Request for OMB Review

Supporting Document

Health and Diet Survey? 2004 Supplement

Submitted by

Consumer Studies Team
Division of Market Studies
Office of Scientific Analysis and Support
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services

SUPPORTING STATEMENT

HEALTH AND DIET SURVEY? 2004 SUPPLEMENT

BY
FOOD AND DRUG ADMINISTRATION

An Information Collection Request is submitted by the Food and Drug Administration (FDA) for the Health and Diet Survey? 2004 Supplement. The proposed collection of information consists of telephone interviews of a nationally representative sample of approximately 2,000 adults in the 50 states and the District of Columbia. Data from the survey are necessary to establish baseline outcome measure of one of the agency's long-term goals: to better consumer understanding of the relationships between dietary fats and the risk of coronary heart disease. Data will also be used to enhance the agency's understanding of consumer attitudes toward diet and health in order to explore effective communication strategies that help consumers make informed dietary and lifestyle choices.

A. JUSTIFICATION

A1. Need for the Collection of Information

The need for this collection of information derives from the agency's objective to obtain current, timely, and policy-relevant consumer information to carry out its statutory functions. The FDA Commissioner is authorized to undertake this collection under 21 USC 393 (Attachment A).

As a public health agency, FDA helps consumers make informed dietary decisions by regulating nutrition information in food and dietary supplement labels, initiating its own consumer education activities, and collaborating with public and private entities in conveying nutrition information to consumers. These activities are aimed at influencing consumer awareness, understanding and behaviors related to diet and nutrition and ultimately health outcomes of the Nation.

Recently, FDA Commissioner Mark McClellan announced the *Improving Healthcare through Better Information* initiative to provide information to consumers that enable them to make prudent decisions regarding the use of FDA-regulated products including foods and dietary supplements. Under this initiative, FDA plans to review and to promote, among other things, inclusion on food labels and restaurant menus information about potential benefits of unsaturated fats, such as monounsaturated, polyunsaturated and omega-3 fatty acids, on the risk of heart disease. In addition, FDA is requiring the mandatory declaration in food

and dietary supplement labels of the amount of *trans* fatty acids. The agency also intends to promote, through product labeling and nutrition education, consumer understanding of the health effects of cholesterol-raising lipids such as saturated fat and *trans* fatty acids.

Under this initiative, the agency has established specific targets to help improve consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of heart disease, the leading cause of premature death and permanent disability in the United States. Specifically, the targets call for incremental increases in the percentage of consumers who correctly identify that cholesterol-raising (cholesterol-lowering) lipids increase (decrease) the risk of heart disease. These targets are directly in line with several of the Department of Health and Human Services' priorities and strategic goals. FDA intends to evaluate and track consumer understanding of the relationships between cholesterol-raising and cholesterol-lowering fats and the risk of heart disease as initial outcome measures of its achievement in progressing toward the said targets.

Nevertheless, the agency lacks baseline information that clearly demonstrates the current levels of consumer understanding. To develop baseline and follow-up data, FDA has identified the Health and Diet Survey as a valid and reliable source of information to evaluate the impact of the Agency's labeling and education activities. Data from this proposed survey and subsequent surveys will be used to develop performance indicators, per Office of Management and Budget's *Program Assessment Rating Tool (PART)* system, to identify and measure incremental improvement in consumer understanding.

Thus, the primary goal of this survey is to establish a baseline of the above-mentioned performance indicators before any new labeling and education initiatives take place. The agency plans to repeat the questions on consumer understanding of dietary fat-heart disease relationships in future Health and Diet Surveys as PART performance indicators.

The secondary goal of this survey is to increase the agency's knowledge of consumer understanding of dietary fat-heart disease relationships and knowledge of their dietary and health attitudes. In order to have a better understanding of why responses to the outcome questions differ among consumers and to be able to design effective consumer education messages, the agency also plans to include in the survey a series of questions on consumer attitudes toward diet, physical activity, and health.

For example, the agency plans to ask how strongly consumers agree with the statement that "what they eat or drink makes a difference in their chance of getting cancer or heart disease." The question is adopted from the U.S. Department of Agriculture 1994-6 Diet and Health Knowledge Survey. Data from the USDA survey suggest that the more a consumer agrees with the

statement, the more likely he (1) thinks nutrition is important in food buying, (2) reads various parts of the food label, (3) looks for nutrient information on the food labels, and, (4) thinks using the food label is better than relying on his own knowledge in food selection. These results in turn suggest that the consumer is more nutrition-conscious and more motivated to look for label information and other information which may include educational messages put out by the agency. Hence, it is more likely that he will have heard of, say, *trans* fat and its relationship with heart disease. These results also suggest that educational messages about the effects of diet on disease risks can potentially increase consumer motivation to read food labels and use information on the labels.

The planned survey also includes several questions aimed at enhancing understanding of current consumer sentiments toward physical activity (e.g., "I am confident that I know how to get enough exercise"), dietary recommendations (e.g., "The amount of calories I eat or drink has more influence on my weight than the amount of fat I eat or drink"), and dietary habits (e.g., "To maintain or control my weight means I have to give up my favorite foods.") Answers to these questions can help reveal the strength of motivation toward healthier lifestyle behaviors, particularly the psychological barriers that may prevent adoption or maintenance of healthier lifestyle behaviors. The information should be helpful to the agency for its deliberation of the focuses and contents of educational messages.

Moreover, the proposed survey includes several questions with the objective of understanding consumer attitudes toward restaurant nutrition information, e.g., "I generally know which fast food items have more calories or fat and which have less calories or fat." These questions can help gauge need for menu labeling and consumer motivation toward looking for and using nutrition information on menus.

The proposed survey also asks consumers about their knowledge of carbohydrate and related topics. With the increasing popularity of carbohydrate diets and food products, there has been a proliferation of label statements about a food's carbohydrate profile. As a result, the agency needs better knowledge of the current level of consumers' understanding and perception of carbohydrate and label information. This knowledge will help the agency identify needs for and develop communication strategies and consumer education programs. Nevertheless, the agency is not aware of any existing source of data that can provide the needed information.

Without this collection of information, the agency will lack baseline information that clearly demonstrates the current levels of consumer understanding of the relationship between consumption of dietary fats and the risk of heart disease. The lack of information will severely limit the agency's capabilities in performing its functions properly. The lack of other information will also hinder the agency's

ability to develop education programs and regulatory policies that help consumers make informed dietary and lifestyle choices.

A2. Purpose and Use of the Information

A2.1 Purpose of Information

The primary purpose of the information collection is to establish baseline indicators of FDA performance in achieving the long-term goal of raising consumer understanding of the relationships between dietary fats and the risk of heart disease. The secondary purpose is to increase the agency's understanding of consumer dietary and lifestyle attitudes to facilitate development of effective communication strategies to help consumer make informed dietary and lifestyle choices.

A2.2 Users and Use of Information

A.2.2.1 *Information items.* The instrument proposed for this collection of information (Attachment B) includes the following topics.

- Understanding of the relationships between the risk of heart disease and dietary fats, including saturated fat, *trans* fatty acids, hydrogenated oil,[1] omega-3 fatty acids, monounsaturated fatty acids, and polyunsaturated fatty acids.
- Attitudes toward diet, health, physical activity, and carbohydrate and related topics.
- Demographics and health status
  - Additional phone numbers
  - Household size and composition
  - Age
  - Education
  - Race and ethnicity
  - Height and weight
  - Perceived weight status
  - Presence of chronic illnesses
  - Household income.

A.2.2.2 and A.2.2.3 *Users and use of the information*. The users and use of collection information are expected to include:

[1] Most products that contain *trans* fatty acid already list its source, hydrogenated oil or partially hydrogenated oil, in their ingredient lists, even without disclosing the amount of *trans* fatty acid in the Nutrition Facts panel. Some consumers may be more familiar with hydrogenated oil or partially hydrogenated oil than with *trans* fat or *trans* fatty acid. Thus, in addition to *trans* fatty acid, it is also useful to know the level of understanding of the relationship between hydrogenated oil and the risk of heart disease.

?? Office of the Commissioner, as a baseline PART indicator of consumer understanding of the relationships between dietary fats and the risk of heart disease;
?? Center for Food Safety and Nutrition (CFSAN), FDA, as background information in exploring and deliberating effective communication strategies and consumer education, and in developing consumer research.

A2.3 Plan of Analysis

A2.3.1 *Purposes of analysis*. To develop a baseline PART indicator and to understand consumer attitudes.

A2.3.2 *Analytical approach*. To develop the indicator, descriptive analyses such as frequencies and proportions are planned for the dietary fat-heart disease information. To understand consumer attitudes, a variety of descriptive and relational analyses are planned, such as (1) distribution of individual variables (i.e., information items) such as frequencies and proportions, (2) cross-tabulations to characterize target variables by categories of classification variables, for example, an attitude item by demographic characteristics, and (3) regressions to identify and measure the associations between target variables and other variables of interest.

A3. Use of Information Technology

The telephone interviewing methodology proposed for this collection of information is the most cost-effective approach to acquiring the needed information. The survey will be administered using a Computer Assisted Telephone Interviewing (CATI) system, since this methodology will minimize possible errors of administration and expedite the timeliness of data processing. Compared to face-to-face interviews, telephone interviews are less intrusive and less costly. Mail surveys are not appropriate for a questionnaire with complicated skip patterns as used in this collection of information. In addition, mail surveys generally have a much lower response rate than telephone surveys.

A4. Efforts to Avoid Duplication and Why Available Information Cannot be Used

The agency conducted a thorough literature review to identify extant, accessible, and similar information that could serve the agency's purpose and needs. Since the primary goal of this collection of information is to establish baseline PART indicators, any existing information would satisfy the agency’s needs if it is nationally representative, and it (1) provides comparable and consistent measures of baseline PART indicators as well as (2) can be expected to provide follow-up PART indicators in the future.

The agency located three surveys that provide nationally representative estimates related to the PART indicators. The agency has concluded that none of the surveys can be used for the purpose of this collection because one or both of the criteria above are not met. Nevertheless, the available information has provided a foundation on which the design of this collection was based.

?? FDA Health and Diet Surveys (HDS)

Major deficiencies: Previous HDSs do not provide comparable and consistent information on PART indicators.

With respect to dietary fat-heart disease relationships, the 2002 and 1995 Health and Diet Survey (HDS) asked about *trans* fat. Respondents were first asked "have you heard of *trans* fatty acids, also called *trans* fat?" and those who answered affirmatively were then asked "do *trans* fatty acids raise blood cholesterol, lower blood cholesterol or have no effect on blood cholesterol?"

However, these surveys provide a less clear picture concerning other fats, because of the wording of the questions. For example, a question asked "have you heard about different kinds of fat, like saturated fat and polyunsaturated fat," and its follow-up question asked "which kind of fat is more likely to raise people's blood cholesterol level, saturated fat, polyunsaturated fat, both, or neither?" Because both saturated and polyunsaturated fats are talked about in these questions, and the fat-cholesterol relationships were not asked in the same manner as was for *trans* fat, it is more difficult to generate from these surveys comparable information on saturated fat or polyunsaturated fat as on *trans* fat. In addition, omega-3 fatty acid was never asked in previous HDSs.

?? 1999 Discovery Health Pulse survey

Major deficiencies: It does not provide comparable and consistent information on PART indicators and timing of future surveys is indeterminate.

This survey asked a series of questions about whether each of monounsaturated fat, omega-3 fatty acids, partially hydrogenated oil, and saturated fat "protects against illness, contributes to illness, or neither protects or contributes to illness."[2] But the survey did not ask about polyunsaturated fat or *trans* fat and the focus of the questions was on illness which is unspecific and likely to be understood to include diseases other than heart disease, or the target of PART indicators. Furthermore, it is not clear whether or when the sponsor of the survey (Discoveryhealth.com) would ask these questions again.

?? 2001, 2002, and 2003 United Soybean Board Consumer Health Tracking surveys

[2] Discoveryhealth.com. 1999. *Discovery Health Pulse: Top-line Poll Results.*

Major deficiencies: It does not provide comparable and consistent information on PART indicators and timing of future surveys is indeterminate.

The survey asked about the perceived healthfulness of *trans* fatty acids, hydrogenated vegetable oils, saturated fats, polyunsaturated fats, monounsaturated fats, and omega-3 fatty acids. Nevertheless, as with the Discovery Health Pulse survey, the focus of the questions? unspecified healthfulness of a fat/oil? is not compatible with the agency's target. Also, the agency cannot predict whether or when the United Soybean Board would ask these questions again.

A5. Methods to Minimize Burden on Small Business

The collection of information will not involve small business.

A6. Consequences to the Agency's Program or Policy Activities if the Collection is not Conducted

Without this collection of information, the agency will not be able to establish baseline indicators of performance in achieving the long-term goal of raising consumer understanding of the relationships between dietary fats and the risk of heart disease.

A7. Special Circumstances

This collection of information fully complies with 5 CFR 1320.5. There are no special circumstances.

A.8 Public Comments and Consultation Outside the Agency

With this request, FDA is requesting for, per 5 CFR 1320.8(d), public comments on the proposed collection of information in the Federal Register of February 18, 2004 (Appendix C). No comments were received.

Prior to this submission, the agency has consulted with non-FDA experts about the proposed questionnaire and has conducted a cognitive interview to refine the proposed questionnaire. The agency has considered and, when appropriate, incorporated in the attached information collection instrument feedbacks from non-FDA experts and the cognitive interview.

The following subject matter and survey research experts were consulted regarding the availability of information, the information items to be collected, the clarity of instructions, and the methodological approach for the data collection.

1. Sharon Mickle
Food Surveys Research Group
Agricultural Research Service
U.S. Department of Agriculture
Beltsville Human Nutrition Research Center
10300 Baltimore Avenue
Building 005, Room 102, BARC-West
Beltsville, MD 20705-2350
Tel: (301)504-0341
E-mail: smickle@rbhnrc.usda.gov

2. Edwin Slaughter
Rodale, Inc.
33 E. Minor St.,
Emmaus, PA 18098-0099
Tel: (610)967-0099
E-mail: ed.slaughter@rodale.com

3. Debra Trunzo
Office of Applied Studies
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 16-105
Rockville, MD 20857
Tel: (301)443-0525
E-mail: dtrunzo@samhsa.gov

4. Barbara Wilson, Beth Canfield, and Lisa Moses
The National Laboratory for Collaborative Research in Cognition and Survey Measurement
National Center for Health Statistics
Centers for Disease Control and Prevention
6525 Belcrest Road
Hyattsville, MD 20782
Tel: (301)458-4582
E-mail: bfw3@cdc.gov

[Responses to 60-day public comments to be inserted here.]

A.9 Payment or Gift to Respondents

Respondents will not receive any type of payment or gift for participation in this collection of information.

A.10 Assurance of Confidentiality and Basis of Assurance

Assurance of confidentiality of information will be provided to all respondents. A statement that "the information will be kept confidential" will be read before each interview. Confidentiality will be assured by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants.

Identifying information will not be included on the data files delivered to the agency. The data collection contractor has standard procedures for assuring the confidentiality of survey respondents. All of the contractor's employees sign a statement agreeing to maintain confidentiality of data. The data will be collected by a computer-assisted telephone interviewing system (CATI) and will be maintained in an automated information system. Access to the CATI files can only be gained through the use of a password which will be specific to this project. Telephone numbers will be retained only until validation and editing are complete; they will be stripped from the database before the data files are sent to the agency.

All electronic data will be maintained in a manner which is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

A.11 Sensitive Questions

The collection of information includes no questions of a sensitive nature.

A.12 Estimated Hour Burden of the Collection of Information

The estimated total hour burden of the collection of information is 490 hours (Table 1). The burden includes 27 thirty-minute interviews to pretest the final instrument (see B.4 for details on this activity). Based on the agency's experience with its previous consumer surveys, the agency estimates that 6,000 individuals will be screened, via a 1-minute (0.02 hour) screener, for eligibility to participate in the survey to achieve a planned sample size of 2,000 completed interviews. The estimated average reporting burden per screened and cooperative participant is 10 minutes (0.17 hours). An additional 200 eligible respondents who initially refuse to participate in the survey but agree upon re-contact ("initial refusers") will be asked a shorter (5 minutes or 0.08 hours in length) questionnaire. The shorter version will focus only on the understanding of the relationships between saturated fat, trans fat, and omega-3 fatty acids and the risk of heart disease. The agency plans to compare the outcome measures between cooperative respondents and "initial refusers." The annualized cost to all respondents for the hour burden for the collection of information is $6,370 at $13 per hour.

Table 1. Estimated Hour Burden

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	27	1	27	0.5	13.5
Screener	6,000	1	6,000	0.02	120
Survey	2,000	1	2,000	0.17	340
Survey ("initial refusers")	200	1	200	0.08	16
Total					490

A.13 Estimated Cost Burden to Respondents Excluding Estimates Shown in A.12 and A.14

All respondent burden is reflected in A12.

A.14 Estimated Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection $183,000. This estimate consists of (1) $143,000 for ? FTE of FDA professional staff to manage the project, analyze the data, and prepare reports and other informational products to be described in A.16, and (2) $140,000 for data collection.

A.15 Program Changes or Adjustments

There are no program changes or adjustments.

A.16 Project Schedule and Plan for Analysis

The planned schedule for the project activities is shown in Table 2.

Table 2. Project Schedule for the Health and Diet Survey – 2004 Supplement

Date	Activity	Audience
Within 5 days after receipt of OMB approval of collection of information	?? Notification to contractor to proceed with data collection activities	Not applicable
Within 135 days after notification to contractor	?? Completion of data collection	Not applicable
Within 165 days after notification to contractor	?? Delivery by contractor of final data files	Not applicable
Within 30 days after receipt of final data files	?? Delivery of preliminary summaries	FDA
Within 90 days after receipt of final data files	?? Delivery of a written final report of summaries and analytical findings	FDA

Following OMB approval, the data collection contractor will conduct pretests, draw the sample, collect the information, and prepare the deliverables in accordance with a Quick Turnaround Research Services contract. The duration of information collection, including pretests, is estimated to last no more than 135 days to allow (1) a 30-day lead time to for pretests, mailing advance letters, and preparing for field operations, (2) a 90-day field period to conduct interviews and to send conversion letters to initial refusals to encourage participation, and (3) a contingency of about 15 days. Data files and all other deliverables will be delivered to FDA within 165 days of written notification to the contractor that OMB approval has been granted.

The collected information will be verified, tabulated and reported as preliminary summaries within 30 days after the agency receives the final data files. A final report, including summaries and analytical findings, will be prepared within 90 days after the agency receives the final data files.

A.17 Displaying the OMB Approval Expiration Date

No exemption is requested.

A.18 Exceptions to the Certification Statement of OMB Form 83.I

No exceptions are requested.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Potential Respondent Universe

The respondent universe for this collection of information will be non-institutionalized adults 18 and older who reside in households with telephones in the 50 states and the District of Columbia. As of 1999, 94 percent of American households have telephone service.[3]

A response rate of 41 percent was achieved in the most recent Health and Diet Survey in 2002. The agency expects to achieve a similar or higher response rate in this collection of information. Measures to maximize the response rate will be discussed in Section B3.

B2. Procedures for the Collection of Information

B2.1 Statistical methodology for collection and sample selection

The survey will be conducted using computer-assisted telephone interviewing (CATI) technology. The interview will consist of two parts: the household screener and the core questions. The household screener will be used to locate eligible households and to identify a designated respondent (DR) as described below. Only one respondent per household will be interviewed.

Households will be selected using a Random Digit Dialing (RDD) procedure by employing GENESYS, a database-assisted sampling methodology. The GENESYS system uses a database of working residential telephone banks for the entire United States to produce a single-stage random sample of residential telephone numbers. RDD samples from the GENESYS system eliminate the reduction in precision caused by the multi-stage cluster designs of traditional RDD procedures. GENESYS samples are widely accepted because of their methodological rigor and efficiency.

The GENESYS database is constructed from three sources: a master list of area code-exchange combinations obtained from BELLCORE, a summary file of listed telephone numbers in the United States obtained from Donnelly, and a summary file obtained from CATI and other sources that cross-references zip codes to telephone exchanges. The telephone numbers in these sources are matched and analyzed to produce a database

[3] U.S. Census Bureau. 2003. Table 1103, *Statistical Abstract of the United States: 2002*. Washington, D.C.

of two-digit banks that contain at least 99 percent of the eligible telephone numbers in the U.S. (A two-digit bank consists of the first eight digits of a 10-digit telephone number within which up to 100 telephone numbers could be assigned, e.g. 123/456-78xx). The database is used to generate a random sample in which every telephone number, whether listed or not, has an equal probability of selection. The sample, unlike a traditional RDD sample, has no design effect associated with clustering of telephone numbers within telephone exchanges.

Identification of the DR will be achieved by the most recent birthday method. Once household eligibility has been established, interviewers will ask to speak with the adult household member who had the most recent birthday. The DR will be selected prior to any questions about at-home status or availability of potential DRs?, and no substitutions will be allowed. If the DR will be unavailable throughout the study period, the household will become ineligible.

Information will be collected by experienced and specifically trained telephone interviewers. Quality control will be assured by periodic monitoring of on-going interviews throughout the study. This monitoring replaces the previously used validation interview, which required maintaining the name and telephone number of the respondent until the validation interview could be completed.

B2.2 Estimation Procedure

Each interviewed person will receive a basic sampling weight equal to the reciprocal of his or her probability of selection. The basic sampling weight will account for multiple telephone numbers in households and household size. Households with more than one residential telephone number have a greater chance of selection; therefore, sampling weights will be adjusted by the reciprocal of the number of residential telephone numbers on which the household receives calls, excluding cell phone numbers. The weights will also reflect the differential probability of selection depending on household size. For example, a person living alone would be selected with certainty, whereas a person living in a household with four other adults would have a one in five chance of being selected.

To compensate for under-coverage and to reduce the mean square error of the estimates, the final base weights will further be adjusted to match most recent Census estimates for sex, education, age, and race/ethnicity.

B2.3 Degree of accuracy needed for the purpose described in the justification

For analyses of the full sample, the proposed sample size (2,000 adults) will provide a precision of approximately ± 1.3 to 2.2 percentage points at the 95 percent confidence level (Table 3). For analyses of subgroups, a standard error of ± 2.5 percentage points is usually acceptable. As shown in Table 3, this level of precision will also be achieved with the proposed sample size for major demographic classifications (e.g., age, gender, education, and race/ethnicity) as well as major subject-matter classifications of respondents (e.g., prevalence of the awareness of saturated fat-heart disease relationship). For instance, suppose the collected information from 2,000 respondents yields an estimate that 60 percent (proportion = 0.6) of the sampled adults know that saturated fat raises the risk of heart disease. We will then expect that, if the sample were drawn 100 times, in 95 times the true percentage of adults with the knowledge will fall somewhere between 62.1 percent (60+2.1) and 57.9 percent (60-2.1).

Table 3. Sampling Error (± percentage points) at the 95 Percent Confidence Level for Different Sample Sizes

	Proportion				
Sample Size	0.1 (0.9)	0.2 (0.8)	0.3 (0.7)	0.4 (0.6)	0.5 (0.5)
2000	1.3%	1.8%	2.0%	2.1%	2.2%
1800	1.4%	1.8%	2.1%	2.3%	2.3%
1600	1.5%	2.0%	2.2%	2.4%	2.5%
1400	1.6%	2.1%	2.4%	2.6%	2.6%
1200	1.7%	2.3%	2.6%	2.8%	2.8%
1000	1.9%	2.5%	2.8%	3.0%	3.1%
800	2.1%	2.8%	3.2%	3.4%	3.5%
600	2.4%	3.2%	3.7%	3.9%	4.0%
400	2.9%	3.9%	4.5%	4.8%	4.9%
200	4.2%	5.5%	6.4%	6.8%	6.9%

B2.4 Use of specialized sampling procedures

No specialized sampling procedures are required.

B2.5 Use of periodic data collection cycles to reduce burden

This is a one-time data collection.

B3. Methods to Maximize Response Rates

In an effort to increase response rate, the agency plans to instruct its contractor to take the following measures:

?? send advance letters to those households whose addresses can be found to notify them the impending interview;
?? make as many call attempts as needed, up to 30 attempts, to complete an interview;
?? extend data collection period to 90 days; and
?? conduct a non-response study to identify potential non-response biases and adjust estimates statistically, if necessary.

Advance letters and a longer data collection period have often been used by survey organizations as part of an effort to increase telephone survey response rates.

Studying non-response may help the agency in identifying significant non-response biases. Existing research has shown that non-response biases in random-digit-dialing national telephone survey may not be as severe as commonly suggested. For example, Keeter et al. (2000) found no measurable differences in findings between a survey with a response rate of 36% and an identical survey with a response rate of 61%, even though potential respondents in the latter were sent advance letters and a $2 incentive.[4] Furthermore, the agency's own study of the 2002 HDS suggests:

?? there are relatively few statistically significant differences in subject matter estimates when respondents are compared by the number of calls needed to complete an interview or by the need for refusal conversion;
?? the few differences exhibit no discernible pattern;
?? there is little association between the content of the subject matter or the type of response measure and estimate differences; and
?? nonrespondens would have provided similar information as respondents in the survey.

In this collection of information, however, the agency plans to conduct a non-response study.

The agency plans to make as many call attempts as needed, up to 30 call attempts, to complete an interview; the 30 attempts include a maximum of 25 attempts to complete the interview after an eligible respondent is identified. Recent research has suggested that any effort beyond 24 attempts does not change national estimates of a random-digit-dialing telephone survey and does not improve response rates by a significant degree.[5]

---

[4] Keeter, S., Miller, C., Kohut, A., Groves, R.M., and Presser, S. 2000. "Consequences of Reducing Nonresponse in a National Telephone Survey." Public Opinion Quarterly 64: 125-148.

[5] Dennis, M., Mathiowetz, N.A., Saulsberry, C., Frenkel, M., Srinath, K.P., Roden, A.-S., Smith, P.J., and Wright, R.A. 1999. "Analysis of RDD Interviews by the Number of Call Attempts: The National

A reasonable number of call attempts will be made to determine whether an "initial contact"—the establishment of the identity of a telephone number (residential or non-residential)—is made. For example, if the first 3 attempts received no response and the fourth attempt received a busy signal. Then the number will be called for a few more times to try to make an initial contact, because the fourth attempt suggests this number has the potential of being a residential number. Only when there is certainty that a number is not a residential number will the limit of five attempts be applied. If a voicemail or answering machine indicates the number is residential, then an initial contact is considered made.

Calls will be staggered over times of the day and days of the week to maximize the chances of making contact with a household and a designated respondent (DR). No-answers after five attempts at initial contact will be regarded as non-households and eliminated from the sample. Whenever possible, household screening and extended interviews with DRs will be completed during the same call.

In addition to the measures mentioned above, the data collection contractor will implement the following procedures to obtain the highest possible response rate:

?? In addition to general training, all interviewers and supervisors will be trained on the specifics of the survey by a member of the project's professional staff. This will include an explanation of the importance and purpose of the collection of information as well as a thorough review and practice reading of the entire information collection instrument.

?? Respondents who initially refuse to participate will be assigned to conversion specialists, who will attempt to complete the interview on a different day. Conversion letters acknowledging a contact attempt and describing the purpose of the study will be sent to non-responders for whom an address match is available in advance of the conversion attempt. Contractor will assign interviewers who have lowest refusal-to-hour ratios to conduct conversion calling

?? A Spanish-speaking interviewer will recontact all households in which the interview could not be completed because of a language barrier and complete the interview using a Spanish version of the instrument.

?? All interviewers will be monitored by a supervisor during the first day of interviewing and intermittently throughout the course of the collection of information thereafter. Production rates and call dispositions will be monitored each day to detect and resolve any problems or discrepancies quickly. Those interviewers who have above-average ratio of number of

---

Immunization Survey." Presented at the Annual Meeting of the American Association for Public Opinion Research.

refusals to hours dialed will be monitored closely and provided corrective feedback to improve their productivity.

?? The contractor will provide detailed descriptions of procedures for assuring quality control, for identifying interviewers who are having difficulties, and for dealing with problems.

?? The contractor will allow respondents to schedule call-back appointments to complete interviews at times that are more convenient to them.

?? To ensure quality control, the contractor will maintain complete call disposition records on every household contacted. In no case will telephone numbers be abandoned prior to achieving one of the following: (1) completed interview, (2) completed conversion attempt or refusal, (3) exhaustion of callbacks, (4) determination that a household is not eligible, and (5) exhaustion of initial contact attempts. When a household is determined to be ineligible, the basis for the determination will be recorded.

The response rate for this study will be defined as follows:

completed interviews / (completed interviews + terminations + interview refusals + callbacks to complete + respondents not available through the field period).

B4. Tests of Procedures or Methods

The agency will have its contractor conduct field pretests in an environment as close as possible to the real interviews. The data collection contractor will administer the full instrument by telephone to 27 randomly-selected adults after OMB approval of the collection of information. Scheduling the pretests close to the beginning of data collection will gain efficiency by using interviewer training for both the pretests and the complete data collection. The pretests will also serve the purposes of addressing problems in respondent selection, interviewer instructions, skip patterns, and design of the computer-assisted-telephone-interview program.

B5. Individuals Involved in Statistical Consultation and Information Collection

The contractor, Synovate, will collect the information on behalf of the FDA as a task order under the Quick-Turn-Around Research Services contract. Leigh Seaver, Ph.D., is the Senior Study Director for Market Facts, telephone (703)790-9099. Analysis of the information will be conducted primarily by staff on the Consumer Studies Team, Division of Market Studies, CFSAN, FDA, and coordinated by Chung-Tung Jordan Lin, PhD, telephone (301)436-1831.

Appendix A 21 USC 393

Sec. 393. Food and Drug Administration

?? (a) In general
There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

?? (b) Mission
The Administration shall -

- (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
- (2) with respect to such products, protect the public health by ensuring that -
  - (A) foods are safe, wholesome, sanitary, and properly labeled;
  - (B) human and veterinary drugs are safe and effective;
  - (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
  - (D) cosmetics are safe and properly labeled; and
    (E) public health and safety are protected from electronic product radiation;
- (3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
  (4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

?? (c) Interagency collaboration
The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

?? (d) Commissioner

- (1) Appointment
  There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the "Commissioner") who shall be appointed by the President by and with the advice and consent of the Senate.

- (2) General powers
  The Secretary, through the Commissioner, shall be responsible for executing this chapter and for -

  - (A) providing overall direction to the Food and Drug Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration;

  - (B) coordinating and overseeing the operation of all administrative entities within the Administration;

  - (C) research relating to foods, drugs, cosmetics, and devices in carrying out this chapter;

  - (D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and
    (E) performing such other functions as the Secretary may prescribe.

?? (e) Technical and scientific review groups
The Secretary through the Commissioner of Food and Drugs may, without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under this chapter, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

?? (f) Agency plan for statutory compliance

- (1) In general
  Not later than 1 year after November 21, 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this chapter. The Secretary shall review the

plan biannually and shall revise the plan as necessary, in consultation with such persons.

- (2) Objectives of agency plan
  The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to -

  - (A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this chapter;

  - (B) maximizing the availability and clarity of information for consumers and patients concerning new products;

  - (C) implementing inspection and postmarket monitoring provisions of this chapter;

  - (D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

  - (E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this chapter for the review of all applications and submissions described in subparagraph (A) and submitted after November 21, 1997; and
    (F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

?? (g) Annual report
The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that -

- (1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f) of this section;

- (2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and
  (3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.

Appendix B Information Collection Instrument
(See a separate document)