### SUPPORTING STATEMENT FOR

# "GENERIC CLEARANCE FOR THE DEVELOPMENT OF NUTRITION EDUCATION MESSAGES AND PRODUCTS FOR THE GENERAL PUBLIC"

Carole Davis, Director, Nutrition Guidance and Analysis Division

Center for Nutrition Policy and Promotion

Food, Nutrition and Consumer Services

United States Department of Agriculture

3101 Park Center Drive, Room 1034

Alexandria, VA 22302

703-305-7600 (office)

703-305-3300 (fax)

E:Mail: Carole.Davis@cnpp.usda.gov

## **TABLE of CONTENTS**

Chapter Page	9
A. JUSTIFICATION	
1. Circumstances Making the Collection of Information Necessary	
2. Purpose and Use of the Information	
3. Use of Information Technology and Burden Reduction5	
4. Efforts to Identify Duplication and Use of Similar Information6	
5. Impacts on Small Businesses or Other Small Entities	
6. Consequences of Collecting the Information Less Frequently6	
7. Special Circumstances Relating to the Guideline of 5 CFR 1320.57	
8. Comments in Response to the Federal Register Notice and Efforts to Consult	
Outside Agency7	
9. Explanation of Any Payment or Gift to Respondents	
10. Assurance of Confidentiality Provided to Respondents	
11. Justification for Sensitive Questions8	
12. Estimates of Hour Burden Including Annualized Hourly Costs8	
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers10	
14. Annualized Cost to the Federal Government	
15. Explanation for Program Changes or Adjustments	
16. Plans for Tabulation and Publication and Project Time Schedule10	
17. Reason(s) that Display of OMB Expiration Date is Inappropriate11	
18. Exceptions to the Certification Statement for Paperwork Reduction Act Submissions11	

### B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS N/A

### C. APPENDICES

APPENDIX 6

APPENDIX 1 Statute section and regulation authorizing nutrition-related research

APPENDIX 2 Public Comments

APPENDIX 3 Response to Public Comment

APPENDIX 4 OMB Burden Statement

APPENDIX 5 Sample Participant Screener

Confidentiality Agreement

### A. JUSTIFICATION

- 1. Circumstances Making the Collection of Information Necessary.
  - a. Delegated Authority and Mission of the Center for Nutrition Policy and Promotion

The Center for Nutrition Policy and Promotion (CNPP) of the U.S. Department of Agriculture (USDA) conducts consumer research to identify key issues of concern related to the understanding and use of the *Dietary Guidelines for Americans* and *MyPyramid* (OMB 0584-0535 exp. July 31, 2012). The *Dietary Guidelines*, a primary source of dietary health information, are issued jointly by the USDA and Health and Human Services (HHS) and serve as the cornerstone of Federal nutrition policy and form the basis for nutrition education efforts of these agencies. *MyPyramid* is a tool which helps consumers understand and use the *Dietary Guidelines*. The information collected from consumer research will be used in the development of the *Dietary Guidelines* and *MyPyramid* messages and products. USDA has the lead responsibility for the 2010 *Dietary Guidelines* revision process from which new messages and materials will be developed. Educational messages and products in support of the *Dietary Guidelines for Americans* and *MyPyramid* will be developed by the CNPP. They may include:

- 1. Messages and products related to the 2010 *Dietary Guidelines for Americans* that help consumers make healthier food and physical activity choices;
- 2. Enhancement of the *MyPyramid* Website to include additional components such as updated nutrition and physical activity personalized tracking and other interactive tools as well as consumer and professional support materials;
- 3. Materials relaying the 2010 *Dietary Guidelines for Americans* and *MyPyramid* for special population groups that might be identified; and
- 4. New policy, messages, materials, and tools that might be developed as a result of the 2010

Dietary Guidelines for Americans revision process.

CNPP works to improve the health and well-being of Americans by developing and promoting dietary guidance that links scientific research to the nutrition needs of consumers. CNPP has among its major functions the development and coordination of nutrition policy within USDA and is involved in the investigation of techniques for effective nutrition communication. Under Subtitle D of the National Agriculture Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3171-3175), the Secretary of Agriculture is required to develop and implement a national food and human nutrition research and extension program, including the development of techniques to assist consumers in selecting food that supplies a nutritionally adequate diet. Pursuant to 7 CFR 2.19(a)(3), the Secretary of Agriculture has delegated authority to CNPP for, among other things, developing materials to aid the public in selecting food for good nutrition; coordinating nutrition education promotion and professional education projects within the Department; and consulting with the Federal and State agencies, the Congress, universities, and other public and private organizations and the general public regarding food consumption and dietary adequacy.

The National Nutrition Monitoring and Related Research Act of 1990 (7 U.S.C. 5341), requires the Secretaries of Agriculture and Health and Human Services to publish jointly every 5 years a report entitled, the *Dietary Guidelines for Americans*. The intent is to provide advice for healthy Americans ages two years and over about food choices that promote health and prevent disease. *MyPyramid* (USDA's Food Guidance System) is USDA's primary nutrition education tool to assist Americans in selecting foods for a dietary pattern that meets *Dietary Guidelines* recommendations. Ensuring that *MyPyramid* is useful to its intended audience and that the food pattern recommendations continue to be scientifically sound, appropriate, and useful to the public

is critical to CNPP's mission and is a major activity included in its 5-year strategic plan in fulfillment of the Government Performance and Results Act of 1993 (31 U.S.C. 9701).

#### b. Justification for data collection

The approval of information collection is necessary to obtain input into the development of educational messages and materials in support of the *Dietary Guidelines for Americans* and the *MyPyramid* Food Guidance System, which will target the general public.

This clearance request describes data collection activities involving a limited set of consumer focus groups, qualitative interviews, and Web-based surveys to obtain information regarding clarity, understandability, and acceptability of the messages and materials during the developmental process and during the product development stage. 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.

Every five years the *Dietary Guidelines for Americans* are revised based on the evaluation of any new scientific information that might be available related to nutrition, health, diet and food consumption patterns. A simultaneous Food Guidance System evaluation takes place in order to ensure that nutritional goals remain accurate and that consumers are being provided with useful advice.

An essential part of the reassessment process is to conduct formative research with consumers to examine their understanding of *Dietary Guideline* and *MyPyramid* concepts as well as their use of and barriers to using them. Some of the information collected will attempt to answer questions about how Americans use health information to help them make choices—for example, how individuals hear and understand dietary guidance and physical activity messages,

and whether and how they use these messages to make decisions about food and physical activity choices. Information is also needed for different audiences, based on various income levels, marital status, education level, race/ethnicity, gender, age, activity levels and desires for weight loss to determine if particular messages are more readily understood and useful, so that guidance can be tailored to meet various needs.

CNPP believes that obtaining qualitative information from consumers is fundamentally necessary for reassessing and revising the *Dietary Guidelines for Americans* and *MyPyramid*.

Qualitative research is particularly useful for gaining insights and a better understanding of the target audience. Without the qualitative data from consumers, CNPP would not be able to incorporate useful messages and materials for the intended audience in any proposed revision of these guidance pieces. Qualitative research consists of open-ended structured discussions or interviews with individuals or small groups of individuals, and most often includes ethnographic studies, depth interviews, and focus groups. Qualitative research techniques provide more depth of information than can be gathered from quantitative techniques and has been selected for this reason.

As part of its commitment to advancing dietary and physical activity guidance in a way that motivates behavior change, CNPP plans to continue its development of nutrition and physical activity recommendations within the *Dietary Guidelines for Americans* and *MyPyramid*. The key is for all messages to be clear and actionable, in order to help improve the health of all Americans.

### 2. Purpose and Use of the Information.

The formative input and feedback information collected will assist CNPP in its efforts to develop practical and meaningful nutrition and physical activity guidance for Americans to help improve their health. The primary users of the research results will be CNPP Staff, FNS

Nutrition Programs, State agencies, and other Federal agencies concerned with developing and/or using practical and meaningful nutrition and physical activity guidance materials with potential to be used nationwide by American consumers.

The primary goal of information collection (through consumer focus groups, qualitative interviews, and Web-based surveys) will be to expand the knowledge base concerning how the *Dietary Guidelines for Americans* and *MyPyramid* recommendations and messages are understood as well as how they can be used by consumers to improve the balance of their food intake with physical energy expenditure for good health. More information is needed about changing behavior related to nutrition and physical activity, including a better understanding of target audience perceptions and potential motivators and barriers for changing dietary and physical activity habits. More information is also needed about responses to message concepts and reactions to nutrition and physical activity education materials. All of this will be helpful in presenting messages that are targeted to various audiences. The information is not nationally representative and no attempt will be made to generalize the findings to be nationally representative or statistically valid.

### 3. Use of Information Technology and Burden Reduction.

CNPP is committed to complying with the E-Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Focus groups concerning Web-site development or testing of materials may be accomplished via computers. Focus group discussions and interviews may be video or audio taped and transcribed to maximize access to detail.

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

This study does not duplicate any prior research. CNPP's review of the literature and programs did not reveal any similar information to be available nor did CNPP find any available information that could be modified for use for the purposes described earlier. USDA does have previous experience using qualitative research techniques in developing nutrition and physical activity education materials for specific target audiences. Focus groups were used in the *Dietary Guidelines for Americans* revision process for the years 1995, 2000 and 2005. Focus groups and usability testing were used in the development of *Dietary Guidelines* implementation tools including the original 1992 *Food Guide Pyramid*, and the most recent *MyPyramid* educational materials.

### 5. Impacts on Small Businesses or Other Small Entities.

There will be no impact on small businesses or other small entities. No small businesses will be involved in this information collection request.

### 6. Consequences of Collecting the Information Less Frequently.

If this information is not collected, USDA's ability to incorporate messages and materials that are practical, meaningful, and relevant for the intended audience in any proposed update of the *Dietary Guidelines for Americans* or *MyPyramid* will be impaired. The National Nutrition and Monitoring and Related Research Act of 1990 requires the publication of a report entitled *Dietary Guidelines for Americans* that shall contain dietary information and guidance for the general public and that shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health programs. USDA's *MyPyramid* is the primary nutrition education tool designed to assist healthy Americans in selecting diets that are consistent with the *Dietary Guidelines*. Collection of data for this project is a critical element of reassessing the *Dietary Guidelines* and *MyPyramid* and helping to ensure that its recommendations continue to be scientifically sound, appropriate, and

useful to the public. CNPP would not be able to carry out this critical element of its mission if these data were not collected.

### 7. Special Circumstances Relating to the Guideline of 5 CFR 1320.5.

There are no special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.5.

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

The Department of Agriculture - Center for Nutrition Policy and Promotion; Agency Information Collection Activities; Proposed Collection; Comment Request--Generic Clearance for the Development of Nutrition Education Messages and Products for the General Public 60-day Federal Register Notice was published on June 2, 2009 on pages 26361-26362 of the Federal Register, Vol. 74, No. 104.

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 was published and was available for comment to the public for a period of 60 days. No comments on cost or hour burden were received.

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

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

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

Focus group and selected 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.

### 10. Assurance of Confidentiality Provided to Respondents.

CNPP and Contractors will follow procedures for maintaining confidentiality consistent with the Privacy Act during all stages of data collection. Exact procedures 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. Respondents will receive information about confidentiality in an advance letter or during the telephone screening process and again before the information collection sessions begin. Respondents will be informed that all information will be kept confidential and will not be disclosed to anyone but the researchers conducting this investigation, except as otherwise required by law. 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, 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.

### 11. Justification for Sensitive Questions.

Information collection will not involve questions of a sensitive nature.

### 12. Estimates of Hour Burden Including Annualized Hourly Costs.

a. Indicate the number of respondents, frequency of response, annual hour burden, and

an explanation of how the burden was estimated.

Testing Instrument	Estimated Number of Individual Respondents	Number of Responses per Respondent	Estimated Time per Response in Hours	Estimated Total Annual Responses per respondent	Estimated Total Annual Burden in Hours
Focus Group Screeners	7,500	1	.25	7,500	1,875
Interview Screeners	7,500	1	.25	7,500	1,875
Focus Groups	500	1	2	500	1,000
Interviews	500	1	1	500	500
Web-based Collections	20,000	1	.25	20,000	5,000
Confidentiality Agreement	21,000	1	.08	21,000	1,753.50
Total	57,000		32	57,000	12,003.50

The total estimated annual burden is 12,003.50 hours. Current estimates are based on both historical numbers of respondents from past projects as well as projections for projects to be conducted in the next three years.

b. Provide estimates of annualized cost to respondents for the hour burdens for collections of information.

Testing Instrument	Total Burden Hrs	Hourly Rate (\$)	Total Cost (\$)
Focus Group Screeners	1,875	18.53*	34,743.75
Interview Screeners	1,875	18.53	34,743.75
Focus Groups	1,000	18.53	18,530.00
Interviews	500	18.53	9,265.00
Web-based Collections	5,000	18.53	92,650.00
Confidentiality Agreement	1,753.50	18.53	32,492.36
Total	12,003.50	18.53	222,424.85

<sup>\*\$18.53</sup> hourly rate is derived from the U.S. Department of Labor, Bureau of Labor Statistics, July 2009. See <a href="http://www.bls.gov/news.release/pdf/empsit.pdf">http://www.bls.gov/news.release/pdf/empsit.pdf</a>

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

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

#### 14. Annualized Cost to the Federal Government.

The Agency incurs costs in setting up testing environments to include such things as hiring contractors, facilitators or moderators, renting meeting space, in 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. Explanation for Program Changes or Adjustments.

This OMB submission is for individual data collection events, which will consist of a one-time data collection. This submission is a revision to a currently approved collection of 3,612.5 hours. The new estimation of burden hours is 12,003.50 resulting in an increase of 8,391 hours, constituting a program change. This increase is a result of a projected increase in the number of projects related to the 2010 *Dietary Guidelines* communication activities.

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

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 CNPP. The reports will describe the focus group and interview testing methods, findings, conclusions, implications, and recommendations for use in the reassessment and potential revision of the *Dietary Guidelines for Americans* and *MyPyramid*. 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 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. Reason(s) that Display of OMB Expiration Date is Inappropriate.

The agency plans to display the expiration date for OMB approval of the information collection on all instruments.

# 18. Exceptions to the Certification Statement for Paperwork Reduction Act Submissions.

There are no exceptions to the certification statement.