

**RESEARCH AS USED BY DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION  
OMB No. #  
SUPPORTING STATEMENT**

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

Section 301 of the National Nutrition Monitoring and Related Research Act of 1990 (7U.S.C.5341) requires the Secretaries of the U.S. Departments of Health and Humans Services (HHS) and Agriculture (USDA) to publish jointly at least every five years a report entitled, *Nutrition and Your Health: Dietary Guidelines for Americans (Dietary Guidelines)*. The report must:

- (1) contain nutrition and dietary information and guidelines for the general public;
- (2) be based on the preponderance of scientific and medical knowledge current at the time of publication; and
- (3) be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.

As mandated by law, the 2005 *Dietary Guidelines* will be jointly produced and published by HHS and USDA. The release of the *Dietary Guidelines* (in the form a of a policy document) by the Secretaries of HHS and USDA in January, 2005, is already widely anticipated by health professionals, the press, and the public.

A Memorandum of Understanding (MOU) exists between HHS and USDA to provide a framework for cooperation between the Departments for preparing the *Dietary Guidelines*. The Office of Disease Prevention and Health Promotion (ODPHP), in collaboration with USDA's Center for Nutrition Policy and Programs (CNPP), is developing communication materials to support the launch of the *Dietary Guidelines* in January, 2005 and thereafter.

There is an urgent need for credible, scientific-based dietary guidance in this nation. The President's *HealthierUS* Initiative identifies "increasing physical activity" and "improving nutrition" as two key focus areas for helping Americans lead stronger, healthier lives. At HHS, Secretary Thompson has mobilized the Department's efforts around chronic disease prevention as outlined in the *Steps to a HealthierUS* initiative. There is an epidemic of overweight and obesity with obesity on the verge of overtaking tobacco as the leading preventable cause of death in America. This is attributed to poor eating habits and lack of physical activity with two out of every three Americans being overweight or obese. Even worse, America's children are more sedentary and overweight than ever before. The number of overweight children has tripled in the past two decades—and diabetes rates have skyrocketed right along with this obesity. In women, overweight and obesity are higher among members of racial and ethnic minority populations than in non-Hispanic white women. In men, Mexican-Americans have a higher prevalence of overweight and obesity than non-Hispanic men, while non-Hispanic white men have a greater prevalence than non-Hispanic black men.

The Office of Disease Prevention and Health Promotion (ODPHP) is requesting emergency, generic OMB review and clearance under the Paperwork Reduction Act (44 U.S.C. Chapter 35) for information collection requirements through focus groups, and Web concept-testing and interviews (on-line testing and usability testing). This information will be used as formative research to develop messages and materials in support of the 2005 *Dietary Guidelines*. It is necessary to obtain emergency review in order to obtain timely, public input to assist with the development of the 2005 *Dietary Guidelines* and supporting communication messages and materials.

The importance of obtaining public input is considerable given the wide-reaching influence and timeliness of the 2005 *Dietary Guidelines*. The *Dietary Guidelines* are the cornerstone of Federal nutrition policy and a "gold standard" for science-based consumer nutrition advice. They form the basis for Federal nutrition policy and healthy eating messages for the public. The communication materials

will fully integrate the Federal nutrition education assets – including the new *Dietary Guidelines*, the Food and Drug Administration's Nutrition Facts Labels, and USDA's Food Guidance System (FGS; formerly the Food Guide Pyramid).

As noted, part of the legislative mandate is to promote the *Dietary Guidelines*. HHS, in collaboration with USDA, is developing communication materials that capture the intent of the 2005 *Dietary Guidelines* and will promote them to the public and other intermediaries – Federal, State, and local government agencies, health and private organizations, dietitians, nutrition educators, health educators and professionals who provide nutrition information to the public.

For intermediaries, knowing about the release of the 2005 *Dietary Guidelines*, being aware or reminded of the value of the *Dietary Guidelines* as an up-to-date, scientifically valid and credible source, and having easy access to *Dietary Guidelines* information will help their efforts to provide the public with credible health messages and information. For the public, this information will help them sort out the validity of various, sometimes conflicting, nutrition and physical activity advice and take steps to change behavior and improve their dietary intake and physical activity.

This emergency, generic clearance request describes data collection activities involving a limited set of consumer and health intermediary focus groups and Web- testing concepts and interviews testing on the understanding of *Dietary Guideline* concepts and use of *Dietary Guidelines* (motivators) and potential barriers. It is critical to get feedback on the clarity, understandability, and acceptance of related messages and materials to support the 2005 *Dietary Guidelines*.

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. Web-concept testing surveys provides a cost-efficient method to obtain qualitative input from a greater number of participants more representative of the U.S. population across the country. This is especially helpful given the intended audience of the *Dietary Guidelines* is all **healthy Americans over age two**.

According to OMB guidance regarding generic clearance, individual memos explaining the exact method for information collection will be submitted, as well as copies of the tools or instruments to be used in gathering the data.

## 2. How, By Whom, Purpose of Collection

The Secretaries of HHS and USDA will jointly release the Dietary Guidelines – as mandated by law every five years – in January, 2005.

If this consumer and intermediary information is not collected, a vital link in gathering information by ODPHP to contribute to the official 2005 *Dietary Guidelines* policy document and supporting communications materials will be missed. On September 21, 2004, HHS accepted **oral** public comment on the *Dietary Guidelines* with numerous organizations and individuals urging that the proposed *Dietary Guidelines* communication messages and materials be tested with consumers. The consensus input during the developmental stage will help ensure the messages and materials resonant with and motivate consumers to make positive behavioral changes.

This emergency, generic clearance request describes data collection activities involving a limited set of consumer and health intermediary focus groups and Web- testing concepts and interviews testing (online testing and usability testing) on the understanding of *Dietary Guideline* concepts and use of *Dietary Guidelines* (motivators) and potential barriers. It is critical to get feedback on the clarity, understandability, and acceptance of related messages and materials to support the 2005 *Dietary Guidelines*.

The use of focus groups and Web concept testing and interviews and interview testing as qualitative research have three major purposes:

- To obtain useful consumer information for the formation of messages and materials;
- To better understand consumers' attitudes and emotions in response to topics and concepts; and

- To further explore messages in context (and materials) that would be beneficial tools for consumers and intermediaries.

Focus groups provide an important role in gathering information because they allow for greater discussion and understanding of consumers' attitudes, beliefs, motivations, and feelings. Web concept and interview testing complement focus groups as cost effective, qualitative methods to reach a diverse cross section of the U.S. population quickly. **This will allow** ODPHP to get input from different audiences that may vary by income level, educational level, race/ethnicity, gender, age, etc.

### 3. Consideration Given to Information Technology

Focus group studies are directed group discussions that do not produce quantitative data, but which enable skilled observers to infer the underlying views and assumptions of the group that are expressed in the discussion. To facilitate interpretation, discussions are recorded so that a written transcripts of the discussions are available for review.

The Web concept-test will be conducted through an already existing Web panel. Participants will be randomly selected from a Web panel with 50,000 potential participants owned by a research group, Knowledge Networks. This company initially used Random-Digit-Dial telephone techniques to invite people to join their Web panel. People who were interested in joining were given free Web-TV devices as well as training on how to connect to the Internet. Participants answer questions each month (no more than three times a month) in exchange for free Internet access that they can use at any time. Participants can view a message or brochure on their screens and then type their thoughts in an open-ended text box. This qualitative method provides a cost efficient way to get input from a more diverse cross section of the U.S. population.

### 4. Duplication or Similar Information

It is not expected that any of the information to be submitted to ODPHP during these focus group studies is duplicative or is already in the possession of the Federal Government. This is especially noteworthy based on the Dietary Guidelines Advisory Committee's assessment of existing scientific research and their recommendation for revised *Dietary Guidelines* for 2005. ODPHP has worked closely with USDA to coordinate the *Dietary Guidelines* message and material development to complement, not duplicate USDA's work on the FGS.

The proposed generic research will allow ODPHP to significantly improve its ability to develop and redefine messages and materials that will be used by both HHS and USDA agencies.

### 5. Minimize Burden to Small Entities

Not Applicable

### 6. Consequences of Not Conducting Collection

If this information is not collected, ODPHP's ability to incorporate messages and materials that are practical, meaningful, and relevant for the intended audience in the 2005 update of the *Dietary Guidelines* will be impaired. The National Nutrition and Monitoring and Related Research Act of 1990 requires that the publication of the *Dietary Guidelines* shall contain dietary information and guidance for the general public and that it be promoted by each Federal agency in carrying out any Federal food, nutrition, or health programs. Collection of data for this project is a critical element of reassessing the *Dietary Guidelines* to ensure that its recommendations continue to be scientifically sound, appropriate, and useful to the public. ODPHP would not be able to carry out this critical element of its mission if these data were not collected.

7. Information Collection Circumstances

The January, 2005, release of the *Dietary Guidelines* necessitates emergency, generic research clearance in order to collect information from consumers and health intermediaries that is vital to the publishing of the actual report, which is mandated by law, and the communication of the report to the public and health intermediaries.

Any additional research deemed necessary post-launch of the 2005 *Dietary Guidelines*, will be collected in accordance with the standard information collection schedule (consistent with 5 CFR 1320.6.).

8. Consultations with Persons Outside FDA

The U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion Proposed Collection; Comment Request – Emergency Generic Clearance for *Dietary Guidelines* Communications Message and Material Development; 30-day Federal Register Notice was published on **[DATE, 2004, on page xxxxx of the Federal Register, Vol. XX, No. XXX.]** A copy of the Federal Register notice is attached.

- a. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data and frequency of collection.

The Federal Register Notice for emergency, generic clearance was published and was available for comment to the public for a period of 30 days.

- b. Consultation with representatives of those from whom information is to be obtained.

Participants for focus groups and Web-concept tests and interviews, interviews and Web-based surveys will not be pre-selected, and for this reason there will be no opportunity to consult with them.

9. Payment or Gift

Focus group and selected Web-interview participants will receive a cash stipend intended to reimburse for expenses such as transportation and childcare costs. Amounts and justifications will be determined on an individual project basis. This information will be included in the memo provided to OMB for each formative input session to be conducted.

The Web concept-interview test will be conducted through an already existing Web panel. Participants will be randomly selected from a Web panel with 50,000 potential participants owned by a research group, Knowledge Networks. This company initially used Random-Digit-Dial telephone techniques to invite people to join their Web panel. People who were interested in joining were given free Web-TV devices as well as training on how to connect to the Internet. Participants answer questions each month (no more than three times a month) in exchange for free Internet access that they can use at any time. Internet access is provided by Knowledge Networks and no further payments or gifts are required.

10. Assurance of Confidentiality

ODPHP and Contractors will follow procedures for assuring and maintaining confidentiality consistent with the Privacy Act during all stages of data collection. Respondents will receive information about confidentiality in an advance letter and again before the information collection sessions begin. Respondents will be informed that all information will be kept strictly confidential by the research team and will not be associated with their names. The release form for the focus groups will cite the Privacy Act.

Respondents in focus group sessions will not know each other and will be asked to introduce themselves by first name only. The focus group sessions will be in a room with a closed door so passers-by cannot

eavesdrop on the discussion. Focus group sessions will be timed to allow more than enough time between sessions to avoid respondents in different groups seeing each other. Individual interviews will be conducted in a private setting.

At the beginning of focus group sessions and, individual interview sessions and prototype testing sessions, the facilitator will explain that the respondents' names and addresses will never be associated with the formative input session results.

The same rules related to privacy considerations apply to Web concept-interview test respondents. No identifying information will be collected and participants will be given confidentiality information before being asked to answer any questions.

11. Privacy

No questions will be asked that are of a personal or sensitive nature.

12. Burden of Information Collection

The total annual estimated burden imposed by this collection of information is approximately 712 hours for research described below and performed within the emergency clearance period.

a. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

Task #	Task	Number screened	# of recruits	# of participants	Minutes of burden	Total # of minutes	Total min translated into hours
1	Web test of messages for DG	0 (no screening needed for Web test)	200	200	200 participants X 25 min for survey=5,000 min 200 participants X 10 min for confidentiality = 2,000 min	7,000 min	117
2	Focus groups w/intermediaries for DG	600	40	30	600 screened X 15 min for screener = 9000 min 30 participants X 120 min for focus grp = 3600 min 30 participants X 10 min for confidentiality = 300 min	12,900 min	215
3	Web -Usability testing (20) for DG	360	24	20	360 screened X 15 min for screener = 5400 min 20 participants X 60 min for usability test = 1200 min 20 participants X 10 min for confidentiality = 200 min	6,800 min	113
4	Consumer focus groups (4) DG	720	48	40	720 screened X 15 min for screener = 10800 min 40 participants X 120 min for focus grp = 4800 min 40 participants X 10 min for confidentiality = 400 min	16,000 min	267
<b>Total</b>		1680	312	290		42,700 min or 712 hrs	

The total estimated annual burden is 712 hours. Current estimates are based on both historical numbers of respondents from past projects.

13. Cost to Respondents

Not applicable. Respondents will have no additional burden beyond the hours burden shown in item 12. Respondents will not need capital equipment, on-going recordkeeping operations, or services to complete the information collection. The only cost to respondents will be value of the time spent responding as explained in the chart above.

14. Costs to Federal Government

ODPHP will incur costs in setting up testing environments to include such things as hiring contractors, facilitators or moderators; renting meeting space; and providing cash stipends, etc. Costs will be determined on an individual project basis and will be included in the memo provided to OMB for each formative input session to be conducted.

15. Reason for Change

This OMB submission is for the individual data collection events, which will consist of a one-time data collection. This is a new information collection, therefore, the total burden constitutes a program change.

16. Statistical Reporting

There are no tabulated results for this information collection.

No complex or analytical techniques will be used for the results of the collection of information. Findings from all data collection will be included in individual summary reports submitted to ODPHP. The reports will describe the focus group and/or Web concept and interview testing methods, findings, conclusions, implications, and recommendations for use in revision of the *Dietary Guidelines for Americans* messages and materials. There will be no specific quantitative analysis of data. No attempt will be made to generalize the findings to be nationally representative or statistically valid.

After data collection has been completed, it is anticipated that the findings will be published in appropriate journals and shared at health and nutrition meetings, and conferences to disseminate information to those who share similar goals of gathering insights about how consumers understand and use nutrition information and how it may impact their behavior.

17. Display of OMB Approval Date

ODPHP is not seeking exemption from this requirement. Please see Appendix III – OMB Burden Statement (Hours) for a sample of what will be included as part of all formative research collection instruments.

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

There are no exceptions to the certification statement being requested.

A. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Information will not be collected requiring statistical analysis employing statistical methods.

B. APPENDICES (follow)

- I. FEDERAL REGISTER NOTICE
- II. CONFIDENTIALITY AGREEMENT
- III.

**APPENDIX I. FEDERAL REGISTER NOTICE**

[PLACE HOLDER]

## APPENDIX II. CONFIDENTIALITY AGREEMENT

OMB BURDEN STATEMENT: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0584-0523. The time to complete this information collection is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

### HHS Focus Group CONFIDENTIALITY AGREEMENT

I, \_\_\_\_\_ **(print name)**, agree to keep all information shown and discussed during the focus group in which I am participating in the strictest confidence.

I agree not to discuss, publish, or otherwise divulge any information I am exposed to, in whole or in part, in any manner or form.

Your comments will be kept confidential and only used for research purposes. Your name will not be divulged in any reports of this focus group. The audio and video tapes of the groups will be viewed only by the team on this project to inform the project's development, and will not be released to the public at any time.

Signed: \_\_\_\_\_

Dated: \_\_\_\_\_