDA will not be serving the public as mandated.

Recently, FDA has been criticized for both delaying disclosure and disclosing too soon the existence of newly detected serious unexpected side effects from the use of certain prescription drugs. Information disclosed to the public about these new and often still emerging and uncertain risks often does not include the context needed for the public to understand fully the limitations of the data behind the public warnings. Despite this, some feedback suggests the

public wants such information at even earlier stages of FDA deciding whether side effects are associated with particular drug use. In fact, the Food and Drug Administration Amendments Act of 2007 includes a requirement for FDA to disclose information about possible new risks at very early stages of investigation of the possibility that risks exist. Yet other feedback, especially from prescribers, suggests that early disclosure may have unintended negative outcomes for patient care. Research has not focused on the impact of the increasingly public disclosure of this relatively uncertain information on physicians and patients, physicians' practices, and the physician-patient relationship.

Communicating effectively about FDA-regulated products involves conveying complex concepts. FDA recognizes that public health education involves more than ensuring the accuracy of product labeling; the agency must also communicate the context of messages to ensure that the words make sense to targeted audiences. For example, in reviewing certain premarket submissions, FDA determines that a product is safe and effective. But that decision is made within a specific legal context, which is that the product meets the legal standard of safe and effective for its labeled or intended use—to read either word as an absolute would be misleading. Whether the public fully understands the ramifications of the legal context within which approvals are made is questionable.

The public also may not understand the significance of the context within which FDA makes decisions about recalls or warnings concerning medical products. Recent studies demonstrate how little consumers know about either statistics or the factors that enter into regulatory decision-making. Consequently, when consumers hear about a newly identified risk associated with a medical product they use, they will not likely process this risk within the context of either the benefits of continuing use of the product, or the risks of stopping use of the product. Thus, even though FDA believes it has objectively informed consumers, their lack of an appropriate cognitive model in which to place this information means that it is likely they have not been effectively informed. Consumers need to understand the closely associated concepts of risk and benefit, as well as each person's role in managing the risks of using FDA-regulated products. This understanding will enable consumers to act in an informed manner in relation to products coming on the market, as well as products being examined for possible revisions to their conditions of approval, or for possible removal from the market.

Finally, there is a natural tension that results from communicating what we know from research about a product's risks and benefits. In research, scientists collect evidence for a population: summary risks and benefits are therefore accurate for a population in general, but may not be so for a specific individual, who may react differently than the "average" individual.

FDA requests OMB approval for conducting parallel surveys of 1,500 noninstitutionalized U.S. adults. One survey of 1,500 subjects will be a telephone survey, and the second survey of another 1,500 subjects will be conducted with members from an Internet survey panel. The annual respondent burden is calculated at 1,428 hours. This information collection has undergone rigorous review by FDA's Research Involving Human Subjects Committee (RIHSC), senior leadership in the Office of Planning, and Paperwork Reduction Act Specialists.

A.2. Purpose and Use of the Information Collection

FDA's Strategic Plan for Risk Communication (announced by the Commissioner in the fall of 2009) calls for this survey to assess the general public's understanding of, and satisfaction with, FDA communications about medical products, and to provide a template for regularly surveying significant FDA target audiences. The information collected will be used by FDA in the development of more effective risk communication strategies and messages. FDA recognizes that these surveys should only be used for internal purposes (e.g., to better understand consumer perceptions).

The surveys will provide FDA insight as to how well the public understands and incorporates risk/benefit information into their belief structures, and how well the public understands the context within which FDA makes decisions on medical product recalls and warnings. Specifically, the surveys (Attachments 3 and 4) will address the research questions listed in Table 1.

Table 1.
Research Questions and Corresponding Survey Items

Research Question	Survey Items	
	Internet Panel	**Telephone**
What is the public's understanding about the benefits and risks of medical products and FDA's role in regulating these products?	2, 3, 13, 19	8, 9, 19, 25
What are common behaviors and beliefs related to the use of medical products (e.g., taking more or less of prescribed daily dose, reading labels)?	4-12, 20-27	10-18, 26-33
When do consumers desire emerging risk information?	14, 15	20, 21
What is the likelihood of consumers reporting serious side effects that might be associated with medical product use?	16-18	22-24
What are consumer perceptions of the credibility of FDA and other potential sources of risk and benefit information?	30, 31	36, 37
How satisfied are consumers with FDA's communications-related performance?	28, 29, 32-37	34, 35, 38-43

Using this information, the agency will more effectively design messages and select formats and distribution channels that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way. Survey findings will be considered by FDA's newly established Risk Communication Advisory Committee in its evaluation of the agency's campaign to provide consumers with the context they need to better understand new, and often uncertain, risk information.

This study will provide insight into the best methodology for future surveys of non-institutionalized adults. Results from the telephone survey will be compared to results from the Internet survey in an effort to validate the quicker and less expensive Internet-based survey methodology.

FDA plans to seek future OMB approval to conduct additional survey administrations to build upon the findings of this study, and to track the agency's communications-related performance over time. Future studies will include questions from this survey that focus on the understandability and usefulness of FDA communications. Specifically, questions related to Drug Facts labels on over-the-counter products, Consumer Medication Information that accompanies prescription drugs, Consumer Update articles, and other materials on the agency's website will provide FDA with trend data as it continually looks to improve these communications. Future survey administrations would also allow FDA to trend satisfaction with its communication performance, including timeliness, transparency, and perceptions of the agency as a source for health-related information. Future studies will not necessarily include all questions from this initial survey. While questions related to general perceptions of medical product risks and benefits will provide FDA with insight to consumers' belief structures and help validate findings from other qualitative studies, they are not intended to track communications over time. Future surveys would be conducted bi-annually at most, allowing at least a year in between survey administrations to carefully consider the results and make changes in communication messages and channels.

A.3. Use of Improved Information Technology and Burden Reduction

The information will be collected through Computer-Assisted Telephone Interviewing (CATI) and an Internet panel survey. These two types of computer-assisted information technology will be used to transmit data collection instruments, collect responses, and process data in a maximally efficient way to reduce the burden on respondents. Closed-ended questions (e.g., multiple-choice items, Likert scales) will be employed whenever possible.

Computer-Assisted Telephone Interviewing (CATI)

The telephone survey is well suited to the use of computer-assisted telephone interviewing technology. CATI's technological capabilities include automated dialing, scheduling unanswered calls or interrupted interviews for efficient callbacks, random selection of respondents, automated skip patterns, instantaneous out-of-range checks, insertion of information from one question to guide a subsequent question, and the automated generation of databases for subsequent analysis. In addition to calling possible participants, the proposed research includes lead letters notifying possible participants of the survey and providing them with a toll-free telephone number to schedule a convenient time to take the survey. CATI systems can track if a participant called in response to a letter or if a survey telephone interviewer initiated the contact.

Internet Panel Survey

With Web-based surveys, respondents complete an on-line survey and then submit the data electronically over the Internet. Web respondents can access and respond to the survey at a time and place that is convenient to them. Data collection for an Internet survey often requires less time and expense than a comparable telephone survey.

A.4. Efforts to Identify Duplication and Use of Similar Information

FDA continuously reviews existing literature related to risk communication and the products it regulates. FDA has had extensive contact with private and public organizations, and regularly consults experts who serve on FDA's Risk Communication Advisory Committee. FDA is unaware of available data similar to that proposed in this data collection.

A.5. Impact on Small Businesses or Other Small Entities

These proposed data collection activities do not impact small businesses or other small entities. These activities focus on people in their roles as individuals during their own time.

A.6. Consequence of Collecting the Information Less Frequently

It is essential for FDA to understand the basic needs of its diverse audiences. Unless the public is able to effectively use FDA communications to make appropriate choices, FDA will not be serving the public as mandated. FDA looks to strengthen the science that supports effective risk communication by using this research to help assess the effectiveness of its current communications and guide the development of future communications.

Communicating effectively about the risks and benefits of medical products involves conveying complex concepts. Without research, FDA cannot fully ensure that its messages are serving their intended purpose. As a result, FDA could be spending millions of dollars on communications that are ineffective in providing consumers with the context they need to better understand new, and often uncertain, risk information. FDA recognizes that risk communication requires more than ensuring the accuracy of product labeling. FDA must effectively assess whether its communication messages are appropriately reaching targeted audiences in an understandable fashion and being incorporated into their belief structures and their behaviors. Continued research is needed to assess the relevance of such messages given dynamic social and environmental factors and the changing education and information needs of the public.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of the information.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of October 5, 2010 (75 FR 61490; Docket No. FDA-2010-N-0502). No comments were received.

FDA took steps to consult experts outside the agency by sending the 60 day notice and a draft questionnaire to its Risk Communication Advisory Committee (RCAC) members on December 21, 2010. FDA welcomed comments on the practical utility of the information to be collected.

FDA received feedback about specific questionnaire items from one RCAC member and edited the questionnaire to adequately address his concerns.

A.9. Explanation of Any Payment or Gift to Respondents

No incentives are planned for the telephone survey. However, as standard practice for Internet panels, non-specific survey incentives will be used to maintain a high degree of panel loyalty and to prevent attrition from the panel. For the households provided Internet appliances and an Internet connection, their 'panel loyalty' incentive is the hardware and Internet service that is provided. For households using their own personal computers and Internet service for survey participation, panelists are credited with points in proportion to their regular participation in surveys. Panelists receive currency credits that can be used for purchasing items (e.g., magazine subscriptions) or periodically receive cash-equivalent checks in amounts reflecting their level of participation in the panel, which commonly results in distributions in the range of $4 to $6 per month.

A.10. Assurance of Confidentiality Provided to Respondents

All data collection and analysis will be performed in compliance with OMB, Privacy Act, and Protection of Human Subjects requirements. Information provided by respondents will be kept private to the extent permitted by law. This will be communicated to respondents by means of notification letters, explanatory texts on the introduction to the Web survey, and scripts read prior to telephone interviews. Respondents will also be advised of the nature of the activity, the purpose and use of the data collected, FDA sponsorship, and the fact that participation is voluntary at all times.

The Contractor will comply with safeguards for ensuring the privacy of data. The Contractor shall destroy all records relating to the personal identity of the participants prior to forwarding any data to FDA. All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy, all presentation of data in reports will be in aggregate form, with no links to individuals preserved. Reports will be used only for research purposes.

FDA's IRB, the Research Involving Human Subjects Committee, have considered this data collection to be exempt from the "Regulations for the Protection of Human Subjects" in accordance with paragraph (b)(2) of 45 CFR Sec. 46.101 (Attachment 6).

A.11. Justification for Sensitive Questions

The surveys do not ask sensitive questions. Demographic questions about race/ethnicity, age, gender, education, and health status are included for the purpose of weighting and tabulating the data collected. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

All results will be reported in the aggregate. Raw data are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval. Again, respondents are assured that the information is voluntary and will be treated as private to the extent permitted by law.

A.12. Estimates of Annualized Burden Hours and Costs

Estimates are based on FDA's and the Contractor's knowledge of previous surveys. For a comparable phone methodology, CDC's 2009 REACH Survey used Addressed-Based Sampling. Where CDC reported a 60% match of addresses to telephone numbers, the Contractor more conservatively estimates 50% for this survey. Although FDA expects most people to have used a medical product in the past 3 months, it conservatively estimates that 75% will be eligible for the survey (which is higher than REACH). Assuming a 45% completion rate (similar to REACH), the Contractor will achieve the goal of 1,500 completed telephone surveys. For a comparable Web methodology, the Experimental Study of Graphic Cigarette Warning Labels that RTI conducted for FDA using Research Now, the proposed website vendor, obtained a 43% response rate from adult smokers (aged 18+) from their Internet panel. Although response rates for Internet panel surveys can vary widely, FDA thinks that interest in this survey on medical products will similarly have broad appeal to most consumers/users.

Prior to administering the surveys with the entire sample, FDA plans to conduct pretests with up to 30 adults (15 telephone and 15 Web) to evaluate the effectiveness of the programming of the interview protocol, online filters, and skip patterns. FDA estimates the burden of this collection of information as follows:

Table 2.
Estimated Annual Reporting Burden

Type of Response	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)[1]	Total Hours
Pretests	30	1	30	15/60	8
Screener	6,700	1	6,700	6/60	670
Telephone survey	1,500	1	1,500	15/60	375
Internet panel survey	1,500	1	1,500	15/60	375
Total					**1428**

[1] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No capital or start-up costs will be incurred as a result of these information collection activities.

A.14. Annualized Cost to the Federal Government

Costs include contractor expenses of $355, 492 for questionnaire development and testing, drawing survey samples, training interviewers, questionnaire programming and data collection, and preparing reports and survey data. In addition, government staff costs may be incurred for monitoring by the government Project Officer and Senior Analyst, projected to be about 25% of an FTE's time per year (522 hours). Given an FDA personnel cost of $48.35 per hour, $25,238.70 would be spent annually on government staff salaries.

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Presentation of results will describe the data as exploratory and descriptive, but, due to the purposeful nature of the statistical sample, cannot be generalized to the U.S. population. Using the quantitative data collected, descriptive statistics—including percentages, cross tabulations, and averages—will be calculated and presented, along with demographic descriptions of study respondents. Information collected from study participants will be subjected to subgroup analyses to uncover potential differences among key groups (defined by gender, age, race/ethnicity, etc.). Statistical analyses may be conducted using cross-tabulation procedures with categorical variables (e.g., chi-square) and between-group procedures with continuous variables (e.g., ANOVA and t tests). Parametric statistical tests will be used in the case of sufficient sample sizes, normal distributions, and continuous or interval data; non-parametric procedures will be used otherwise.

FDA makes survey results available to a variety of health program planners at Government agencies, voluntary organizations, health professional organizations, and medical institutions. In addition, FDA may present the findings of its work at professional association meetings, including those of the American Public Health Association and Drug Information Association. Some results may be published in professional journals such as the Journal of Public Policy and Marketing.

The data collection will require approximately 22 weeks from survey programming to preparation of data and reports. A project time schedule is shown below:

Project Time Schedule

Activity	Time Schedule
Finalize survey programming	5 weeks after OMB approval
Collection of data	12 weeks after OMB approval
Delivery of data, codebook, and methods report	19 weeks after OMB approval
Delivery of tabulated data	22 weeks after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The data collection will consist of parallel surveys of 1,500 noninstitutionalized U.S. adults (3,000 total respondents) that will take no more than 15 minutes to administer. FDA contracted with Research Triangle Institute (RTI) to conduct these surveys.

The proposed sample size will result in a 95% confidence interval of (0.473, 0.526), for a proportion equal to 0.50, assuming a design effect of 1. That is, FDA will have 95% confidence that the corresponding true population value will lie between 0.473 and 0.526 if the sample estimate is 0.50. This calculation accounts only for sampling variance and does not incorporate bias and other sources of error.

For both the telephone and Internet panel surveys, the Contractor will use a sample selection procedure that results in a sample that is similar to the population within the United States with respect to age, gender, geographic distribution, and race/ethnicity. Participants will be recruited according to the screener criteria asked in the first items of the surveys; respondents must (a) have themselves used either over-the-counter (OTC) drugs, prescription drugs, medical devices, or biologics within the past three months, or (b) been the primary caregiver for a family member who has used such medical products within the past three months.

B.2. Procedures for the Collection of Information

The telephone survey will use an Address-Based Sampling (ABS) methodology. ABS improves the telephone survey's reach beyond that of a traditional Random Digit Dial (RDD) methodology by minimizing the risk of systematic exclusion of households from the survey sample. In addition to including households with a landline telephone number on record, ABS will be used to also include households that are cell phone-only. Results from the 2006 National Health Interview Survey suggest that one out of every eight American adults live in cell phone-only households. The percentage of cell phone-only households is highest among younger adults (25% of 18 to 24 year olds, and 29% of 25 to 29 year olds). Results also indicate lifestyle differences. For example, cell phone-only adults are more likely to be current smokers than adults living in households with a landline (30% vs. 19%).[1] Given the known differences in demographics and lifestyle preferences between cell phone-only and landline adults, ABS offers a way to reduce this potential problem of coverage bias. ABS will also include households that do not have a phone number on record.

For the telephone survey, the Contractor will send an initial mailing (Attachment 7) to the entire telephone survey sample (approximately 30,000 households), providing a toll-free telephone number to call to take the survey. The Contractor expects to answer calls from a few hundred potential call-in respondents. The majority of responses will come from records with attached

[1] "Wireless Substitution: Early Release of Estimates Based on the National Health Interview Survey, July – December 2006. (PDF)" Blumberg, Stephen J., and Julian V. Luke. May 14, 2007a. Report by the U.S. Centers for Disease Control and Prevention.

telephone numbers where the Contractor will have trained interviewers call households to conduct the survey. The contractor will use computer-assisted telephone interviewing (CATI) to complete the interviews. The Contractor shall send a second mailing (Attachment 8) to nonresponding addresses not matched to a phone number to further solicit their participation.

The Internet panel will be constructed by filling quotas in a number of key subpopulations defined by various demographic and socioeconomic variables. The goal will be to make the sample resemble the U.S. population with respect to these variables. The online data collection vendor will use a recruitment methodology that invites pre-validated individuals to participate in its Consumer Panels. In order to supply a sample of both the general population and hard-to-reach audiences, the Internet panel members will be recruited from a diverse set of consumer and business-to-business sources using a "by-invitation-only" approach. This means that the online data collection vendor will be able to control and manage the demographic make-up of the panel "up front" and send an invitation email (Attachment 9) to only the types of individuals that fit the current normalization needs of the panel. The online data collection vendor will send one email reminder (Attachment 10) to Internet panel nonrespondents to further solicit their participation. These panel establishment methodologies are fully compliant with CASRO guidelines.

Both the telephone and Internet panel survey samples will be decomposed into random subsamples or replicates and these replicates will be released such that completed interview targets are achieved without unduly affecting the response rate. Once a replicate is released it will be completely worked in the field until nonresponse conversion attempts are exhausted.

The Contractor will program the Internet panel questionnaire to be a self-administered online survey that is consistent with the telephone survey. Access to the online survey shall be controlled through a process of enrollment and ID/password distribution. The ID/password are built into the landing page URL to enter the survey. The respondent clicks the URL in the survey invitation e-mail to enter the Contractor landing page. From the landing page, the respondent clicks a link to enter the survey. The telephone and Internet panel surveys will include parallel content, with only minor differences to assist telephone respondents in their comprehension of the questions and recall of response options.

For both surveys, professionally recognized procedures will be followed in each information collection activity to ensure high quality data. Examples of these procedures include the following:

- The telephone survey will be monitored both visually and audibly by supervisory staff during all shifts;
- After a small amount of live completed data is gathered (usually no more than 25 completes), early data validation will be conducted and periodic checks will continue throughout the study;
- Data submitted through on-line surveys will be subjected to statistical validation techniques (e.g., disallowing out-of-range values, detecting persons who complete the survey outside the expected time range).

The final data for both samples will be weighted independently to adjust for unequal probabilities of selection, variable nonresponse, and overall poststratification that brings in line the weighted sample distributions with known corresponding population distributions.

B.3. Methods to Maximize Response Rates and Deal with Non-response

The Contractor for the online data collection will recruit approximately 14,000 individuals, Experience with online experimental studies suggests that about 15% of those who are sent survey invitations will complete a study. The Contractor for the telephone survey will send recruitment letters to approximately 30,000 possible participants, receive calls to a toll-free number provided in the survey, and call households to which a telephone number can be matched. It is estimated that 75% to 80% of the persons reached by phone will complete the survey.

Past experience has shown that the proposed amount of over-recruitment generally ensures a respectable response rate. FDA believes that the issue of medical product safety will be of high interest to the public and that they will consequently be very interested in participating in the survey. Nonetheless, RTI will conduct a non-response analysis to determine whether there are significant differences between those who agreed to participate and those who did not.

The Contractor has conducted cognitive interviews with nine members of the public to help improve understandability of the questionnaire, reduce participant burden, and enhance interview administration. The Contractor will also implement several procedures proven effective in previous studies to maximize response rates:

- Potential respondents will be informed about the importance of these studies and encouraged to participate.
- Lead letters will be sent to telephone survey sample members. A second mailing will be sent to nonresponding addresses not matched to a phone number.
- A dedicated toll-free number will be established by the Contractor to allow potential telephone respondents to confirm the study's legitimacy and take the survey.
- Interview staff will be able to provide respondents with the name and telephone number of an official at FDA. This official will confirm with respondents the importance of their participation.
- Experienced, highly-trained staff will conduct all telephone interviews. Training topics will include study objectives, question-by-question reviews of data collection instruments, strategies for engaging respondents, and techniques for fostering respondent cooperation and survey completion.
- For telephone interviews, up to 20 call-backs will be made to encourage participation. Outgoing calls that result in a disposition of no answer, a busy signal, or an answering machine will be automatically rescheduled for subsequent attempts. Up to 20 outgoing calls to a given number with dispositions of the sort listed will be made before declaring it a non-response.
- Well-defined conversion procedures will be established. If a respondent for a telephone survey declines to be interviewed, a member of the contractor's conversion staff will

contact the respondent to explain the importance of their participation. Conversion staff are highly experienced telephone interviewers whose style and persuasive abilities have demonstrated success in eliciting cooperation. They receive a pay differential to acknowledge these skills, which also serves as an incentive to the interviewer pool, whose completion rates are carefully monitored to assess their qualifications to serve as conversion staff.

- The surveys are designed to be completed in a reasonable amount of time (15 minutes) to minimize break-offs.
- Should a respondent interrupt a survey for any reason, such as needing to attend to a personal matter, the respondent will be able to continue at a later time. For the telephone survey, the interviewer will reschedule or have a predictive dialer automatically reschedule the interview for completion at a later time. For the Internet panel survey, the respondent will be allowed to continue by clicking the same link they utilized to open the survey. The study will be available for respondents to continue up until the time the survey is closed or reaches its quota.
- An invitation email will be sent to Internet panel survey sample members. Nonrespondents will receive one e-mail reminder from the online data collection vendor requesting their participation in the survey.
- Fielding of the surveys will occur over at least a 1 to 2-week period for the on-line version of the survey and data collection for the telephone survey will take place over a 5 to 7 week period to allow sufficient time for the lead letters to be delivered by the U.S. Postal System and increase the waiting times in between call attempts, which typically increases the response rate (i.e., the up to 20 call attempts are spread out over time). Based on past experience, this time frame will allow the contractor to reach individuals who are on vacation, out of the home during irregular periods, have a temporarily disconnected telephone, or who are not answering the phone for some other reason.

B.4. Test of Procedures or Methods to be Undertaken

The Contractor has conducted cognitive interviews with a total of nine members of the public to get feedback on the survey content. The face-to-face interviews were conducted with adults (18 years or older) that differed in age, gender, and education. This feedback from the public was used by FDA to evaluate and refine the draft questionnaire, helping to ensure survey questions and response options are understandable and appropriate.

The Contractor will also pretest the telephone and Web survey administration methods prior to implementing the main study. Pretesting will help evaluate the effectiveness of the programming of the interview protocol, online filters and skip patterns. Thirty pretest participants will be randomly drawn from the sample populations (15 randomly dialed and 15 from the Internet panel).

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Karol Krotki (RTI) will be responsible for the design of statistical and sampling procedures undertaken as part of these data collection activities. Brian Lappin (FDA) and Michael Burke (RTI) will be responsible for the tabulation and analysis of data collected.

C. ATTACHMENTS

1. The Federal Food Drug and Cosmetic Act, Section 1003(d)(2)(D)
2. Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4))
3. Internet Panel Questionnaire
4. Telephone Questionnaire
5. 60-Day Federal Register Notice
6. Statement of Exemption from 45 CFR 46
7. Initial Letter to Telephone Sample Members
8. Second Letter to Nonresponding Addresses Not Matched to a Phone Number
9. Initial Email to Internet Panel Sample Members
10. Second Email to Nonresponding Internet Panel Sample Members