Supporting Statement for

Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative *Trans* Fat Disclosures on the Nutrition Facts Panel

OMB No. 0910-0532

Submitted by:

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

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A. JUSTIFICATION

1 Need and Legal Basis

The Food and Drug Administration (FDA) regulates the labeling of food products under the Federal Food, Drug and Cosmetic Act of 1938 as amended by the Nutrition Labeling and Education Act of 1990 (NLEA).

In the Federal Register of November 1999, FDA published a proposed rule (64 FR 62746) to amend regulations on nutrition labeling to require that the amount of *trans* fatty acids (*trans* fat) present in a food be included on the Nutrition Facts Panel (NFP). The purpose of the proposal was to better enable consumers to understand the contribution of the product to a total diet as mandated by NLEA. In the proposal, FDA agreed with the argument made by a petitioner that consumers need to know the levels of *trans* fat in a food product to be able to judge the nutritional significance of that product in the context of the total diet. Dietary *trans* fatty acids, like saturated fats, have adverse effects on blood cholesterol levels and the public health recommendation is to keep intake as low as possible.

The agency initially proposed that *trans* fat levels be disclosed on the NFP as part of the saturated fat declaration (combining the gram amount of saturated fat and *trans* fat and recalculating the percent Daily Value (DV) to include *trans* fat). A footnote was proposed to indicate the amount of *trans* fat included in the combined amount.

Comments to the proposal argued against combining *trans* and saturated fat amounts into a single amount on grounds that there was no scientific or public health basis for applying the saturated fat DV to this combined amount. In November 2002 (67 FR 69171) the agency reopened the comment period and proposed that the declaration of *trans* fat on the NFP be on a separate line immediately under that for saturated fat, without an accompanying percent DV declaration, but with an accompanying footnote stating, "Intake of *trans* fat should be as low as possible." The purpose of the accompanying footnote was to ensure that the *trans* fat information "be conveyed to the public in a manner which enables the

public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet," as specified in the NLEA.

Several comments challenged the agency's assumptions about how the accompanying footnote would be interpreted by consumers. Three separate research studies were submitted (Center for Science in the Public Interest (CSPI), 2003; International Food Information Council (IFIC), 2003; Conagra Food, 2003) that showed limitations in the public's ability to use and understand the quantitative *trans* fat information in the presence of the proposed footnote. These studies provide some empirical evidence to support arguments made in a number of other comments that the proposed footnote might distort the appropriate understanding of the dietary significance of *trans* fat relative to other fatty acids, thereby causing the public to make poorer, rather than healthier, product choices. Since this is the opposite of the intended effect of the proposed footnote, the agency has determined that a systematic study is required to assess what kinds of footnotes or other decision aids are best able to help the public use the quantitative *trans* fat information in the NFP to make healthful dietary choices.

In June 2003, FDA issued a final rule that requires disclosure of quantitative *trans* fat information on the NFP on a separate line without any accompanying footnote (68 FR 41434). At the same time, the agency issued an Advance Notice of Proposed Rule Making (ANPRM) asking for comments about possible footnotes to help consumers better understand *trans* fat declarations on the product label (68 FR 41507). The agency asked for information about whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the NFP to enhance consumers' understanding about such cholesterol-raising lipids and how to use disclosed information on the label to make healthful food choices. The proposed study is intended to evaluate the ability of several possible footnotes and cueing schemes to enable consumers to make heart-healthy food choices in order to provide empirical support for possible policy decisions about the need for such requirements and the appropriate form they should take.

The authority for FDA to collect the information for this experimental study derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Food, Drug, and Cosmetic Act (the act) (21 USC § 393(d)(2)). (A copy of this statutory section is included as Attachment A.)

2. Information Users

The Office of Nutritional Products, Labeling and Dietary Supplements in FDA's Center for Food Safety and Applied Nutrition is the primary user of this information. The information objectives for the study are to:

1. Evaluate possible label formats and dietary guidance footnotes to determine whether and to what extent these labeling options contribute to misunderstanding or misapplying the quantitative *trans* fat information declared on the NFP.

2. Assess the effectiveness of labeling options using measures that represent consumer understanding and ability to use quantitative information about *trans* fat and other fatty acids in realistic product selection situations

3. Assess the role that a consumer's prior knowledge about the nutritional significance of *trans* fat plays in determining the impact of *trans* fat- related label information.

The study uses an experimental design where effects of various proposed footnote conditions are estimated by exposing random samples of participants to controlled experimental conditions. Stimulus differences between conditions consist entirely of the experimentally manipulated label treatments that embody different possible versions of proposed footnotes or label formats. Because individual differences are randomly distributed across conditions, it is possible to use standard statistical techniques such as analysis of variance and multivariate regression analysis to test observed treatment effects between conditions.

The study uses an Internet panel for data collection. Internet panels have proven substantially equivalent to mall intercept methods. They allow visual presentation of study materials, experimental manipulation of study conditions, and the random assignment of subjects to condition. The study will use a convenience sample drawn from a large national consumer panel with almost one million participating households developed by the data collection contractor, Synovate.

Participants will be adults, aged 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 54 experimental conditions. As existing members of the Internet panel, participants are notified by e-mail about the availability of a new survey. They are invited to go to a secure website to complete the survey. They will be asked to thoroughly review the package labeling of products presented to them in pairs and then

answer questions about the product's perceived health benefits, choice preferences, risk/benefit tradeoffs, and other questions.

Manipulations

Product Types/Fatty Acid Profile

It is necessary to demonstrate the generalizability of observed effects across a representative range of product types to ensure that some unique aspect of a particular product type is not responsible for the observed effects. We propose to include three product types in the study that represent typical kinds of products that contain significant amounts of *trans* fatty acids: donuts, margarine and a frozen lasagna dinner. Attachment B shows the two fat profiles for each product.

Label Format Options

We propose to test three label format variations for presenting *trans* fat information on the NFP.

1. Label Format 1 is the current *trans* fat label, which went into effect January 1, 2006. Declarations of saturated and *trans* fat are on separate lines with a %DV for saturated fat, but not for *trans* fat.

2. Label Format 2 is that suggested in the Institute of Medicine (IOM) report (IOM/NAS, 2002). Declarations of saturated and *trans* fat are on separate lines, but one %DV is included in the Nutrition Facts box for these nutrients together.

3. Label Format 3 is the format implemented by Health Canada. Declarations of saturated and *trans* fat are on separate lines with a "+" symbol indicating they are to be combined with one %DV for these nutrients together.

Footnote Options

For all footnote conditions, the NFP uses Label Format 1 (current label). The control condition is identical to Label Format 1 (Footnote Option 7).

1. Footnote Option 1. a. Asterisk by *trans* fat b. Footnote: "Intake of *trans* fat should be as low as possible."

2. Footnote Option 2 (CSPI proposed option). a. Asterisk by saturated fat and *trans* fat b. Footnote: "Combined intake of saturated and *trans* fat should be as low as possible."

3. Footnote Option 3. a. Asterisk by saturated fat and *trans* fat b. Footnote: "Combined intake of saturated and *trans* fat should be kept as low as possible while maintaining a nutritionally adequate diet."

4. Footnote Option 4. a. Asterisk by saturated fat and *trans* fat b. Footnote: "Combined intake of saturated, *trans* fat and cholesterol should be kept low."

5. Footnote Option 5. a. Asterisk by saturated fat, *trans* fat, and cholesterol. b. Footnote: "Intake of saturated fat, *trans* fat and cholesterol should be kept low."

6. Footnote Option 6. a. Asterisk by saturated fat, *trans* fat, and cholesterol. b. Footnote: "Intake of cholesterol-raising substances should be kept low."

7. Footnote Option 7 (Control). No asterisks and no footnote.

Information Manipulation

Given the current limited level of *trans* fat knowledge in the population (e.g., see Kozup, Burton & Creyer, 2006), and the aim of the *trans* fat labeling policy to increase such knowledge, we propose to systematically manipulate the *trans* fat knowledge of participants. Participants in the "Full Information" condition will be briefed about relevant facts concerning *trans* fat prior to seeing any product labels. Participants in the "No Information" condition will not be given any information about *trans* fat.

The manipulation of prior knowledge will allow evaluation of the effectiveness of policy options under conditions approximating the current distribution of knowledge in the population as well as conditions representing greater familiarity with the nutritional consequences of the *trans* fat. (Attachment C: *Trans* Fat Information Sheet)

The draft Full Information material was revised based on comments received to the Federal Register notice published February 6, 2006 (71 FR 6076) (the February 2006 Federal Register notice). Additional revisions may be made as a result of pretesting.

Experimental Design

The basic experimental design is

Information Treatment (Full Information/No Information) X Product Type (Donut, Margarine, Frozen Lasagna Dinner) X Format/Footnote Conditions (9) results in a fully crossed design with 54 conditions.

Each cell will contain 60 respondents, (Total N=3240) which will provide adequate power to identify small to medium size effects (i.e., r = .15-30) for all main effects and first order interactions with power = (1-beta) well in excess of .80. Power for second and third order interactions will necessarily be smaller, but even for third order interactions power = .65.

As noted above, the Office of Nutritional Products, Labeling and Dietary Supplements is the primary user of this information. The information provided by the study will inform regulatory initiatives announced in the June 2003 ANPRM and elaborated in the February 2006 Federal Register notice. The results will be made available as part of the docket so that all interested parties can comment on and benefit from the findings.

3. Improved Information Technology

The study relies on a commercially available Internet panel as the sample frame from which participants can be randomly drawn and assigned to experimental conditions. All data collection will take place over the Internet. Historically experimental studies were conducted using a mall intercept methodology in which participants are recruited from shopping malls across the country. Participants must interrupt their activities to participate. Internet panels allow participants to participate from their own homes at a time most convenient to them. Responses are collected electronically, eliminating coding of questionnaires, and procedures are more effectively standardized than when data collection relies on individual interviewers at multiple locations.

4. Duplication of Similar Information

The proposed study is not duplicative of existing information. The proposed study is based in part on several studies submitted as comments to the *trans* fat rule (CSPI, 2003; IFIC, 2003, Conagra Food, 2003). A recent experimental study of *trans* fat labeling reported no effect of *trans* fat levels on perceived relevant disease risk unless information about the health effects of trans fats was provided prior to seeing the label (Kozup, Burton & Creyer, 2006.) Some of the measures used in the present study are based directly on measures used in that research, particularly the two product choice task measures. The study addresses a number of flaws in these previous research studies, including the inclusion of necessary control conditions, testing a wider range of possible footnote options, using more realistic labels, and evaluating prior knowledge effects, that will strengthen the validity and generalizability of results for the policy process.

5. Small Businesses

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

6. Less Frequent Collection

This study is a one-time data collection.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

Consumer understanding of *trans* fat declarations has been the subject of extensive public comments since the November 1999 publication of the proposed rule. These comments were carefully considered in the formulation of the present research design. Important features of the proposed study are based on preliminary research from industry, consumer groups and public health organizations.

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

As noted above, in accordance with 5 CFR 1320.8(d), on February 6, 2006 (71 FR 6076), a 60-day notice for public comment was published in the Federal Register. FDA received two letters in response to the notice, each containing multiple comments. (1). One comment stated that the organization concurs with the objectives of the study and believes the information from this study will be useful to FDA in developing labeling policy to assist consumers with interpretation of *trans* fat claims in food labeling.

(2). Another comment expressed concern that the NFP of only one of the three product pairs (margarine) showed polyunsaturated fat and monounsaturated fat content and recommended that the NFPs for all three products tested in the study show the fuller fat profile.

FDA disagrees with the recommendation that the NFPs for all three products tested in the study disclose a fuller fat profile. Most NFPs do not include the optional polyunsaturated fat and monounsaturated fat content. Typically, this information is disclosed on NFPs for products that are entirely or largely composed of fat (e.g., butter, margarine, and cooking oils). In these cases, the fat profile may be shown in greater detail because consumers may use this information to select among alternative food products. The NFPs for the product pairs tested in the study are consistent with actual donut, margarine and frozen lasagna labels. Because the recommended change would limit products tested in the study to those such as butter, margarine and cooking oils, FDA will retain the NFPs as proposed.

(3). One comment suggested that the NFPs should not reflect rounding, to minimize potential consumer confusion. The comment specifically recommended that FDA edit the study NFPs containing declarations of polyunsaturated and monounsaturated fats (i.e., for the margarine product pair) to declare total fat grams in an amount equal to the sum of the four listed fatty acids.

FDA agrees that for the margarine labels, which include the four fatty acids under total fat, the fatty acids gram amounts declared should add up to the total fat gram amount to avoid raising questions or distracting the participants in the margarine conditions.

(4). One comment suggested that, for the margarine labels, FDA should edit the polyunsaturated and monounsaturated values to be as equal as possible in the product pairings to ensure that the focus is on the saturated fat and *trans* fat content.

FDA disagrees with the suggested change to the NFPs for the margarine product pairs. In order to keep the values for the polyunsaturated and monounsaturated fats identical in the margarine pairs, the saturated fat content would become unrealistically high in one label because it is the only fat component that could increase when *trans* fat equals zero.

(5). One comment noted that only one of the NFPs for the three products tested in the study showed some cholesterol present in the product; the other two products disclosed cholesterol as zero. In particular, the comment identified lasagna as unlikely to contain zero milligrams of cholesterol.

FDA agrees that zero cholesterol is not likely to be a realistic amount of cholesterol disclosed on a NFP for a lasagna product and has revised the NFPs for the lasagna pairs. In addition, FDA changed a product category from cookies to donuts and the NFPs for the new donut product pair include a small amount of cholesterol, appropriate to this product category.

(6). One comment critiqued the draft Full Information treatment language. The comment criticized the one-page summary because it 1) did not identify calories in the discussion of fat as a major source of energy; and 2) did not relate the calorie contribution of fat to that of carbohydrates and protein. The comment also criticized the information about sources of *trans* fat because it omitted mention of natural sources of *trans* fat in the diet, which the comment suggested would help ensure factually correct and balanced information about sources of *trans* in the diet. The comment questioned the value of stating that *trans* fat extends shelf life and has desirable taste characteristics since many saturated fat sources are relatively shelf stable and have desirable taste characteristics.

FDA agrees and has revised the Full Information treatment to incorporate these concerns. Calories and other sources of energy are now mentioned in the introductory passage. Natural sources of *trans* fat are now mentioned and the similarity between *trans* fat and saturated fat in terms of shelf life and taste are now addressed. The revised draft will be included in the study pretest and further revisions will be made if FDA determines they are needed based upon pretest results.

(7). One comment suggested consumer confusion may be caused when a NFP for a product discloses zero grams of *trans* fat but the ingredient list discloses an ingredient that contains *trans* fat, as is permitted by the *trans* fat labeling regulations. The comment concluded that FDA should add experimental conditions in which this occurs. The comment suggested that for this situation the study should test language for a footnote to the ingredient list to explain that there may be a *trans* fat ingredient in the product when the NFP shows *trans* fat as zero.

FDA disagrees with the proposed addition to the study's experimental conditions. Under existing *trans* fat labeling regulations, food manufacturers are allowed to list amounts of *trans* fat less than 0.5 g per serving as zero (0) on the NFP. While such situations occur in the marketplace and are permitted by the *trans* fat labeling regulations, whether this causes consumer confusion is an issue outside the scope of the proposed research, which focuses on the effects of NFP footnotes and alternative presentations of trans fat information in the NFP on consumers' ability to correctly identify more healthful food products. The Office of Nutritional Products, Labeling and Dietary Supplements has received and responded to a separate letter on this topic from the commenter.

In the Federal Register of December 18, 2006 (71 FR 75762), FDA published a 30-day notice requesting public comment on the collection of information in FDA's Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosures on the Nutrition Facts Panel (NFP). Due to an error in the dates section caused by the Office of the Federal Register, the 30-day notice was republished on March 7, 2007 (72 FR 10220). One letter was received by OMB in response to the notices. The commenter expressed support for the planned study, but did not provide comments responsive to the comment request on the four specified aspects of the collection of information; therefore, these non-responsive comments will not be addressed in this document.

9. Payment/Gift to Respondent

The proposed study uses an existing consumer Internet panel as its sample frame. Participants complete interview instruments without specific reimbursement, but they receive small tokens of appreciation and are eligible for prizes as a consequence of their ongoing participation in the panel.

10. Confidentiality

There is no identifying information associated with the panel member as part of the survey. Personal information about participants is received as part of the panel enrollment process and is used for sample targeting purposes by the contractor. The government receives no identifying information. 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, Synovate, will collect these data and will not provide FDA identifying information on the respondents.

11. Sensitive Questions

This study does not include any sensitive questions.

12. Burden Estimate (Total Hours and Wages)

The total annual estimated burden imposed by this collection of information is 820 hours for this one-time collection (Table 1).

Table 1. Estimated Annual Reporting Burden[1]

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	40	1	40	0.25	10
Study	3,240	1	3,240	0.25	810
Total					820

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

These estimates are based on FDA's experience with previous consumer studies. The pretest of the final questionnaire is designed to minimize potential problems in the administration of the experiment. The pretest is predicted to take each respondent 15 minutes to complete.

The study will be conducted with 3,240 panel members. Based on past experience, the interview length will average 15 minutes.

13. Capital Costs (Maintenance of Capital Costs)

There are no costs to respondents.

14. Cost to Federal Government

The estimated total cost to the federal government is $204,500. This includes the costs paid to the contractor to program the study, draw the sample, collect the data, and create a database of the results, plus the costs associated with peer reviewers. FDA contracted with Synovate for data collection services. Peer reviewers were paid under personal services contracts.

Contractor estimated cost =	$198,800
Peer reviewers =	$ 5,700
Total =	$204,500

15. Program or Burden Changes

This collection of information was discontinued in 2004. FDA is now ready to conduct the study and is reinstating this information collection.

16. Publication and Tabulation Dates

The Agency will begin data collection within 4 weeks of OMB approval. Data collection is expected to take up to 6 weeks. Data analysis will likely be complete within 6 weeks from completion of the data collection.

The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. Preliminary results are expected to be available within 5 months from OMB approval and may be disseminated via presentations and articles at trade and academic conferences, publications, and Internet posting.

17. Display of OMB Approval Date

The OMB Approval Date will be displayed on the questionnaire.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

No exceptions are requested.

Part B COLLECTION OF INFORMATION USING STATISTICAL METHODS

1. Universe and Sampling

The study uses an Internet panel methodology which has proved substantially equivalent to mall intercept methodologies in that it allows visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. The study will be implemented using a convenience sample drawn from a large national consumer panel with nearly one million households. The consumer Internet panel includes consumers who span the full range of education, age, race and income characteristics in the population.

Synovate, Incorporated's Internet panel will be used to procure a study sample for the experiment. Synovate's panel consists of 500,000 households who have agreed to participate in research studies conducted through the Internet. This panel was not constructed using random digit dialing procedures but rather by recruiting through multiple media. The panel was designed to closely match the general population on major demographic characteristics.

Participants will be adults, aged 18 and older, who agree to participate in a study about foods and food labels. Each participant will be randomly assigned to one of the 54 experimental conditions.

2. Procedures for Collecting Information

Participants will view two-dimensional mock-ups that show the back panels of food packages, with the major part of the display constituted by the NFP. For each product category, participants will see a side by side presentation of the back panels of two products and answer questions about their choice preference, the selected product's perceived health benefits, how the selected product compares to the typical product in its category, and background questions regarding label use, dieting, and standard demographics (sex, age, education). (See Attachment F: Draft Questionnaire.)

The key measures for the study are expressed choices between two products described by their NFPs. The pair of panels presented to a participant embody one of the seven footnote/cueing schemes or NFP format options to be tested. Respondents are asked to pick the healthier product, report the reasons for their choice, and rate the selected product with respect to perceived nutrition characteristics and expected health effects.

Key Product Perception Questions

(1). Based on what you see on the labels, which product (A or B) would you choose as being healthier to eat yourself or to serve to your family?

(2). How would you rate this product compared to the typical product in the [donut/margarine/frozen lasagna] category?

Will be asked with respect to amount of fat, sodium, cholesterol, saturated fat and *trans* fat.

(3) How likely is it that eating this product as a regular part of your diet would raise your risk of [disease/health condition]? 7-point rating scale from 1 ("Very Likely" l) to 7 ("Very Unlikely")

Will be asked for four health conditions (heart disease, high blood cholesterol, overweight and high blood pressure).

(4). Do you consider this product to be high, medium or low in… [list of nutrients-calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, carbohydrates]?

Half the participants will be randomly assigned to the Full Information condition. In the Full Information condition, participants will read a one-page summary of the current state of scientific evidence for the health effects of *trans* fat in the diet. Nutrition scientists at FDA will review the summary for accuracy. The Full Information summary will be presented prior to viewing any labels.

3. Methods to Increase or Maximize Response Rates

Participants are sent multiple reminders asking them to complete the interview instrument. Because participants are practiced at accessing and completing such instruments, no additional measures are necessary.

4. Tests of Procedures or Methods

The contractor will conduct three waves of Internet pretests. The first wave will include up to 15 participants. Any procedural problems identified in the first wave will be addressed and the revised procedures tested on a second wave of up to 15 participants. If additional modifications are needed, the revised procedures will be tested on up to 10 participants. Prior experience shows that this number of pretests will be sufficient to identify and correct any procedural problems in the study.

5. Identification of Consultation

The contact individuals are Alan S. Levy, Ph.D., Consumer Studies Staff, Office of Regulations and Policy, HFS-727, telephone (301) 436-1762 (Project Officer), and Brenda M. Derby, Ph.D., Consumer Studies Staff, Office of Regulations and Policy, HFS-727, telephone (301) 436-1832 (Statistician), and W. Burleigh Seaver, Ph.D., Senior Vice President, Synovate/Market Facts, (703) 790-9099.

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