Supporting Statement for

Experimental Study of *Trans* Fat Claims on Foods

OMB No. 0910-0533

Submitted by:

Consumer Studies Staff
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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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 (FDCA) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA).

As part of the overall FDCA mandate to encourage informed consumer choice, the NLEA mandates FDA to take account of the public health goal of encouraging healthy dietary practices in the population by encouraging label statements on food products that help consumers place products in the context of their total diet. Nutrient content claims are regulated under this authority. They are considered signals to consumers that products that bear such claims can appropriately play dietary roles that may lead to desirable health benefits. As such, they are subject to certain restrictions to ensure that consumers are given correct signals that are truthful and not misleading. (403 (r) (2) (A) of the act (21 U.S.C. § 343 (r) (2) (A)).

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. Mandatory disclosure of *trans* fat amounts was also seen as a necessary requirement to allow nutrient content claims for *trans* fat. 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.

Several comments on the proposed *trans* rule cited research that suggested when *trans* fat is emphasized on the food label by a footnote about its dietary significance, consumers tended to overweight the importance of *trans* fat relative to other fatty acids, causing them to make poorer, rather

than healthier, product choices (Center for Science in the Public Interest (CSPI), 2003; International Food Information Council (IFIC), 2003; Conagra Food, 2003) A similar phenomenon may occur when consumers see a nutrient content claim or related claim about the level of *trans* fat in a food product. The claim may draw attention to and emphasize the desirability of low *trans* fat levels relative to the amounts of other heart-health relevant nutrients (saturated fat, cholesterol) in the product. FDA published final regulations for the declaration of *trans* fat in the NFP (68 FR 41434) but deferred a decision on *trans* fat claims until consumer research demonstrates that such claims will not similarly confuse consumers about the relative healthfulness of products with differing fatty acid profiles.

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 proposed study are to:

1. Evaluate the impact of *trans* fat nutrient content claims ('low *trans,*' '*trans* free,' '0 grams *trans* fat') on consumer understanding of product characteristics across a representative range of product types likely to make such claims.

2. Evaluate the role that consumer ability to interpret and use fatty acid profile information about food products plays in mediating the impact of *trans* fat nutrient content claims.

3. Assess the effectiveness of labeling options intended to help consumers interpret and use *trans*-related nutrient content claims. The labeling options include short statements of nutrition guidance, front panel disclosure of saturated fat and cholesterol content, and label referral statements ("see back panel for more information") on the principal display panel (PDP).

The study uses an experimental design where effects of the selected labeling options 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 labeling statements intended to help consumers use and interpret *trans*

fat claims on food products. 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. This study will use a convenience sample drawn from a large national consumer panel with 1 million households developed by the data collection contractor, TNS Intersearch.

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 144 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.

The effects of possible policy options will be measured in terms of judgment accuracy, i.e., the ability of participants to (1) make correct decisions when selecting products, (2) make correct attributions about the nutritional characteristics of a product, and (3) correctly judge how a product contributes to the total diet.

Manipulations

Product Types/Fatty Acid Profiles

One way to impose a metric for measures of judgment accuracy is to vary the objective characteristics of the stimuli. The relevant dimension for this study is the pattern of the fatty acid profiles for the selected products. We propose to systematically vary the fatty acid profiles for three types of food typical of products likely to use *trans* fat nutrient content claims (margarine, crackers, and pound cake). For each food, three fatty acid profiles will be displayed in the Nutrition Facts Panels to represent varied levels of overall healthfulness (Low Profile, Medium Profile, High Profile) for either a *trans* fat free product or a reduced *trans* fat product in that category (See Attachment B). The profiles vary in terms of total fat, saturated fat, *trans* fat, cholesterol and calories as appropriate to the product category and the three profile levels. In this way, we can observe the effect of the fatty acid profile on participants' judgments about the product as well as the effect of possible nutrient content claims and accompanying information statements.

***Trans* Fat Nutrient Content Claims and Interpretive Aids.**

We propose to test three forms of *trans* fat label claims and four conditions that add other information to help improve judgment accuracy as well as a control condition:

1. *Trans* fat free claim

2. Zero (0) grams *trans* fat claim

3. Reduced *trans* fat claim (percent reductions are tailored to the three product types)

4. *Trans* Fat Claim w. front panel disclosure of saturated fat and cholesterol content.

5. *Trans* Fat Claim w. "see back panel for important information about saturated fat and cholesterol content"

6. *Trans* Fat Claim w. nutrition guidance statement, i.e., "Keep your intake of saturated fat, *trans* fat and cholesterol low"

7. *Trans* Fat Claim w. front panel disclosure of saturated fat and cholesterol content w. nutrition guidance statement.

8. No Content Claim (control condition)

The specific claims and statements by product are shown in Attachment C.

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 *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 D: *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 6079) (the February 2006 Federal Register notice). Additional revisions may be made as a result of pretesting.

Experimental Design

The experimental design is as follows:

Information Treatment (Full Information/No Information) X Product Type (margarine, crackers, pound cake) X Fatty Acid Profile (low, medium, high) X Label Treatment (8). This results in 144 cells.

Since the key experimental hypotheses concern the effects of the labeling conditions on judgment accuracy, we expect to collapse across product type conditions when testing the experimental hypotheses. We estimate that 20 subjects per cell (N= 2,880 participants) 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 at the .05 significance level. Power for second and third order interactions will necessarily be smaller, but even for third order interactions, statistical power will be =.80 at the .10 significance level.

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.) In addition, FDA is aware of a number of studies that have evaluated the impact of other nutrient content claims on consumer perceptions of product characteristics (see References). The procedures and measures used in this study are wholly consistent with this previous research. However, none of the previous research has addressed the specific issue of *trans* fat claims, and in this respect the present research will advance our understanding of the area.

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 and possible *trans* fat nutrient content claims has been the subject of extensive public comments since the November 1999 publication of the proposed rule. 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 E). The reviewers provided comments on the study design and questionnaire which are incorporated into the proposed study design.

As noted above, in accordance with 5 CFR 1320.8(d), on February 6, 2006 (71 FR 6079), a 60-day notice for public comment was published in the Federal Register. FDA received one letter in response to the notice, containing multiple comments.

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(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 suggested that FDA change the labels used to describe the three fatty acid profiles in the study ("good profile," "medium profile," and "poor profile") because these descriptors were seen as overly negative. The comment recommended alternative language ("low profile," "medium profile" and "high profile") as a way to ensure that the products are not characterized as "good foods" or "bad foods."

This suggestion has been implemented. The terminology suggested in the comment adequately conveys the intended profile differences.

(3). 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.

In the Federal Register of December 15, 2006 (71 FR 75554), FDA published a 30-day notice requesting public comment on the collection of information in FDA's Experimental Study of Trans Fat Claims on Foods. One letter was received by OMB in response to the notice. The commenter expressed strong 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 points for completing surveys which they may redeem for small tokens of appreciation.

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, TNS Intersearch, will collect these 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).

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 730 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	2,880	1	2,880	0.25	720
Total					730

[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 2,880 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 $205,669. 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 has contracted with TNS Intersearch for data collection services. Peer reviewers were paid under personal services contracts.

Contractor estimated cost =	$199,969
Peer reviewers =	$ 5,700
Total =	$205,669

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.

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 Internet panel with one million households. The consumer panel includes consumers who span the full range of education, age, race and income characteristics in the population. By implementing the study in such a sample frame the generalizability of the findings to a large fraction of the general population is ensured.

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 144 experimental conditions.

2. Procedures for Collecting Information

Participants will be asked to review the package labeling of one product presented to them and then answer questions about the product's perceived health benefits and nutritional characteristics and other questions (see Attachment F: Draft Questionnaire).

Participants will view a two-dimensional color mock-up of a food label. For each product, the front panel will be presented first, followed by some questions about the product. Then the participant will look at the back panel of the product label that contains a Nutrition Facts Panel (NFP) for the food product. Participants then answer a series of product perception questions related to expected health benefits and perceived nutritional characteristics of the product.

Key Product Perception Questions

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

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

2. 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]?

3. Overall, how important would [this margarine/pound cake]/[these crackers] be as part of a healthy diet? On a scale from 1 to 7 where 1 means "Very Important" and 7 means "Not at all Important."

Background questions will include standard demographics, current food label use, and health status.

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.

Analysis Plan

This study can be viewed as an evaluation of the impact of *trans* fat content claims on judgment accuracy. Judgment accuracy will be bounded by the performance of participants in several comparison conditions: those who see no *trans* fat content claims, those who are "fully informed" about *trans* fat, and those who see the same product with varying fatty acid profiles. The impact of *trans* fat content claims and accompanying information statements will be assessed by estimating the discrepancy between participants' judgments made under these conditions compared to participants' judgments made under the respective comparison conditions. It will be possible to estimate the experimental effects of content claims and accompanying statements compared to no claims, depending on whether participants are fully informed or not, and depending on the product's fatty acid profile. Analysis of variance with specific contrasts and multivariate regression techniques will be used.

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 David B. Lambert, Ph.D., Senior Vice President, TNS Intersearch, (215) 442-9638.

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