Comparing Nutrition Knowledge, Attitude and Behavior among English-dominant Hispanics, Spanish-dominant Hispanics, and Other Consumers

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) has the responsibility to protect public health by assuring the safety and security of our nation's food supply and by assuring that foods are effectively labeled. In addition, the FDA is responsible for advancing public health by helping the public to get the accurate, science-based information they need to use foods to improve health. As part of its regulatory responsibility for safety of the food supply, the FDA develops and disseminates consumer messages about food safety and nutrition. As a member agency, the FDA supports the Department of Health and Human Services policies related to infant and child health, nutrition, and obesity prevention.

FDA conducts research and educational and public information programs relating to food safety pursuant to its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C) (21 U.S.C. 393 (d)(2)(C)), to conduct research relating to foods, drugs, cosmetics and devices in carrying out the act.

Recent estimates suggest that Hispanics (defined as those who identify themselves as of Hispanic or Latino origin) are the largest and fastest growing minority group in the nation; the proportion of the U.S. population that was Hispanic was 14 percent in 2005 and is projected to increase to 29 percent in 2050 (Ref. 1).

Data from the U.S. Centers for Disease Control and Prevention (CDC) indicate that, in 2005-2006, 34.3% and 32.7% of the U.S. adult population are obese and overweight, respectively (Ref. 1). According to the CDC, Hispanics had 21% higher obesity prevalence than whites in 2008 (Ref. 2). CDC data also indicate variations in prevalence of obesity among adults of different race-gender groups; for example, during 2006-2008, non-Hispanic blacks had the greatest prevalence of obesity (35.7%), followed by Hispanics (28.7%), and non-Hispanic whites (23.7%); non-Hispanic black women had the greatest prevalence (39.2%), followed by non-Hispanic black men (31.6%), Hispanic women (29.4%), Hispanic men (27.8%), non-Hispanic white men (25.4%), and non-Hispanic white women (21.8%) (Ref. 2).

While some Hispanics living in the United States use the English language exclusively or more often than Spanish (English-dominant Hispanics), other U.S. Hispanics predominantly use the Spanish language in their daily lives (Spanish-dominant Hispanics) (Ref. 4). Since most U.S. food labels are in English, Spanish-dominant Hispanics' understanding and use of food labels may differ from that of English-dominant Hispanics and of non-Hispanics who use English exclusively. In addition, both English-dominant Hispanics and Spanish-dominant Hispanics may have different awareness, perceptions, and behaviors than English-speaking non-Hispanics on issues of health, nutrition, and food consumption (Ref. 5-9).

Existing research suggests that, in addition to language and other demographic differences, acculturation is an important factor associated with individual differences in dietary and public health related perceptions, attitudes, and behaviors among Hispanics. Acculturation is defined as the change in behavior and values by immigrants when they come in contact with a new group, nation, or culture (Ref. 10). Immigrants may possess different degrees of acculturation depending on the time of migration and other factors, such as the dominant culture of the neighborhoods where they live and work and type of education received (Ref. 11-12). Hence, variation in the degree of acculturation can lead to differences in lifestyle and behaviors, including behaviors related to dietary choices and to use and understanding of nutrition information on food labels, because of English proficiency and degree of assimilation into the values, lifestyles, and diets prevalent in this country. The existing research has shown the influence of acculturation on Hispanics' perceptions, attitudes, and behaviors relating to public health factors including dietary practices, nutrition, the health practices of pregnant women, obesity, coronary heart disease, Type 2 diabetes, alcohol consumption, and smoking behavior (for example, Refs. 11, 13-22).

2. Purpose and Use of the Information Collection

This study is intended to provide answers to research questions such as whether and how much Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics differ in their knowledge, attitude, and behavior toward food label use, nutrition, and health among three population groups and the role that demographic and other factors may play in any differences.

The study will use an experimental design by collecting and statistically testing differences in responses to an essentially identical questionnaire by the three population groups. The study will employ quantitative methodologies, such as Analysis of Covariance and regression, to compare and test response differences among the three population groups, after controlling for demographic and health variations between participants.

FDA needs an understanding of how different population groups perceive and behave in terms of food label understanding and use, nutrition, and health to inform possible measures that the Agency may take to help consumers make

informed dietary choices. FDA is aware of no consumer research on a nationwide level of the impact of language and acculturation on Hispanics' dietary choices and label use.

The study is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. The results of the study will not be used to develop population estimates. The results of the study will be used for informing possible measures that the agency may take to help consumers make informed dietary choices.

3. Use of Improved Information Technology and Burden Reduction

The proposed information collection will recruit respondents and conduct experiments via the Internet. FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's request. The Internet mode of data collection is more appropriate than other modes, e.g., telephone or in-person, because of its advantages in respondent burden, cost, administration, speed, and absence of interviewer effects.

4. Efforts to Identify Duplication and Use of Similar Information

As shown in A.1 above, the agency is aware of the vast literature that has examined the Latino population and their health issues from various angles. In addition, the agency has contacted knowledgeable researchers and conducted a thorough literature review. The agency concluded that the proposed data collection will not duplicate any similar study and the existing knowledge base and literature do not meet the agency's informational need.

The extant literature, however, has two major limitations that restrict its usefulness to the agency. First, although some research has examined the influence of acculturation on Hispanics' perceptions, attitudes, and behaviors relating to nutrition and health, there has been no research that compared how these perceptions, attitudes, and behaviors may differ between more-acculturated Hispanics, less-acculturated Hispanics, and other consumers who are not Hispanics. Since different perceptions, attitudes, and behaviors can impact individuals' health outcomes and public health information and education may be more effective if they are targeted to different subgroups' needs, there is a need to compare and contrast the differences to help better understand the sources of differences and help develop strategies to enhance the usefulness of information and education. Second, most literature focused on specific topics, such as knowledge of dietary fats or dietary behaviors, rather than a larger set of perceptions, attitudes, and behaviors that may have general implications on individuals' health, such as reading and understanding of food labels, which affect dietary choices. Information on such topics is especially important to the agency because its responsibilities under the Nutrition Labeling and Education Act of 1990.

We have requested feedback from several academic researchers who have conducted research related to Hispanic population's health and nutrition issues. The following three researchers responded to our request and provided their comments. We have carefully considered the input from these three experts and incorporated their suggestions when appropriate and necessary.

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5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. Without this study, FDA will not have the needed information to understand how the nutrition and health perceptions, attitudes, and behaviors of Hispanics may differ from other population groups. The lack of understanding would impede the agency's ability to provide better information useful to as many individuals as possible, which in turn can elevate the nutrition and health status of the general population.

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

No special circumstances will occur in the data collection.

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

   The Federal Register Notice of proposed data collection was published on March 1, 2011 (76 FR 11251-11252). FDA received one paperwork reduction comment on the proposed Follow Up Study for Infant Feeding Practices Study II.

9. Explanation of Any Payment or Gift to Respondents

   We will recruit members on the Knowledge Networks' KnowledgePanel and KnowledgePanel Latino to participate in the study. Knowledge Networks (KN) provide two types of incentives: non-specific survey specific and survey specific incentives.

   Non-specific survey incentives are used to maintain a high degree of panel loyalty and to prevent attrition from the panel. For the households that are provided Internet appliances and an Internet connection by KN, their 'panel loyalty' incentive is the hardware and Internet service that KN provides free. For households using their own personal computers and Internet service for survey participation, KN enrolls the panelists into a points program that is analogous to a 'frequent flyer' program, in that respondents are credited with points in proportion to their regular participation in surveys. Panelists receive cash-equivalent checks approximately every four to six months in amounts reflecting their level of participation in the panel, which commonly results in distributions in the range of $4 to $6 per month.

   For this study, a $5 survey-specific incentive will be paid to Spanish-dominant participants because KN has found this is essential for obtaining the cooperation of these individuals.

   We plan to conduct nine cognitive interviews, mostly with Spanish-dominant adults. Participants will be paid $25 for a 30-minute interview.

10. Assurance of Confidentiality Provided to Respondents

    All data will be collected with an assurance that the respondents' answers will remain confidential. Identifying information will not be included in the data files delivered by contractors to the agency. FDA will assure the privacy of the data to the extent permitted by law. The study instrument will contain a statement assuring respondents of the privacy of the information.

    KN will collect the study data and follow its standard confidentiality and privacy policy:

    "Survey responses are confidential, with identifying information never revealed without respondent approval. When surveys are assigned to KnowledgePanel Members, they receive notice in their password protected e-mail account that the survey is available for completion. Surveys are self-administered and accessible any time of day for a designated period. Participants can complete a survey only

once. Members may leave the panel at any time, and receipt of the laptop and Internet service is not contingent on completion of any particular survey.

All KN panelists, when joining the panel, are given a copy of the Privacy and Term of Use Policy. The privacy terms are also available electronically at all times to panelists via the Panel Member website. The Privacy and Terms of Use Policy is posted at http://www.knowledgenetworks.com/company/privacy.html."

In addition, all electronic data will be maintained in a manner that 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).

11. Justification for Sensitive Questions

The study will ask respondents their height, weight, perceived health, perceived weight status, special diets, and status and risk perception of chronic illnesses. This information is needed for two purposes. First, we are interested in investigating how these personal characteristics affect respondents' nutrition- and health-related perceptions, attitudes and behaviors. Second, in that personal characteristics may explain some of the variations in respondents' perceptions, attitudes and behaviors, the study will examine these variations by controlling for personal characteristics.

The agency's experience with these questions suggests that the overwhelming majority of respondents feel comfortable in providing this information. For example, in the Experimental Study of Health Claims on Food Packages (OMB Control No. 0910-0565), the item non-response rates due to refusal were <1% for height, perceived weight status, special diets, and status and risk perception of chronic illnesses. Only the question of weight received a non-response rate of 6%.

Despite the evidence above, the experimental study will put a sentence before asking health status questions that reads "the next few questions may seem a bit personal, but we need this information because this survey is about nutrition and health." We have used this sentence in previous data collections.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The estimated total hour burden of the collection of information is 826 hours (Table 1). This estimate is 496 hours lower than the 1,322 hours published in the 60-day notice and reflects 20 fewer hours for pretest invitation and 476 fewer hours for survey invitation. Recent evidence available to the agency suggests the study will not need to send as many invitations as originally estimated to achieve

its target sample sizes in pretest and survey. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

Table 1. Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive interview screener	72	1	72	0.083 (5 min.)	6
Cognitive interview	9	1	9	0.5 (30 min.)	5
Pretest invitation	360	1	360	0.033 (2 min.)	12
Pretest	180	1	180	0.25 (15 min.)	45
Survey invitation	4800	1	4800	0.033 (2 min.)	158
Survey	2400	1	2400	0.25 (15 min.)	600
Total					826

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

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $13,439 (826 x $16.27) at $16.27 per hour (the 2010 median wage rate in the U.S.) See http://www.bls.gov/oes/current/oes_nat.htm#00-0000.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection $300,000. This includes the value of a task order to execute the collection of information and the value of a Full-Time-Employee to develop, monitor and analyze the data collection.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We plan to complete data collection and analysis within two years from the date of OMB approval. The planned schedule for the project is shown in Table 2.

The purpose of tabulation is to quantitatively and qualitatively analyze the data and summarize findings to meet the informational needs. Commonly accepted statistical techniques such as descriptive analysis, analysis-of-variance (ANOVA), and regression will be used to analyze the experimental data.

Table 2. Project Schedule

Date	Activity
Within 1 day following OMB approval	Notification to contractor to proceed with data collection
Within 45 days following OMB approval	Completion of data
Within 75 days following OMB approval	Completion of data delivery by the contractor
Within 135 days following OMB approval	Completion of preliminary analyses
Within 180 days following OMB approval	Beginning of review, clearance, and dissemination of preliminary findings

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." In describing the data collected and results of the analysis, FDA will clearly acknowledge that the experimental data does not provide nationally representative population estimates such as consumer attitudes, knowledge, or behaviors but provides valid and quantitative estimates of differences across experimental conditions.

The dissemination may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site.

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

The OMB approval and expiration date will be displayed on all materials associated with the study. No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.