SUPPORTING STATEMENT

HEALTH AND DIET SURVEY

OMB No. 0910-0545

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health and Diet Survey is a voluntary consumer survey intended to gauge and track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition and physical activity. The authority for FDA to collect the information derives from the FDA Commissioner's authority provided in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The survey consists of two independent data collection activities. One collection, entitled "Health and Diet Survey—General Topics," tracks a broad range of consumer attitudes, awareness, knowledge and self-reported behaviors related to key diet and health issues. The other collection, entitled "Health and Diet Survey—*Dietary Guidelines* Supplement," will provide FDA with updated information about consumer attitudes, awareness, knowledge, and behavior regarding various elements of nutrition and physical activity based on the key recommendations of the *Dietary Guidelines for Americans*, which are jointly issued by the Department of Health and Human Services (HHS) and Department of Agriculture every five years.

2. Purpose and Use of the Information Collection

The information to be collected with the Health and Diet Survey—General Topics will include: (1) awareness of diet-disease relationships; (2) food and dietary supplement label use; (3) dietary practices including strategies to lose or maintain weight; and, (4) awareness and knowledge of dietary fats. This survey has been repeated every three years over the course of the past several years for the purpose of tracking changes and trends in public opinions and consumer behavior, with some new questions added or omitted or partially modified each iteration in response to current events. In the next three years, FDA plans to field the Health and Diet Survey -- General Topics survey in 2008 and anticipates that it might have the need for additional follow-up surveys in 2009 and 2010. For example, in developing possible changes to the current Nutrition Facts label, the agency will need information on consumer views and understanding of some of the items listed on the label and this information may not be available anywhere. Being able to field a timely survey with targeted questions would be very useful to us, especially within the context of the broader understanding gained with the Health and Diet Survey -- General Topics survey questionnaire. The information to be collected with the Health and Diet Survey—*Dietary Guidelines* Supplement will include: (1) opinions about the nutrition information provided by the government; (2) awareness and familiarity with government nutrition programs and publications such as the Food Guide Pyramid and the *Dietary Guidelines for Americans*; (3) knowledge of the relationships between food choices, exercise habits, weight loss, and health; (4) choices surrounding exercise, calorie intake, saturated and trans fats, fruits and vegetables, whole grains, dairy, fish, meat, cholesterol,

carbohydrates, salt, and sugar. The survey will also ask about use of Federal nutrition information, special diet, weight status, health status, and demographics.

FDA and other Federal agencies will use the information from the Health and Diet Survey to evaluate and develop strategies and programs to encourage and help consumers adopt healthy lifestyles. The information will also help the FDA and other Federal agencies evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health.

3. Use of Improved Information Technology and Burden Reduction

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.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative collection of this information. No comparable data are collected by any other means. The Health and Diet Survey is periodically repeated to track changes in consumer awareness and practices. The research survey provides valuable consumer information specific to the Congressionally-mandated review of nutrition science every five years by the Federal government in the form of the *Dietary Guidelines for Americans*. The survey is a derivative of the *Dietary* and using its information to shape reference measures with resulting data accumulated with cross tabs by specific populations (over sample of Hispanic and African Americans) and other factors (age, gender, education, health status, etc.) Since the 2004 data was obtained before the release of the *Dietary Guidelines*, the survey has a pre-intervention reference point, allowing for the tracking of changes in attitudes, knowledge, and behaviors as a result of the *Dietary Guidelines* (2005) and into future iterations. The Department of Health and Human Services (HHS) collaborated with FDA to use the Health and Diet survey as an evaluation mechanism at OMB's recommendation.

The Health and Diet Survey-General Topics questionnaire is fielded once every three years and, if events warrant, may be fielded once annually during each year of the three-year approval period, with appropriate modifications to specific portions of the questionnaire (addition and/or removal of questions). If changed, the questionnaire would be submitted to OMB for review and approval.

5. Impact on Small Businesses or Other Small Entities

The collection of information will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

If this information is collected less frequently, current, essential, and national data of consumer

knowledge, perceptions, attitudes, and practices pertinent to foods and dietary supplements will not be available to the FDA. The lack of information will severely limit the agency's capabilities in performing its functions properly to promote and protect the public health.

The information from the *Dietary Guidelines* provides a blueprint for action; however, putting knowledge into practice can be challenging and changing behavior is usually a long-term proposition. Fielding of this survey provides an on-going, consistent mechanism to monitor American eating habits and lifestyle choices over time, recognizing that adopting more healthy, active lifestyles will take a concerted effort— from the Federal government, health experts, the food and agriculture sectors, business leaders, state and local governments, scientists and researchers, and teachers and parents and individuals. The survey demonstrates that HHS is committed to monitoring American's progress overtime with an on-going evaluation mechanism in place. Without the survey, we lose a tracking mechanism designed specific to the *Dietary Guidelines* information released every five years and used as the benchmark for Federal nutrition policy in this nation.

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

Assurance of confidentiality of information will be provided to all respondents. The information collection provisions of the Health and Diet Survey do not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation, or require the disclosure of trade secrets or other confidential information. The collection fully complies with 5 CFR 1320.5(d)(2).

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

In accordance with 5 CFR 1320.8(d), in the Federal Register of May 25, 2007 (72 FR 29332), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

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).

Confidential information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

The Health and Diet Survey proposes to ask respondents their height, weight, self assessment of weight status, special diets, and status and risk perception of chronic illnesses. The Agency's experience with these questions suggests that the overwhelming majority of respondents feel comfortable in providing this information. For example, in the Health and Diet Survey ─ 2004 Supplement, the item non-response rates due to refusal are 1% on height, 2% on weight, 0% on self-assessed weight status, and 0.1% on diet restrictions. That survey asked about awareness of chronic illnesses and risk perceptions as a group ("Have you ever been told by a doctor or other healthcare professional that you have any of the following health conditions. I don't need to know which condition, just whether you have any of them."). Only 0.2% of respondents refused to answer the awareness of chronic illness question and 0.3% the risk perception question, respectively.

To mitigate potential privacy concerns, the following sentence is read immediately prior to the group of questions concerning health status: "The next few questions may seem a bit personal. But we need this information because this survey is about nutrition and health." This sentence appeared in the Health and Diet Survey ─ 2004 Supplement at the same location in the questionnaire and before the health status questions. It is likely that the low item non-response rates mentioned above were attributable to this sentence.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 states and the District of Columbia. Participation will be voluntary.

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
General Topics: Pretest	27	1	27	0.25	6.75
General Topics: Screener	10,000	1	10,000	0.02	200
General Topics: Survey	3,000	1	3,000	0.25	750
Dietary Guidelines Supplement: Screener	4,000	1	4,000	0.02	80
Dietary Guidelines Supplement: Survey	1,200	1	1,200	0.22	264
Total					1,300.75

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

FDA has based its estimate of the number of respondents and the burden hours per response on its experience with the Health and Diet Survey over the past three years. The agency will use a screener to select an eligible adult respondent in each household to participate in the survey. For the Health and Diet Survey—General Topics data collection activity a total of 3,000 adults in the 50 states and the District of Columbia will be interviewed by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions and 15 minutes (0.25 hours) to complete the entire survey. Prior to the administration of the survey, the agency plans to conduct a pretest to identify and resolve potential problems. The pretest will be conducted with 27 participants; we estimate that it will take a respondent 15 minutes (0.25 hours) to complete the pretest. In the next three years, FDA plans to field the Health and Diet Survey -- General Topics survey in 2008 and anticipates that it might have the need for additional follow-up surveys in 2009 and 2010. Table 1 reflects an *annual* burden of 956.75 hours estimated for the Health and Diet Survey—General Topics (956.75 hours represents the total of hours attributable to the pretest, screener and survey). In the event that additional follow-up surveys are fielded, it will not be necessary to add additional burden hours to Table 1.

For the Health and Diet Survey—*Dietary Guidelines* Supplement data collection activity a total of 1,200 adults in the 50 states and the District of Columbia will be interviewed by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions and 13.2 minutes (0.22 hours) to complete the entire survey. Target sample size of the combined data collection is 4,200 respondents who complete the survey.

Costs to Respondents. FDA estimates that the average hourly wage of the respondents is $15 per hour. The overall estimated cost incurred by the respondents is $19,511.25. (1,300.75 burden hours X $15/hr = $19,511.25).

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

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

14. Annualized Cost to Federal Government

The estimated total cost to the Federal Government for this information collection $343,000. This estimate consists of (1) $43,000 for 2 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) $300,000 for data collection. These costs would increase in the event that the agency has a need for additional follow-up surveys in 2009 and 2010.

15. Explanation for Program Changes or Adjustments

FDA increased its estimate of the total burden hours from 1,083 hours to 1,300.75 hours, an increase of 217.75 hours. The increase in burden hours is due to an increase in the estimated number of respondents, which results from the addition of a pretest and screener to the Health and Diet survey (27 respondents for a 15 minute pretest, and 10,000 respondents for a 1.2-minute

screener). The newly added pretest and screener add 206.75 hours and, thus, are primarily responsible for the 217.75 hour increase.

16. Plans for Tabulation and Publication and Project Time Schedule

For the Health and Diet Survey- General Topics, the planned schedule for the project activities is shown in Table 2.

Table 2. Project Schedule

Date	Activity	Audience
Within 3 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 180 days after notification to contractor	• Delivery by contractor of final data files	Not applicable
Within 6 months after receipt of final data files	• Delivery of oral and written preliminary summaries	FDA
Within 18 months after receipt of final data files	• Delivery of a written final report of summaries and analytical findings	FDA
Within 18 months after receipt of final data files	• Response to information requests	FDA and public
Within 24 months after receipt of final data files	• Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	Public

Following OMB approval, the data collection contractor will draw the sample, conduct the survey, and prepare the deliverables in accordance with the Quick Turnaround Research Services contract. The duration of information collection is estimated to be approximately 135 days to allow (1) a 15-day lead time to prepare for pretests, advance letters, and field operations, and (2) a 120-day field period to conduct interviews and to send conversion letters to initial refusals to encourage participation. Data files and all other deliverables will be delivered to the FDA within 180 days of written notification to the contractor that OMB approval has been granted.

As stated above, the goal of the collection of information is to (1) enhance the agency's understanding of consumer knowledge, perceptions, attitudes, and practices, (2) enrich deliberations of the agency's regulatory and educational initiatives, (3) help the agency track trends in consumer knowledge, perceptions, attitudes, and practices related to dietary supplements and food, and (4) help the agency evaluate the effectiveness of the Nutrition Labeling and Education Act (NLEA) of 1990 in promoting public health. Hence, the priority of project activities after the agency’s receipt of final data files is to meet the agency's information needs. These activities will primarily consist of written and oral presentations of preliminary summaries as well as a written final report of summaries and analytical findings. In addition, journal manuscripts and oral and/or poster presentations will be planned to disseminate the information to the public, including professionals, academics, and industry and consumer organizations. These activities are aimed to create value-added products to share and exchange information on current consumer knowledge, perceptions,

attitudes, and practices related to dietary supplements and food and to encourage dialogues between the agency and the public on issues related to these matters. The dialogues will help improve the effectiveness of the agency's regulatory and education initiatives in promoting and protecting the public health.

For the Health and Diet Survey – *Dietary Guidelines* Supplement, the survey report is made available in hardcopy and online to accommodate requests and encourage sharing of the content to help shape related programs and interventions. The report provides valuable information related to the *Dietary Guidelines for Americans* that the Department will want to reference and over time, the research will demonstrate insight into American attitudes, awareness and behaviors on healthy eating and physical activity. The survey will only become increasing more valuable over the coming years, as the connections between the measurements are followed, and the increase in trend data helps to shed light on the impact of the *Dietary Guidelines.* Survey results are expected in early 2008 with preliminary plans to field it again pre-release of the *Dietary Guidelines for Americans* 2010, and post launch.

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

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.

B. Statistical Methods (used for collection of information employing statistical methods)

1. Respondent Universe and Sampling Methods

The respondent universe for this collection of information will be non-institutionalized adults 18 and older who speak English in households with telephones in the 50 states and the District of Columbia. As of 1999, 94 percent of American households have telephone service.[1]

A response rate of 34 percent was achieved in the collection of a subset of the information in this survey that was conducted in 2004. The agency expects to achieve a similar or higher response rate in this collection of information.

2. Procedures for the Collection of Information

2.1 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

[1] U.S. Census Bureau. 2002. Table 1126, *Statistical Abstract of the United States: 2001*. Washington, D.C.

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 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 DR, 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.

The survey will over-sample African-American and Hispanic households by dividing the population into three strata: a stratum of geographic areas with high concentrations of African-American population, a stratum of geographic areas with high concentrations of Hispanic population, and a stratum with the remainder of the U.S. The first two strata will be sampled with higher rates. These sampling rates will be determined to achieve the desired numbers of African-American and Hispanics based on estimated incidences within each stratum. The final sample numbers for Hispanic and African-Americans will occur at random from the sample without screening. The geographic areas with higher African-American and Hispanic concentrations will be identified using GENESYS.

2.2 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 (1) multiple telephone numbers in households, (2) household size, and (3) nonresponse. 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 recent Census totals for sex, education, and race.

2.3 Degree of accuracy needed for the purpose described in the justification

For analyses of the *General Topics* survey, the proposed sample size (3,000 adults) will provide a precision of approximately ± 1.1 to 1.8 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) as well as major subject-matter classifications of respondents (e.g., dietary supplement users, vitamin/mineral users). For instance, suppose the collected information from 3,000 respondents yields an estimate that 80 percent (proportion = 0.8) of the sampled adults have taken one or more vitamins or minerals in the past 12 months. We will then expect that, if the sample were drawn 100 times, in 95 times the true percentage of users will fall somewhere between 81.4 percent (80+1.4) and 78.6 percent (80-1.4).

For analyses of the *Dietary Guidelines* Supplement, the proposed sample size (1,200 adults) will provide a precision of approximately ± 1.7 to 2.8 percentage points at the 95 percent confidence level. Over-sampling of African-American and Hispanic households will achieve 200-300 completed interviews in each category. So if the collected information yields an estimate that 40 percent (proportion = 0.4) of the sampled adults report familiarity with some government information about nutrition, we will expect that in 95 times out of 100 times of sampling, the true percentage of African Americans that are familiar with said information will fall somewhere between 46.8 percent (40+6.8) and 33.2 percent (40-6.8).

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)
3000	1.1%	1.4%	1.6%	1.8%	1.8%
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%

2.4 Use of specialized sampling procedures

No specialized sampling procedures are required.

2.5 Use of periodic data collection cycles to reduce burden

This is a one-time data collection.

3. Methods to Maximize Response Rates

In an effort to increase response rate, the agency plans 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 35 call attempts, to complete an interview;
- extend data collection period from 75 days to 120 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, however, has shown that non-response biases in random-digit-dialing national telephone survey may not be significant. 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.[2]

The agency plans to make as many call attempts as needed, up to 35 call attempts, to complete an interview; the 35 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.[3]

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 4 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 day and days of the week to maximize the chances of making contact with a household. No-answers after these attempts at initial contact will be regarded as non-

[2] 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.

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

households and eliminated from the sample. Whenever possible, household screening and extended interviews with designated respondents (DR's) 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.

- A Spanish speaking interviewer will recontact all households in which the interview could not be completed because of a language barrier.

- 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.

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

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 + screening refusals).

4. Tests of Procedures or Methods

Two types of tests of the collection procedure are planned to minimize collection burden on respondents and improve quality of collected information.

The first type of tests is cognitive interviews; the primary purpose of these interviews is to understand the mental processes that respondents use to answer survey questions. Nine randomly selected adults were asked dietary supplements questions contained in earlier drafts of the

instrument, and probed the mental processes they went through in providing the answers. The focus of analysis was on (1) comprehension of the meaning of certain questions or words, and (2) strategies used to recall information and to arrive at an answer.

In producing the submitted instrument (Appendix B), the agency has considered findings from the cognitive interviews.

The second type of tests is field pretests focusing more on the length of the questionnaire and respondent burden in an environment as close as possible to the real interviews. The data collection contractor will administer the full instrument by telephone to nine randomly-selected adults shortly before OMB approval of the collection of information is expected. 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.

5. Individuals Involved in Statistical Consultation and Information Collection

For the General Topics survey, the contractor, Westat, Inc. will collect the information on behalf of the FDA as a task order under the Quick-Turn-Around Research Services contract. Pat Dean Brick, Ph.D., is the Senior Study Director for Market Facts, telephone 301-251-4382. Analysis of the information will be conducted primarily by staff on the Consumer Studies Team, Division of Market Studies, CFSAN, FDA, and coordinated by Conrad J. Choinière, PhD, telephone (301) 436-1844. For the *Dietary Guidelines* Supplement, Synovate, Inc. will collect the information. Valerie Fuller, Ph.D., is the Project Director. Analysis of the information will be conducted by Porter Novelli under the supervision of Adams Burn.