

Request for OMB Review

Supporting Statement for

**Experimental Study of Qualified Health Claims:
Consumer Inferences about
Monounsaturated Fatty Acids from Olive Oil,
EPA and DHA Omega-3 Fatty Acids,
And Green Tea
0910-0592**

Submitted by:

Office of Regulations and Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services

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**Experimental Study of Qualified Health Claims:
Consumer Inferences about Monounsaturated Fatty Acids from Olive Oil, EPA and
DHA Omega-3 Fatty Acids, and Green Tea
Supporting Statement for Information Collection Request**

Approval is requested for an experimental study assessing consumers' reactions to four qualified health claims that have been allowed by the Food and Drug Administration (FDA) under enforcement discretion. The first claim relates consumption of monounsaturated fatty acids from olive oil to a reduced risk of coronary heart disease. The second claim relates consumption of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) fatty acids, referred to as "EPA and DHA omega-3 fatty acids," to a reduced risk of coronary heart disease. The third and fourth claims relate consumption of green tea to a reduced risk of breast and prostate cancers.

A. JUSTIFICATION

A.1 Necessity for the Information Collection

FDA regulates health claims in the labeling of food products under the Nutrition Labeling and Education Act of 1990 (NLEA). NLEA regulations establish general requirements for health claims in food labeling. A manufacturer is required to provide the scientific evidence supporting a proposed health claim to FDA for review before the claim may appear in labeling (§§ 101.14(c)-(d), 101.70 (21 CFR 101.14(c)-(d), 101.70)). If FDA determines that there is significant scientific agreement among experts that the proposed health claim is supported by the totality of publicly available evidence, FDA issues a regulation authorizing the claim. Health claims must be "complete, truthful, and not

misleading” (§101.14(d)(2)(iii)) and must "enable[] the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet" (§ 101.14 (d)(2)(v)).

In 2003, an FDA Task Force on Consumer Health Information for Better Nutrition issued a report that provided guidance on an interim procedures and a review process for health claims that do not meet the significant scientific agreement (SSA) standard. These claims, referred to as “qualified health claims,” are given qualifying language to distinguish the level of scientific evidence for the claim. Qualified health claims are issued letters of enforcement discretion and do not go through rulemaking, as with SSA health claims. The report also identified the need for consumer research to examine ways to communicate the level of scientific support associated with qualified health claims.

In the fall of 2004, FDA issued letters of enforcement discretion for two qualified health claims about the relationship between risk of coronary heart disease and consumption of monounsaturated fatty acids from olive oil and EPA and DHA omega-3 fatty acids, respectively. The qualified health claims appear below:

1. Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product [Name of food] contains [x] grams of olive oil.

2. Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name

of food] provides [x] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat and cholesterol content.]

In June 2005, FDA issued a letter of enforcement discretion for two qualified health claims about the relationship between risk of breast and prostate cancers and consumption of green tea. The qualified claims appear below:

1. Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.

2. One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on the studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.

In November 2005, FDA released the results of a prior study of qualified health claims to assess the effectiveness of claim language and grading schemes for conveying the level of scientific evidence supporting the claim. The study showed that report card schemes helped consumers distinguish between various levels of scientific support. However, the report card scheme inadvertently conveyed other nutrient and product attributes to consumers. In particular, report card schemes resulted in “halo effects” and other misperceptions concerning the general healthfulness and quality of the product. In addition, the study showed that consumers attributed higher levels of scientific support to certain qualified health claims bearing a grade of “B” than to non-graded claims that meet

FDA's standard of "significant scientific agreement" (SSA). Thus, the study proposed here will further explore the report card grading scheme by modifying it in two ways. First, the study will test the ability of grade disclaimers to correct for some of the misperceptions created by report card schemes observed in the earlier study. Second, the study will include SSA claims as "A" grade claims within the report card grade scheme.

The study proposed here is part of an ongoing effort by FDA to collect data concerning qualified health claims and their impact on consumer perceptions and behavior. Previous FDA studies have examined hypothetical qualified health claims to evaluate ways to communicate the strength of scientific evidence supporting a claim. This study will examine four qualified health claims and two SSA claims to evaluate whether consumers comprehend the information in the claim and whether consumers understand the relative significance of the information in the context of a total diet. In addition, the study will broaden FDA's understanding about how consumers interpret qualified health claims, particularly as they pertain to the level of scientific evidence conveyed by the message and to any differences there may be between qualified health claims on dietary supplements versus foods.

A2. How, By Whom, and the Purpose for Collecting This Information

The objectives of the proposed study are:

1. Evaluate whether consumers distinguish the level of scientific support for each of the allowed claims above.
2. Evaluate whether consumers understand that the health benefit from monounsaturated fats from olive oils depends on a substitution of fats in the diet.

3. Evaluate how consumers evaluate health claims for substances that do not have a minimum effect level, such as for EPA and DHA omega-3 fatty acids.
4. Determine if consumers evaluate health claims on dietary supplement labels differently than when the same claim appears on conventional food labels.

The claims above represent three levels of scientific support for qualified health claims as described in the evidence-based ranking system. With the inclusion of SSA claims, four levels of scientific support will be represented in the study. Each claim will be matched with one food product and one dietary supplement. The study design is based on the controlled presentation of realistic product labels that carry the qualified health claims listed above. There are four control conditions in the design, representing important types of label statements and label users. These constitute benchmarks against which one can assess the direction and magnitude of effects due to communications about the strength of scientific evidence for the health claims, as well as other variations in the label, such as the inclusion of a nutrient content claim.

The claims will be examined through a Web-based experimental protocol. Consumers will be selected from an Internet panel of 500,000 consumers. Participants will be adults, aged 18 or over, who have recently shopped for groceries or dietary supplements. The study sample will be reasonably diverse in terms income, race and education. Before looking at the product label, each respondent will answer questions concerning prior knowledge and usage/consumption of EPA and /DHA omega-3 fatty acids, monounsaturated fatty acids from olive oil, green tea, and dietary supplements. Additional background information, such as demographics, health status, and current label use will also be collected.

Each participant will be randomly assigned to conditions and be asked to examine a realistic-looking label for a product. Likely products used in the study are two foods, such as tuna (for EPA and DHA omega-3 fatty acids) and olive oil (monounsaturated fatty acids from olive oil), a beverage (green tea), and three dietary supplements, such as fish oil (EPA and DHA omega-3 fatty acids), olive oil extract, and green tea extract. Sample labels to be used for the study are found in Attachment 2. The participants will answer a short set of questions concerning their perceptions of the product (expected health benefits, perceived nutritional value) and the level of scientific support for the health claims. They will also answer questions to measure their comprehension of usage information contained within the claim to achieve the claimed health benefit and quantities needed to achieve the potential health benefit.

The Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) is the primary user of this information. The results will assist the FDA in decisions concerning petitioned health claims for foods and dietary supplements.

A3. Use of Technology to Reduce the Burden on the Public

The study uses electronic collection of information. Respondents to the study are selected from an Internet panel. They view labels and respond to questionnaires over the Internet using personal computers or Web-enabled televisions in their homes.

A4. Identification and Use of Duplicate Information

In 2004, researchers from FDA evaluated consumer responses to qualified health claims and evaluated several options for communicating to the consumer the level of scientific evidence supporting these claims. The results of the study indicate two primary findings that will be further explored with the study proposed here. First, report card

schemes help consumers determine the level of scientific support for health claims, but also result in mistaken inferences about other nutrient and product attributes. Second, when SSA grades are not assigned an “A” grade, consumers perceive qualified claims with a “B” grade for scientific support as having greater scientific support than SSA claims.

The proposed study assesses reactions to actual qualified health claims that have been allowed under the Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 2003). In contrast, the previous study assessed consumers' responses to various forms of qualifying language similar to that allowed under enforcement discretion, but not found in the marketplace. The current study will assess actual health claims that appear in the marketplace, thereby lending the study greater ecological validity than the previous study. In addition, the current study evaluates the effect of the health claims on conventional foods and dietary supplements, whereas the previous study evaluated claims only on conventional foods. In response to the previous study's findings, the study will examine means by which the report card scheme may be qualified to ensure that consumers do not perceive the report card grade as an assessment of a product's overall quality. Specifically, some conditions will employ the report card scheme in conjunction with the text, “This rating is not a grade for the product's quality, safety, or overall healthfulness.” The study will also ascertain the effectiveness of including SSA claims with other qualified health claims within the report card scheme.

The agency has reviewed the literature on consumer research on qualified health claims. The current literature does not answer the questions of interest for this study.

A5. FDA’s Efforts to Reduce Burden on Small Business

There is no impact on small business from this data collection.

A6. Impact of Not Collecting This Information or Collecting Information Less Frequently

This study is a one-time data collection. FDA is operating under interim procedures for reviewing qualified health claims. Consumer data are important to the development of procedures for reviewing future petitions for qualified health claims. A central consideration for qualified health claims is the importance of ensuring that such claims can be made in a way that is not misleading to consumers.

A7. Special Circumstances That Occur When Collecting This Information

No special circumstances.

A8. Identification of Outside FDA Sources

This Information Collection Request was written prior to receiving public comments. The study will be revised in response to public comments, as needed.

A9. Payment or Gifts Offered to Participants

There will be no payments or gifts directly associated with this study. However, the Internet panelists are rewarded several ways. They receive points for every survey invitation that they receive, whether they qualify or not. Points are redeemable for gifts and prizes. The amount of points given to panelists is influenced by the survey length and complexity. The panelists are also eligible for a bi-monthly sweepstakes that awards one Grand Prize of \$10,000.

A10. Method of Ensuring Confidentiality

All respondents will be provided with the assurance of confidentiality. The study will include information explaining to respondents that their information will be kept confidential. An independent contractor for the FDA will collect the data and will not provide FDA identifying information on the respondents, in accordance with the terms of the contract. Thus, the confidentiality of the information submitted 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).

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).

A11. Use of Sensitive Questions

This study does not include any sensitive questions.

A12. Burden Hours and Cost Associated With This Information Collection

The total sample size is 7,440. Based on previous experience with Internet panel studies, FDA estimates the total annual burden for this one-time collection of information to be 1,196 hours.

Estimated Annual Reporting Burden

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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Pre-test	30	1	30	0.16	5
Experiment	7,440	1	7,440	0.16	1,191
Total					1,196

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

A13. Annual Cost Estimate to Participants

There are no costs associated with this data collection outside the burden reflected in A12.

A14. Cost Estimate to FDA

The estimated cost to the federal government is approximately \$178,000. This includes fees paid to the contractor to program the study, draw the sample, collect the data, and create a database of the results.

A15. Changes from Previous Approval

This is a new data collection.

A16. Statistical Reporting

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 data does not provide nationally representative estimates of consumer attitudes, knowledge, or behavior.

The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature

of any such dissemination has not been determined, but may include presentations and articles at trade and academic conferences, publications, and Internet posting.

A17. Display of the OMB Approval Date

No exemption is requested.

A18. Exceptions to Section 19, “Certification for Paperwork Reduction Act Submissions”

No exceptions are requested.

Part B COLLECTION OF INFORMATION USING STATISTICAL METHODS

B1. Universe and Sampling

Respondents are adults, aged 18 and older. Respondents are randomly assigned to experimental conditions in this experimental study. The study does not use statistical sampling. Respondents are volunteers, recruited from an Internet panel of 500,000 consumers. The purpose of the study is to assess the impact of different verbiage and graphics for conveying health claims on dietary supplement labels. Although the study will not provide nationally representative estimates of consumer attitudes and self-reported behaviors, as in a survey, it will provide scientific data that are appropriately analyzed with statistical methods.

B2. Procedures for Collecting the Information

Each respondent is randomly assigned to a single treatment condition that consists of a series of questions about a product label. The respondent answers the questionnaire and submits responses from a personal computer or Web-enabled television. Each of the approved and petitioned health claims will appear on a variety of products: three foods and three dietary supplements. Responses will be evaluated across claims and across products to determine whether differences in how consumers interpret claims arise because of language differences in claims or because of the type of product on which the claims appear.

B3. Methods to Increase or Maximize the Response Rates

The project relies on the use of an existing Web-enabled/Internet panel to enlist respondents. The panel includes people who have expressed interest in sharing their opinions via the Internet. To help ensure that the response rate is as high as possible, the agency will:

- Design a protocol that minimizes burden (short in length, clearly written, and with appealing graphics);
- Test the draft protocol in a pretest to ensure that it minimizes burden and refine as appropriate;
- Administer the study over the Internet, allowing respondents to answer questions at a time and location of their choosing;
- E-mail a reminder to the respondents who do not complete the protocol after beginning the study;
- Provide contact information on where to get help for respondents who may have questions as they complete the data collection instrument.

B4. Tests, Procedures, or Methods Used

The sample size is 7,440. Each individual is randomly assigned to experimental conditions. Conditions consist of one of ten products and one of several labeling scenarios (see attached protocol). The experiment consists of a total of 124 cells with 60 subjects in each cell. Sixty (60) individuals per experimental condition (cell) allows for sufficient power to hypothesize a moderate effect size of 0.5, with alpha equal to .05 and a beta equal to 0.2. Effect size is defined as the difference in cell means divided by the standard error. A General Linear Model will be employed to measure the effects of experimental variables on the outcome measures. Individual differences (prior beliefs

and attitudes, health status and demographics) will be included as covariates in the analysis.

The products used in the experiment will be (1) tuna fish; (2) olive oil; (3) fish oil supplement; (4) olive oil supplement; (5) green tea beverage; (6) green tea supplement; (7) oatmeal; (8) soluble fiber capsules; (9) orange juice; or (10) plant sterol extract. The labeling scenarios include labels that feature no claim, a qualified health claim, a modified version of a qualified health claim, a nutrient content claim, a combination of a qualified health claim and a nutrient content claim, a qualified health claim accompanied by a report card grade schematic, or a qualified health claim with report card grade schematic accompanied by additional disclaimer language clarifying the intent of the report card grade. The additional disclaimer language is as follows: “This rating is not a grade for the product’s quality, safety, or overall healthfulness.”

The contractor will conduct pretests to test experiment procedures. The pretests will field the study with a small group of participants from the Internet panel. The purpose of the pretests is to determine if the study has been properly programmed, to detect technical difficulties that may be experienced by respondents, and to determine if the study is reasonable in length. Changes to procedures or the questionnaire will be submitted to OMB prior to data collection.

B5. Identification of Consultation

The contact individuals are Conrad J. Choiniere, Ph.D. (Project Officer), Division of Social Sciences, Consumer Studies Staff, HFS-727, telephone (301) 436-1844, and Linda Verrill, Ph.D., Division of Social Sciences, Consumer Studies Staff, HFS-727, telephone (301) 436-1765.

ATTACHMENTS

Attachment 1: Draft Protocol and Draft Questionnaire

Attachment 2: Sample Product Labels