Experimental Study on Consumer Responses to Nutrient Content Claims on Fortified Foods

OMB No. 0910-NEW

SUPPORTING STATEMENT Part A

Abstract

This ICR is for a one-time data collection consisting of a research study whose overall objective is to examine consumer reactions to nutrient content claims on the food label of vitamin fortified snack products (e.g., cookies, candy, and carbonated beverages). Study participants will be asked to submit information via a web-based questionnaire. In addition to responding to questions about food consumptions and shopping behaviors, experimental study tasks will include participants' selection of a preferred product for purchase, participants' evaluations about a food product's nutritional attributes and overall healthfulness. The study is part of the Agency's continuing effort to provide consumers with information to assist them in making informed dietary choices and constructing healthful diets. The Agency is interested in using this study to inform future consideration of its policy on fortification related to snack foods.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) regulates the labeling of food products under the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act (NLEA) of 1990 (Public Law No. 101–535). The FDA's policy on fortification (21 CFR 104.20) establishes a set of principles that serve as a model for the rational addition of nutrients to foods. The FDA has an interest in the American public achieving and maintaining diets with optimal levels of nutritional quality, wherein healthy diets are composed of foods from a variety of nutrient sources. The FDA does not encourage the addition of nutrients to certain food products (i.e., sugars or snack foods such as [cookies] candies, and carbonated beverages). Despite FDA's policy on the fortification of snack foods, products that FDA considers inappropriate for fortification have recently entered the marketplace. For example, there are cookies on the market which are fortified with nutrients that advertise the fortification on the front panel of the product. Additionally, there are now candies available for sale that have been fortified with a variety of vitamins and minerals. The candy labels contain nutrient content claims referencing the fortification. FDA is interested in studying the effects of the nutrient content claims on some fortified snack foods in order to determine whether the claims influence both consumers' perceptions about the healthfulness of these foods and their dietary choices.

The FDA, as part of its effort to promote public health, proposes to conduct a controlled, randomized experiment to explore consumer responses to expressed and implied nutrient content claims on the labels of snack foods such as cookies, carbonated beverages, and candy. The study is a part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will be used primarily to inform the Agency's understanding of how claims on the packages of fortified snack food may affect consumers' perception of the product or the label, which may in turn affect their dietary choices. The results of the study will not be used to develop population estimates.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

Participants for this data collection are individuals.

The study is part of the Agency's continuing effort to provide consumers with information to assist them in making informed dietary choices and constructing healthful diets. The information collection will explore consumer responses to expressed and implied nutrient content claims on the labels of snack foods such as cookies, carbonated beverages, and candy to help enhance FDA's understanding of consumer response to fortification claims made on fortified snack foods. Results of the study will inform the Agency's understanding about consumers' current perceptions and use of nutrient content claims on fortified snack foods and will be used to evaluate the current FDA policy on fortification of snack foods.

The data collection will include a single experimental study whose overall objective is to examine consumer reactions to 8 expressed or implied nutrient content claims on vitamin fortified cookies, candies, and a soft drink. The study will use a 15-minute Web-based questionnaire to collect information from 7,500 English-speaking adult members of an online consumer panel maintained by a contractor. Researchers will endeavor to collect samples that reflect the U.S. Census on gender, education, age, and ethnicity/race

Participants will view randomly assigned label images and answer questions about their perceptions and reactions to the label. Product perceptions (e.g., healthiness, potential health benefits, levels of nutrients) and purchase/choice questions will constitute the measures of response in the experiment. To help understand the data, the study will also collect information about participants' background, such as purchase and consumption of similar products; nutrition knowledge; dietary interests; motivation regarding label use; health status and demographic characteristics.

Conditions for the study include the following: 10 products (two kinds of chips, two kinds of cookies, two types of candy, and a soft drink); 10 nutrient content

claims, including 1 with a referral statement. All the claims to be tested reference at least one added nutrient and are similar to - or variants of - "as much [nutrient] as a serving of [food product]" or "good source of [nutrient]". Each participant will first be randomly assigned to t a product selection task. Then, following questions on food consumption, they will be randomly assigned to view a single product label about which they will respond to questions that comprise the dependent measures in the study. Each participant will be able to access the Nutrition Facts label to assist them in responding to the questions, if they so choose. Information on whether the Nutrition Facts label was accessed will be retained. All label images will be mock products resembling actual food labels found in the marketplace.

The following hypotheses led to the study design:

H_1: The presence of a claim for added nutrients on a fortified snack food (such as cookies, candy, or soft drinks)

(a) reduces nutrient information search (truncation);
(b) positively influences perceptions of product healthfulness,
    (b1) decreases perceptions of negative health effects related to over-consumption,
    (b2) negates the effects of a more healthful nutrition profile;
(c) increases product purchase desirability levels;
(d) increases likelihood of consumption;
(e) increases perceptions of product value;
(f) encourages substitution (of this product for a more nutritionally rich food source).

$H_{2:}$ The presence of a claim for added nutrients on a fortified snack food (such as cookies, candy, or soft drinks) *accompanied by a disclosure/disclaimer adjacent to the claim* will mitigate effects tested in $H_{1a\text{-}f}$.

H_3: For every fortified product, individual claims will significantly differ from each other on product evaluations.

Results of this study will be used to inform FDA policy makers on consumer reactions to expressed and implied nutrient content claims on cookies, candy, and soft drinks. The information will help FDA determine if the current policy on fortification of snack foods is adequate for ensuring that information on the food label helps consumers make informed dietary choices.

3. Use of Improved Information Technology and Burden Reduction

The study will use a web-based questionnaire. Web-based questionnaires not only reduce the burden on participants, but also minimize possible administration errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, web-based surveys are less intrusive and less costly.

4. Efforts to Identify Duplication and Use of Similar Information

No comparable data have been collected by any other entities. The experimental study proposed here will provide valuable information specific to consumer reaction to these fortification claims on fortified snack foods.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection.

If this information is not collected, FDA will not know how consumers respond to snack foods bearing expressed and implied nutrient content claims that draw consumers' attention to the fact that the product is fortified. This lack of information on fortified snack foods would impede FDA's ability to evaluate its policy on fortification in light of changes in the marketplace since the policy came into effect. The study is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require participants to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus two copies of the information; or retain records for more than 3 years. The design of the experimental study will not produce results that cannot be generalized to the response universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential information.

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 August 15, 2012 (77 FR 48988), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received six letters in response to the notice, each containing one or more comments. The comments, and the agency's responses, are discussed in the following paragraphs. One of the comments received was not responsive to the comment request on the four specified aspects of the collection of information. This non-responsive comment will not be addressed in this document. We respond to the remaining comments in this document. For ease of reading, we preface each comment with a numbered "Comment;" and each response by a corresponding numbered "Response." We have numbered each comment to help distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, or importance, or the order in which it was received.

(Comment 1) Four comments expressed support for the utility of the study for FDA's mission, stating that use of the study results will help FDA 1) fulfill its role as a steward of the public health; 2) continue to help consumers use the food label to make informed consumption decisions; and 3) help FDA to continue the policy against fortifying sugars or snack foods such as cookies, candies, and carbonated beverages.

(Response 1) FDA agrees with the comments.

(Comment 2) Reacting to FDA's declaration in the 60-day notice (77 FR 48988), that it intends to use "a mock snack product" to study nutrient content claims on fortified foods, one comment requested that FDA limit testing of such claims to sugars, cookies, candy, and carbonated beverages.

(Response 2) FDA agrees with the comment. FDA will limit testing of nutrient content claims on fortified snack foods to mock cookies, candy, and carbonated beverages.

(Comment 3) One comment requested that FDA use images of actual commercially available labels for fortified snack products in the study instead of the proposed mock snack food labels, claiming that use of actual labels will increase the external validity of the studies.

(Response 3) FDA disagrees with the comment. Actual labels will increase the external validity of the findings but actual labels also are highly likely to introduce brand effects, a bias that may be difficult to separate from effects of the claims themselves, which is the focus of the study.

9. Explanation of Any Payment or Gift to Participants

Cognitive interview participants will be recruited from a commercial database of residents in the Washington, D.C. metropolitan area. Each participant will receive a cash incentive of $40 to participate in a one-hour interview.

The study participants will be drawn from a panel maintained by Research Now. Research Now provides its Internet panel members with a token incentive as part of their continuous participation in the Internet panel. Panel members earn e-Rewards currency for the time they spend answering market research surveys. The appropriate incentive that panel members receive for participation is based on an approximate length of the survey. Members can redeem their earned currency for a variety of valuable rewards that are of interest to them. Some examples of incentive partners include Pizza Hut, Best Buy, J C Penney's, and Macy's, American Airlines, Hertz, Target, iTunes, and various publication companies for magazine subscriptions, among others. There is no additional payment or gift associated with participation in the study proposed here.

10. Assurance of Confidentiality Provided to Participants

All data will be collected with an assurance that the participants' answers will remain confidential. The study instrument will contain a statement that responses will be kept confidential. 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). Identifying information will not be included in the data files delivered by contractors to the agency. Information will be kept private to the extent permitted by law.

Confidentiality will be assured by using independent contractors, RTI and Research Now, to collect the information, by enacting procedures to prevent unauthorized access to participant data, and by preventing the public disclosure of the responses of individual participants. The contractors will only share data and/or information with FDA in an aggregated form or format, which does not permit FDA to identify individual participants.

Neither Research Now nor RTI will share personal information regarding panel members with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in the data files delivered to the agency. FDA and RTI will receive data for analysis in aggregate form. Although Research Now retains contact information on participants for honoraria purposes, individually identifiable information is not shared with anyone, including FDA and RTI; it is stored separately from the survey data file and is not linked in any way to participant responses.

RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. Research Now takes the following security measures to ensure separation between participants' identity and their survey data. First, the survey instrument has no personally identifying information (PII) on it. No participant name, address, email address, phone number or any other kind of PII appears on the survey. The only way a survey is identified is with a digital identification number. Second, while the invitation method, whether email, mail or direct mail will inherently have PII information included, this will not be combined with survey responses, so the responses from the survey are not linked to the PII. Third, screener data shall be considered part of the survey data. Research Now will provide the results of the screener questions for all panelists, regardless of whether they qualify for the study. However, Research Now will not retain responses to screening questions for those who are deemed ineligible for any other purpose outside the scope of this project. Fourth, Research Now will retain study records for the duration of the study. Upon final delivery of data files to RTI and completion of the project, Research Now will destroy all study records including data files upon request. Research Now will not be able to supply or access this information for any reason, even at the request of RTI, once destroyed. Finally, data coming directly from the survey engine are stored in a proprietary database. While this data is not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to RTI by Research Now will be sent via encrypted files.

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 does not include any questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA plans to conduct cognitive interviews by screening 75 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,600 invitations, each taking 2

minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 400 of them complete a 15-minute (0.25 hours) pretest. The total for the pretest activities is 153 hours (53 hours + 100 hours). For the survey, we estimate that 32,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 7,500 of them complete a 15-minute (0.25 hours) questionnaire. The total for the survey activities is 2,931 hours (1,056 hours + 1,875 hours). Thus, the total estimated burden is 3,099 hours.

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

Activity	Number of Participants	Number of responses per Participant	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1. (60 minutes)	9
Pretest invitation	1,600	1	1,600	0.033 (2 minutes)	53
Pretest	400	1	400	0.25 (15 minutes)	100
Survey invitation	32,000	1	32,000	0.033 (2 minutes)	1,056
Survey	7,500	1	7,500	0.25 (15 minutes)	1,875
Total					3,099

12b. Annualized Cost Burden Estimate

The annualized cost to all participants for the hour burden for the collection of information is $52,683. (3,099 x $17) at the 2012 median wage rate in the U.S.[1]

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

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

14. Annualized Cost to the Federal Government

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed April 2013.

The estimated total cost to the Federal Government for this information collection $200,000. This includes the value of the task order to develop and conduct 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 data collection. The new burden hours are due to a one-time data collection and its related pre-test and screener.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to help inform consideration for the possible modification of FDA's policy on fortification (21 CFR 104.20). The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. Final results of the study may be summarized for publication in a peer-reviewed scientific journal. The planned schedule for 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 the 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 the 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

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 studies are not intended or to be used for developing nationally representative population estimates of consumer attitudes, knowledge, or behaviors and that the studies provide valid and quantitative estimates of differences across experimental conditions.

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.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    No exceptions are requested.

List of Appendices:

A	Cognitive Interview Screener
B	Cognitive Interview Guide
C	E-mail Invitation to Pretest
D	E-mail Invitation to Questionnaire
E	Study Questionnaire
F	Sample of Mock Food Labels