

Supporting Statement for OMB Review

**Experimental Study of Health Claim Disclaimers on  
Foods**

Submitted by:

Office of Scientific Analysis and Support  
Division of Market Studies  
Food and Drug Administration  
Department of Health and Human Services

November 14, 2003

**Experimental Study of Health Claim Disclaimers on Foods**  
**Supporting Statement for Information Collection Request**

Approval is requested for an experimental study of health claims for conventional foods to evaluate the communication effectiveness of various possible labeling statements (i.e., disclaimers) to convey different levels of scientific support for health claims.

**A. JUSTIFICATION**

**A.1 Necessity for the Information Collection**

The Food and Drug Administration (FDA) regulates the labeling of food products and dietary supplements under the Nutrition Labeling and Education Act of 1990 (NLEA). NLEA regulations established general requirements for health claims in food labeling. A manufacturer is required to provide a description of the scientific evidence supporting a proposed health claim to FDA for review and authorization before the claim may appear in labeling.

In a 1999 court case, *Pearson v. Shalala (Pearson)*, plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision to not authorize four specific health claims. FDA lost this case in the Court of Appeals on the grounds that the First Amendment does not permit FDA to prohibit health claims on dietary supplements without showing that less extreme remedies, such as the use of disclaimers, would fail to remedy the potential harm caused by the potentially misleading claim. FDA had no evidence demonstrating that disclaimers could not correct for deceptiveness, so the Court overturned the existing regulations as not giving sufficient deference to First Amendment considerations and required that disclaimers be considered

as remedies to render claims non-misleading. In October 2000 FDA published a notice announcing its intention to exercise “enforcement discretion” regarding certain categories of dietary supplement health claims that did not meet the significant scientific agreement (SSA) standards (FR 65, 59855-59857) and in December 2002 the guidance was expanded to include conventional foods as well as dietary supplements (FR 67, 78002-78004).

FDA announced an initiative “to make available to consumers more and better information about the health benefits of foods and dietary supplements,” (FDA’s Consumer Health Information for Better Nutrition Initiative, December 18, 2002, FR 67, 78002-78004) with the ultimate goal to help American consumers make sound dietary decisions, thereby reducing the risk of certain diseases and improving the public health. As part of this initiative the Commissioner announced the FDA Task Force on Consumer Health Information for Better Nutrition (Task Force), with representatives from the FDA, the Federal Trade Commission and the National Institutes of Health (January 16, 2003).

The Task Force issued a report that provided guidance on an interim review process for health claims on food labels and identified the need for consumer research to examine ways to communicate the level of scientific support associated with health claims that do not meet the traditional SSA standard (“Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, July 10, 2003; 68 FR 133 41387-41390).

The proposed study focuses on health claims on conventional foods. Because dietary supplements present unique issues and questions, it is not feasible to include both

food and dietary supplement products in this study. FDA intends to conduct a similar experimental study of health claim disclaimers on dietary supplements in the future.

The logic of the study is to examine several possible options for communicating to consumers about the strength of scientific evidence that underlies a given health claim. These options will be tested across a range of health claims, each associated with a food product appropriate to carry the claim. The claims will vary in terms of the actual strength of supporting scientific evidence. Claims will be presented to consumers with varying levels and forms of disclaimers about the strength of scientific evidence supporting the claim. The major goal of the research is to determine if it is possible to effectively communicate the actual strength of science associated with a given health claim, and if so, which form of disclaimer works best (see Attachment 1: Proposal for Experimental Study of Health Claim Disclaimers on Foods).

The impact of disclaimers is examined across a range of measures that capture what is conveyed by the claim and disclaimer on the label as well as the impact of the label claim on attributions about the food product that displays the claim

Wording approaches for disclaimers are based on options identified in the task force discussions. Specific disclaimer language was developed in consultation with the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) to correspond to the three levels of scientific support for qualified claims described in the evidence-based ranking system. Because of limits due to sample size and number of conditions, only one food product per health claim is feasible. As a result food and claim are confounded:

Level A Claim (HCP1): Calcium and reduced risk of osteoporosis/fortified orange juice

Level B Claim (HCP2):       Omega-3 fatty acids and reduced risk of heart disease/ tuna  
Level C Claim (HCP3):       Selenium and reduced risk of cancer/eggs  
Level D Claim (HCP4):       Lycopene and reduced risk of cancer/spaghetti sauce

The study design is based on the controlled presentation of realistic two-dimensional product labels that carry health claims for the four nutrient/disease relationships listed above (see Attachment 2: Sample Labels). Disclaimer level conditions and wording options are nested within the four health claims. Four different schemes for communicating strength of science are tested: Point-Counterpoint language (PC), Embedded language (E), Report Card (RC) and Graphic (G). Each scheme adopts the four-level strength of science ranking system proposed by the Task Force Report. To increase the efficiency of the design, all four levels of disclaimer will not be implemented for every health claim/product. Only disclaimer levels one level above and one level below the “correct” level of scientific support for the health claim will be tested (see Attachment 3: Schemes and Label Conditions (Appendix 1: Experimental Study of Health Claim Disclaimers on Foods)).

There are four control conditions in the design, representing important types of label statements and label users that constitute benchmarks against which we can assess the direction and magnitude of effects due to communications about the strength of scientific evidence for the health claims (see Attachment 1).

During the experimental session, each subject will see two products and go through the same experimental protocol and sequence of questions for each product. By obtaining two data points from each subject, the efficiency of the sample is greatly increased, but it becomes necessary to control for possible learning and order effects. Product pairings and order of presentation will be fully counterbalanced within each

experimental condition. To minimize the likelihood of interference between label treatments, each respondent will see one label condition with a level of science disclaimer and one label condition with either a “no health claim” control or an unqualified statement of the substance/disease health claim. The key measures for this study are a level of science conveyance rating and product perception questions about the labeled food product (expected health benefits, perceived nutrition ratings).

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

Data will be collected using a mall intercept methodology. Under a task order contract, Taylor Nelson Sofres Intersearch will implement the study in six shopping malls nationwide. Each site will have a central interviewing facility and will be responsible for recruiting respondents, obtaining respondents with the required background characteristics, conducting the interviews and documenting the interview experience, as needed. Respondents (N=1,920) will be randomly assigned to an experimental condition. Each site will have a complete replicate of the experimental design.

The Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) is the primary user of this information. This study examines specific approaches and wordings proposed by the Task Force, FDA management and ONPLDS that systematically vary approaches for each of the newly proposed disclaimer levels across a variety of products and nutrient/disease health claims.

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

The study does not involve electronic collection of information. It relies on conventional procedures for shopping mall intercept one-on-one interviews.

#### **A4. Identification and Use of Duplicate Information**

There is no other research currently available that addresses the specific options for communicating the level of scientific support underlying qualified health claims associated with the recently proposed four-level rating scheme for health claims described in the interim guidance document. Prior to designing the study, FDA reviewed the consumer research literature related to health claims and disclaimers on foods and dietary supplement (see References). The most relevant study is by the Federal Trade Commission (FTC) on disclaimers for health claims in food advertising (Murphy, Hoppock and Rusk, 1998). The FTC study differs from the proposed research in several important respects, directly related to the different regulatory approaches for advertising versus labeling. The focus in the segment of the FTC study that focuses on strength of science claims is limited to “ad takeaway,” a narrower context than is needed by FDA in assessing the impact of qualified claims on food labels. The proposed study examines health claims in the context of other food label information typically available to consumers when they encounter health claims, such as product specific nutrient information in the Nutrition Facts Panel. Insights from the FTC research are incorporated into the proposed study; for example the health claim message conveyance questions are comparable to the FTC 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. The interim procedures provide guidance to industry regarding how the agency will respond to qualified health claims until the agency can promulgate notice-and-comment rulemaking. However, guidance documents do not establish legally enforceable responsibilities and are intended only as recommendations. Interim procedures strain the agency's limited resources for reviewing health claims and create uncertainty for industry.

Consumer data are important to the development of new regulations for health claims. A central consideration in the development of a new regulatory framework for health claims is the importance of ensuring that such claims can be made in a way that is not misleading to consumers. The agency recognizes that it is unknown whether consumers can distinguish between differing levels of scientific support and there are no consumer data currently available to assess the effectiveness of wording options proposed for conveying the different levels.

#### **A7. Special Circumstances That Occur When Collecting This Information**

No special circumstances.

#### **A8. Identification of Outside FDA sources**

The proposed experimental study was presented to the FDA Task Force and revised based on Task Force member input (see Attachment 4: Members of the Consumer Health Information for Better Nutrition Initiative Task Force).

In developing the study protocol and questionnaire, FDA consulted with organizations and individuals that have an established interest and expertise in consumer research on similar topics. Staff at the Federal Trade Commission (FTC) provided input

and reviewed drafts of the proposal. FTC deals with similar consumer issues related to health claims in product advertising and has conducted research on disclaimers in food advertising, as noted earlier (Murphy, Hoppock and Rusk, 1998). FTC briefed FDA on ongoing research to follow-up the 1998 study and met with FDA researchers to discuss the proposed FDA study. FTC research staff reviewed drafts of the study and the proposal was revised to incorporate FTC's comments.

FTC Reviewers:

1. Pauline M. Ippolito, Associate Director, Bureau of Economics
2. Mary K. Engle, Associate Director for Advertising Practices, Bureau of Consumer Protection.
3. R. Dennis Murphy, Bureau of Economics, Division of Consumer Protection
4. Michelle Rusk, Bureau of Consumer Protection, Division of Advertising Practices

The revised proposal was sent to three external peer reviewers at academic institutions with expertise in consumer research and labeling topics. The reviewers provided comments on the study design and questionnaire. The proposed study incorporates the comments from the peer reviewers.

Peer Reviews:

1. Manoj Hastak, PhD  
Associate Professor and Chair of Marketing Department  
Kogod School of Business  
American University, Washington, DC
2. Alan Mathios, PhD  
Associate Professor and Department Chairperson  
Department of Policy Analysis and Management  
Cornell University, Ithaca, NY
3. Debra Ringold, PhD

Associate Dean and Professor of Marketing  
Atkinson School  
Willamette University, Salem, Oregon

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**

The proposed study uses a mall intercept methodology to recruit volunteers. It is industry practice to offer a modest monetary incentive to respondents. This study will provide an incentive of \$3.00-\$5.00 to (amount based on mall location).

**A10. Method of Ensuring Confidentiality**

No identifying information about individual is included in the data file or other information provided to the government by the contractor. At the conclusion of individual interviews, are asked to provide their first name, address and telephone number for validation purposes. This is an essential control measure to ensure the validity of the data. Identifying information for interview validation will be destroyed once data collection is complete. This information will never be made available to the government.

**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 is 1,920. Based on past experience, recruitment and interviewing will average 18 minutes.

Estimated Annual Reporting Burden<sup>1</sup>

Number of	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,920	1	1,920	.30	576

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

**A13. Annual Cost Estimate to**

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

**A14. Annual Cost Estimate to FDA**

FDA has contracted with Taylor Nelson Sofres Intersearch for data collection services. Peer reviewers were paid under personal services contracts.

Contractor estimated cost =	\$250,443
Peer reviewers =	\$ 5,700
Total =	\$256,143

**A15. Changes from Previous Approval**

This is a new project.

**A16. Publishing the Results of This Information Collection**

A final report of the study procedures and results will be issued at the end of the data collection period, as specified in the contract. The results will be presented to FDA management and the report will be made available to the docket and on FDA's website, as part of any future proposed rulemaking on qualified health claims. It is anticipated

that the findings will be presented in FDA reports and in publications in scientific journals.

**A17. Reason for Not Displaying the OMB Approval Date**

The OMB Approval Date will be displayed on the questionnaire.

**A18. Explanations 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, who do at least half the household grocery shopping, and who are able (with or without corrective lenses) to read small print (see Attachment 5: Draft Screener and Draft Questionnaire).

This is an experimental study in which respondents are randomly assigned to experimental conditions. It does not use statistical sampling. Respondents are volunteers, recruited using standardized procedures, from shopping malls in multiple locations across the country.

The purpose of the study is to examine relationships among variables to assess the impact of different options for conveying information on food labels, not to provide nationally representative estimates of consumer attitudes and self-reported behaviors, as in a survey. The methodology is similar to that used by FTC to conduct copy tests of advertisements. It provides scientific data that are appropriately analyzed with statistical methods.

### **B2. Procedures for Collecting the Information**

Respondents are recruited in shopping malls, using quota samples based on gender, age and education. Each respondent is randomly assigned to a particular treatment condition that consists of a series of questions about two food product labels. A trained interviewer administers the questionnaire.

In order to evaluate a variety of approaches to conveying strength of science underlying health claims on food labels, the study is organized into four “schemes” as described earlier. Attachment 2 shows the experimental conditions and schemes for the four health claim/product combinations. The design is not fully crossed. The correct claim/disclaimer condition is indicated with an asterisk.

### **B3. Methods to Increase or Maximize the Response Rates**

Trained recruiters will invite individuals to participate in the study. A small stipend will be offered.

### **B4. Tests, Procedures, or Methods Used**

The contractor will conduct nine pretests to test procedures. Changes to procedures or the questionnaire will be submitted to OMB prior to data collection.

### **B5. Identification of Consultation**

The contact individuals are Brenda M. Derby, Ph.D., Division of Market Studies, Consumer Studies Team, HFS-727, telephone (301) 436-1832 (Project Officer), and Alan S. Levy, Ph.D., Division of Market Studies, Consumer Studies Team, HFS-727, telephone (301) 436-1762 (Senior Scientist), and David B. Lambert, Ph.D., Senior Vice President, TNS Intersearch, (215) 442-9638.

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## **ATTACHMENTS**

Attachment 1: Proposal for Experimental Study of Health Claim Disclaimers on Foods

Attachment 2: Appendix 1: Experimental Study of Health Claim Disclaimers

Attachment 3: Members of the Consumer Health Information for Better Nutrition Initiative Task Force

Attachment 4: Draft Screener and Draft Questionnaire

Attachment 5: Sample Labels

Level A Claim: Calcium and osteoporosis/Orange juice

Level B Claim: Omega-3 fatty acids and heart disease/tuna

Level C Claim: Selenium and cancer/Eggs

Level D Claim: Lycopene and cancers/Spaghetti sauce