

Request for OMB Review  
Supporting Statement for  
An Experimental Study of Carbohydrate Content Claims on Food Labels

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. Circumstances Necessitating Information Collection**

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.) The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535) amended the act. Section 403(r)(1)(A) of the act (21 U.S.C. § 343(r)(1)(A)), added by the 1990 amendments, states that a food is misbranded if it is a food intended for human consumption which is offered for sale and for which a claim is made on its label or labeling that expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of nutrition labeling, unless such claim uses terms defined in regulations by FDA under section 403(r)(2)(A) of the act (21 U.S.C. § 343(r)(2)(A)). (A copy of this statutory section is included as attachment B.)

In 1993, FDA published regulations that implemented the 1990 amendments. Among these regulations, 21 CFR 101.13 sets forth general principles for nutrient content claims (see 56 FR 60421, November 27, 1991; 58 FR 2302, January 6, 1993). (A copy of this statutory section is included as attachment C.) Other regulations in Subpart D of 21 CFR Part 101 define specific nutrient content claims, such as "free," "low," "reduced," "light," "good source," "high," and "more" for different nutrients and calories and identify several synonyms for each of the defined terms. In addition, 21 CFR 101.69 establishes the procedures and requirements for petitioning the Agency to authorize nutrient content claims. (A copy of this statutory section is included as attachment D.)

The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) amended section 403(r)(2) of the act by adding sections 403(r)(2)(G) and (H) (21 U.S.C. § 343(r)(2)(G) & (H)) to permit

nutrient content claims based on published authoritative statements by a scientific body, when FDA is notified of such claim in accordance with the requirements established in these sections (see attachment B)..

Current FDA regulations make no provision for the use of nutrient content claims that characterize the level of carbohydrate in foods because FDA has not defined, by regulation, terms for use in such claims. Consumer and industry groups have petitioned the FDA to amend existing food labeling regulations to define terms for use in nutrient content claims characterizing the level of carbohydrate in foods.

## **2. How, By Whom, Purpose of Collection**

The FDA has received six different petitions to define various carbohydrate content claims for food labeling. This supporting statement describes a proposed experimental study that would enhance the Agency's understanding of consumer response to such claims and, therefore, assist the Agency in responding to the petitions.

The information objectives for this proposed experimental study are to evaluate carbohydrate content food label claims and disclosure statements in terms of their effects on consumer understanding and consumers' ability to make appropriate product judgments for healthy dietary practices.

The label claims and statements that would be tested in the proposed study include "low carb," "x grams net carbs," "carbconscious," and "good source of carb." The study would also include no claim, control labels. Where relevant, this study would test carbohydrate content claims with and without the following disclosure statements on the front panel: (1) "see nutrition information for fat content," (2) "see nutrition information for sugar content," and (3) "not a low-calorie food." Participants would be exposed to either one front panel or both a front panel and corresponding Nutrition Facts Panel (sometimes abbreviated, "NFP") for one of three products: a bread, a juice drink, or a frozen dinner. The Nutrition Facts Panels would vary to create more and less healthful product profiles. All participants would be asked the same series of questions.

### *Primary Hypotheses*

The following are the primary hypotheses to be tested in this experiment. Differences would be measured in the perceived amounts of nutrients, likelihood of purchasing the product, ratings of the healthfulness of the product, and likelihood of the product helping someone to manage their weight (for the

“low,” “net” and “carbconscious” claims) or the likelihood of the product helping someone to have more energy (for the “good source” claims).

Hypothesis 1: Among respondents who see the front panel only, those who see a “low carb,” “net carb,” or “carbconscious” claim will evaluate products differently than those who view the no claim, control label.

Hypothesis 2: Among respondents who see the front panel only, those who see a “low carb” or “carbconscious” claim with a fat or calorie disclosure will evaluate the product differently than those who view the “low carb” or “carbconscious” claim without the fat disclosure or calorie disclosure, respectively.

Hypothesis 3: Among respondents who see the front panel only, those who see a “good source of carb” claim will evaluate the product differently than those who view the no claim, control label.

Hypothesis 4: Among respondents who see the front panel only, those who see a “good source of carb” claim with a sugar disclosure will evaluate the product differently than those who view the “good source of carb” claim without the sugar disclosure.

Hypothesis 5: Among respondents who view the front and back labels, those who view a “low carb,” “carbconscious” or “net carb” claim with a *healthier low carb* NFP will evaluate the product differently than those who view the same front panel with a *less healthful low carb* NFP.

Hypothesis 6: Among respondents who view the front and back labels, those who view a “low carb” or “carbconscious” claim with a fat or calorie disclosure and a *less healthful low carb* NFP will evaluate the product differently than those who view a “low carb” or “carbconscious” claim with a *less healthful low carb* NFP, but without a fat or calorie disclosure, respectively.

Hypothesis 7: Among respondents who view the front and back labels, those who view a “low carb,” “carbconscious,” or “net carb” claim with a *healthier, low carb* NFP will evaluate the product differently than those who view a no claim, control front panel with a *healthier low carb* NFP.

Hypothesis 8: Among respondents who view the front and back labels, those who view a “good source of carb” claim with a sugar disclosure and a *high carb* NFP will evaluate the product differently than those who view a “good source of carb” claim with a *high carb* NFP, but without a sugar disclosure.

Hypothesis 9: Among respondents who view the front and back labels, those who view a “good source of carb” claim with *healthier high carb* NFP will evaluate the product differently than those who view a “good source of carb” claim with a *less healthful high carb* NFP.

Hypothesis 10: Among respondents who view the front and back labels, those who view a “good source of carb” claim with a *healthier, high carb* NFP will evaluate the product differently than those who view a no claim control with a *healthier, high carb* NFP.

The proposed experimental study data would be collected via the Internet from 9,360 members of a consumer panel maintained by the research firm Synovate. Synovate’s Internet panel consists of approximately 600,000 households that have agreed to participate in research studies conducted through the Internet. Most households in the panel will respond to mail or telephone surveys, as well as Internet surveys like this one.

Panel members are recruited by a variety of means designed to reflect all segments of the population. They are required to have a computer with Internet access. Typical panel members receive three or four invitations per month to participate in research projects. Studies begin with an e-mailed invitation to the sampled respondents.

Each panel member has provided demographic data for their household that allows for the selection of samples that resemble closely the distribution of the U.S. population on age, gender, education, and race/ethnicity. Overall, the panel tends to under-represent minorities, low income households, and the elderly.

For this proposed study, members of Synovate's consumer Internet panel have been screened for diet status through brief questions included in a quarterly multi-topic survey that Synovate emailed to all of its Internet panel members. The over 173,000 people who responded to the diet status screening questions would be eligible to be sampled for the experiment.

Conventional statistical techniques for experimental data, such as descriptive statistics, analysis of variance, and regression models would be used to analyze the data. Covariates used in the analysis would include diet status, age, race/ethnicity, gender, and education.

This proposed data collection would be one-time only. No successive related data collections are planned.

### **3. Consideration Given to Information Technology**

This proposed study would use the Internet for data collection. Members of the sample, who are part of a consumer opinion panel, would receive an invitation to participate in the experiment to their email address. People who choose to participate would respond from their personal computer at a time of their choosing. The respondents would view the product labels and study questions on their computer screen and would register their responses using their keyboard and mouse. The Internet was selected as the means to collect data to minimize burden cost-effectively.

### **4. Identification of Information**

Before conceptualizing this proposed study, the Agency reviewed the consumer research submitted by the petitioners, evaluated the literature for relevant material, and conducted a series of focus groups. The

data submitted by the petitioners do not answer the questions of interest in this study. A review of the literature indicated that there is no directly comparable existing research on consumer understanding of carbohydrate content claims. However, the more broad literature on consumer response to nutrient content claims was used to inform the study design, as were data from the Agency's focus groups.

Although both previous research on nutrient content claims and the focus group data provide important context for this project, they do not provide answers to the questions of interest in this experiment. To directly apply existing consumer research on various nutrient content claims to carbohydrate content claims is not appropriate. Total carbohydrate claims may be understood differently by consumers than other nutrient content claims about which there exists a body of research for three reasons. First, carbohydrate content claims already exist in the form of such claims as "sugar-free" and "good source of fiber." Second, petitioners have requested authorization for both "low" and "good source" claims for this one nutrient. No other nutrient is authorized for both "low" and "good source" claims. The 2005 U.S. Dietary Guidelines<sup>1</sup> provide recommendations to consumers related to components of carbohydrate to choose and other components of carbohydrate to limit. It could be difficult for consumers to apply such dietary guidance to total carbohydrate claims. For example, the 2005 Dietary Guidelines recommend that consumers choose fiber-rich produce and whole grains often and that they limit foods with added sugar or caloric sweeteners. Third, reaction to "net carbohydrate" and similar statements has yet to be explored in existing research.

Several previous studies were used to inform the design of this experiment. The results of a study by Roe, Levy and Derby<sup>2</sup> suggest that when a nutrient-content claim is available on the front panel, consumers may not bother to read the Nutrition Facts Panel. This is of particular interest relative to "net carbohydrate" statements, where the information explaining the term may be found on a back panel. Taking this research into consideration, this proposed experiment would have some of the participants exposed only to the front panel and others exposed also to the Nutrition Facts Panel. The Roe et al. study also suggests that claims are associated with a "halo" effect, such that participants perceive that attributes unrelated to the claim are associated with the product. The proposed experiment is designed to help understand whether

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1 U.S. Department of Health and Human Services and U.S. Department of Agriculture (January 12, 2005), *Dietary Guidelines for Americans 2005*.

2 Roe, Brian, Alan S. Levy, and Brenda M. Derby, (1999), "The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Results from FDA Experimental Data," *Journal of Public Policy and Marketing*, 18 (Spring), 89-105.

carbohydrate claims are associated with misattribution of health benefits. In this experiment, disclosure statements would be used to understand whether such information could redress misattribution.

Research by Garreston and Burton<sup>3</sup> suggests that consumers have greater trouble evaluating fiber information on food packages than they do information on fat. Matching a fiber claim with an incongruous Nutrition Facts Panel is less likely to affect trust in the claim than matching a fat claim with incongruous Nutrition Facts. Manipulating fiber is one way products could qualify for carbohydrate claims. “Net carbohydrate” statements can be based on calculating total carbohydrate minus fiber.

During the summer of 2004, to assist in developing this study, the Agency conducted a series of focus groups to gauge consumer understanding of various carbohydrate content claims on food packages. Focus groups are guided discussions led by a trained moderator. This research method is often used to collect qualitative information on a specific topic. Focus groups results are not generalizable. These eight focus groups with American consumers, conducted in four U.S cities, produced some important findings about familiarity with and interest in various carbohydrate claims on food product labels. Major findings were:

- Participants seemed misinformed about nutrients that fall into the category of carbohydrate.
- Participants appeared to think of carbohydrate in terms of particular foods rather than a nutrient. They were quick to suggest a distinction between “good carbs” (grains, fruits, and vegetables) and what they called “bad carbs” (breads, rice, pasta, and potatoes), which were also referred to among participants as “white carbs.”
- Participants seemed unable to make meaningful distinctions between various carbohydrate content claims.
- Participants appeared split on their approach to nutrition. Some tried to maintain a balanced daily diet that includes different nutrients. Others specifically focused on calories or a select nutrient when choosing foods.
- Participants claimed to have seen “low carb” labels in stores, however only a small handful said they currently look for, purchase, or would purchase products making carbohydrate

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3 Garreston, Judith A., and Scot Burton (2000), “Effects of Nutrition Facts Panel Values, Nutrition Claims, and Health Claims on Consumer Attitudes, Perceptions of Disease-Related Risks and Trust,” *Journal of Public Policy and Marketing*, 19 (Fall), 213-227.

content claims.<sup>4</sup>

Based on the findings from the focus groups, there is uncertainty as to how consumers might notice, evaluate, and use carbohydrate content claims on food packages. The proposed experimental study would provide quantitative data to help answer unresolved questions about consumer reaction to carbohydrate content claims.

## **5. Small Businesses**

No small businesses would be involved in this data collection.

## **6. Less Frequent Information Collection**

The proposed data collection is one-time only. There are no plans for successive data collections relative to carbohydrate content claims on foods labels.

## **7. Information Collection Circumstances**

This collection of information fully complies with 5 CFR 1320.5. There are no special circumstances.

## **8. Consultations with Persons Outside FDA**

The 60-day public comment notice was published in the Federal Register on April 8, 2005, Volume 70, Number 67 (Docket No 2005N-0120). (A copy of the 60-day Federal Register notice is included as attachment E.) FDA received eight comments on this proposed data collection. The first comment is from a citizen; the second is from National Starch Food Innovation; the third is from The Sugar Association; the fourth is from the American Dietetic Association; the fifth is from the Grocery Manufacturers of America; the sixth is one combined comment from the Grain Foods Foundation, Wheat Foods Council, North American Millers' Association, and the American Bakers Association; and both the seventh and eighth comments are from the Calorie Control Council.

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<sup>4</sup> FDA (August 26, 2005). "Carbohydrate Labeling Focus Group Internal Report." Unpublished draft.

The first comment is related to the validity of the methodology and assumptions used by FDA. The comment indicated that the sample size for the study is 150,000 households and that this sample is too large.

The sample for this study is not households and it is not 150,000 (150,000 is the number of respondents originally estimated to reply to the screener). The sample size for the study is 9,360 consumers. In the study design originally planned, the sample size was justified by the proposed subgroup analyses. In the revised design, which does not include subgroup analyses, the sample size is justified by a smaller estimated effect size. Overall, the sample size is a reflection of the number of conditions, the number of products, and a power analysis.

The experimental conditions in the study design include claims contained in the carbohydrate petitions and claims already found in the marketplace. These experimental conditions are required to test the study hypotheses. A wide variety of food products could be eligible for carbohydrate content claims. The Agency, therefore, believes that it is important to include different types of products in the study to make certain that the cause-effect relationships found are not product-specific. The sample size per condition per product is 180 respondents. This figure is based on (1) 0.05 alpha, (2) 0.80 power, (3) two-tailed mean tests, and (4) an estimated effect size between small and medium, roughly 0.30. Based on this figure, the total sample size required for the analysis is 9,360 (the product of multiplying 180 by each condition and relevant product (see section B1 of this Supporting Statement)).

The second comment addresses ways to enhance the quality, utility, and clarity of the information to be collected. The comment argues that the term total carbohydrate should be changed to exclude fiber. The change suggested by the comment would make testing a “net carbohydrate” statement unnecessary. The commenter would like this proposed data collection to include a condition in which total carbohydrate is defined with fiber excluded.

The Agency’s goal for this proposed data collection is to better understand how consumers perceive a variety of front panel carbohydrate content claims and related statements. Testing consumer response to new definitions for total carbohydrate on the Nutrition Facts Panel is outside the scope of this data collection.

The third comment is related to whether this study would have practical utility and also poses questions and offers ways to enhance the quality, utility, and clarity of the information to be collected. The comment states that there is no evidence that carbohydrate should be restricted and therefore no need to

amend current regulations to allow carbohydrate content claims on food labels. The comment argues that, by extension, there is no need for the proposed data collection.

The Agency disagrees that the study should not be undertaken. FDA has received petitions asking the Agency to amend existing regulations to permit carbohydrate content claims on food labels. This proposed data collection would be used to enhance the Agency's understanding of consumer response to such claims and, therefore, provide context for the Agency's response to the petitions.

The third comment also addresses four methodological issues. (1) The comment argues that respondents should evaluate several aspects of the products included in the study and that respondents should evaluate the test products relative to similar products. (2) This comment questions whether the study can demonstrate whether consumers making real-life nutrition decisions would review the Nutrition Facts information when the front panel includes a carbohydrate content claim. (3) The comment argues that understanding consumer response to qualifying information on the front panel is important because products may be reformulated to meet guidelines for a carbohydrate content claim. The reformulated products may make substitutions, like removing sugar and adding fat. The comment argues that equally prominent information related to modifications is important to ensure consumers are not misled. The comment suggests a statement such as "Reduced carbohydrate, \_\_% fewer calories, \_\_% more fat." (4) The comment suggests that the study should evaluate consumer response to carbohydrate content claims based on modifications to serving size.

In response to the methodological issues raised in the third comment: (1) The proposed study questions do ask respondents to evaluate several aspects of the test product and to consider the test product relative to another, similar product. (2) Several design features will help the Agency understand whether consumers might take into consideration information that is not part of the front panel. The proposed data collection is designed to evaluate the response to carbohydrate content claims with consumers who only have access to the front panel compared to responses to the same questions from consumers who have access to both the front panel and the full Nutrition Facts information. Among test conditions, the product profiles presented on the Nutrition Facts Panel will vary. Some respondents will see a product with a carbohydrate content claim on the front and Nutrition Facts information for a more healthful product. Others will see the same package design, with the same claim, but the Nutrition Facts information will be for a less healthful product. (3) The proposed study is designed to evaluate consumer response to

claims when the front panel also includes a disclosure statement and when it does not include such a statement. The statements included in the study would be “see nutrition information for fat content,” “see nutrition information for sugar content,” and “not a low-calorie food.” These statements will appear on the test labels with the prominence defined in regulation (21 CFR 101.13(h)(4)(i)) (see attachment C). (4) Modifications to serving size do not drive consumer understanding of the claims themselves and are outside the scope of this data collection.

The fourth comment expresses agreement with the objectives and research questions associated with this data collection. The comment then addresses ways to enhance the utility of the information collected. The comment requests that FDA’s consumer research on labeling issues be more general, rather than focused on one nutrient. The comment also suggests that consumer research include in-person observation in actual-use settings.

FDA believes that it is necessary for this study to focus on carbohydrate claims, rather than on labeling issues in general, in order to best inform the Agency about how consumers may react to these content claims on food labels. Total carbohydrate claims are unique from other nutrient content claims for two reasons. First, petitioners have requested authorization for both “low” and “good source” claims for total carbohydrate. Currently, no nutrient is authorized for both “low” and “good source” claims. Second, the 2005 U.S. Dietary Guidelines<sup>5</sup> provide recommendations to consumers related to types of carbohydrate to choose and other types of carbohydrate to limit. For example, the Guidelines recommend that consumers choose fiber-rich produce and whole grains often and that they limit foods with added sugar or caloric sweeteners. Although FDA has not authorized nutrient content claims for total carbohydrates, consumers already find claims for certain types of carbohydrate in the marketplace, such as “sugar-free” and “good source of fiber.” To gather meaningful data, the sample for this study, the foods included as stimuli, and the label claims must be specific to the issues surrounding carbohydrate content labeling. Many questions included in the study protocol, however, may be appropriate for other labeling studies.

Conducting this study in-person in actual-use settings would not be practical and poses methodological challenges. Consumers use labels while shopping, at home, and in other settings. Collecting data in these settings with an adequate sample for the proposed analysis would increase the costs of the study and increase respondent burden. In addition, consumers may alter their typical behavior when

being tracked by a data collector while shopping or being watched in their home as they prepare foods. The methodology proposed for this study is appropriate for meeting the research objective of evaluating how consumers react to different labeling alternatives for carbohydrate content claims. The study design and performance tasks selected will require consumers to make judgments based on content claims and other nutrition facts. The statistical analysis of the data will determine whether carbohydrate labeling options provide consumers with the information needed to make accurate decisions.

The fifth comment addresses ways to enhance the quality, utility, and clarity of the information to be collected. The comment suggests that the questions included in the protocol be straightforward and specific. The comment expresses concern about using terms like “healthier” or “more desirable.” The comment recommends that the study labels include disclosure statements for fat only when the nutrition profile of the product would require such a statement under the current regulations. The comment disagrees with the testing of a sugar disclosure due to the lack of a daily value for sugar on which to base such a statement. The comment also expresses support for testing carbohydrate content claims with a “not a low-calorie food” disclosure, but considers a declaration of calories per serving or “see nutrition information for calorie content” better options to emphasize the importance of calories. Finally, the comment requests that the Agency make available the definitions of the carbohydrate claims prior to conducting this study.

The Agency agrees that the questions should be straightforward and specific and designed them with those objectives in the forefront. The terms “healthier” and “more desirable” are not included among the study questions. Use of a fat content disclosure statement in this study will be consistent with current regulations (CFR 101.13(h)(1)) (see attachment C). The sugar disclosure used in this proposed study would accompany a “good source of carb” claim. In the study, the disclosure would appear on a product with “good source of carb” on the front panel and information in the Nutrition Facts box that indicates that most of the carbohydrate in the product is sugars. The goal of this test is to better understand how consumers react to a “good source of carb” claim on a product high in sugar and low in other carbohydrates. The Agency disagrees with the comment’s suggestion to test a declaration of calories per serving or “see nutrition information for calorie content” in lieu of “not a low calorie food.” The Agency considers the statement “not a low calorie food” to be an appropriate, explicit statement to make consumers more aware of calories. The disclosure “not a low calorie food” is currently seen by consumers in the marketplace when “sugar-free”

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5[1] U.S. Department of Health and Human Services and U.S. Department of Agriculture (January 12, 2005), *Dietary*

claims are made on products that are not low calorie. The experimental study looks at ranges of carbohydrate content levels for the products to explore differences in consumer reaction.

The sixth comment argues that the study methods are sound and suggests ways to enhance quality, utility, and clarity of the information to be collected. The comment suggests substituting the soda and frozen dinner stimuli with pasta, cereal, orange juice or any fruit. The comment does not offer a reason for these preferences. The comment also proposes testing white bread and whole grain bread as separate products.

In the revised study design, the soda is replaced by a juice drink. The three products proposed for this study were selected to understand whether consumer perception of carbohydrate content claims varies when the claim is on a label for a traditionally high-carbohydrate staple (bread), a beverage (juice drink), and a complete meal (frozen dinner). The Agency does not agree that any of the specific substitutions suggested in the comment would improve the study. The label for the bread does not indicate whether it is white, wheat, or another grain. Consumers will view a label claim on the front panel for bread labeled simply “home-style.” Some of the respondents who view the Nutrition Facts Panel for the bread will see a higher-fiber, lower-fat bread, while others see a lower-fiber, higher-fat bread. The analysis will evaluate the differences in perception of the claims when the nutrient profile suggests a more healthful versus a less healthful product.

The seventh comment and eighth comments address the quality, utility, and clarity of the information to be collected. The comments request that this data collection test changes to the carbohydrate section of the Nutrition Facts Panel. One of these comments requests that fiber and sugar alcohols be listed separately from other carbohydrates. The other of the comments proposes moving carbohydrates with reduced caloric value from the carbohydrate listing on the Nutrition Facts Panel and adding a listing called “low calorie ingredients,” which would include the subheadings listings “fiber” and “other.”

Evaluating any proposed changes to the Nutrition Facts Panel is outside the scope of this data collection. This data collection is designed to evaluate consumer understanding of carbohydrate claims on the front panel.

The 30-day Federal Register notice published on August 17, 2005 (Volume 70, Number 158). FDA received one comment to the 30-day Federal Register notice from Kraft Foods Global, Inc.

The comment questions why the Agency is conducting consumer research on an issue that is a matter of nutritional science. This study is not designed to challenge nutritional science, but rather to help the Agency evaluate consumer understanding of the science-based claims, with and without disclosure statements.

The comment argues that since nutrient content claims are “direct objective statements about the level of nutrient in food relative to an authoritative reference value,” the Agency should not explore whether carbohydrate claims convey any meaning beyond the food’s carbohydrate value. The Agency believes that it is important to understand whether claims on food packages are confusing or misleading to consumers. Consumers may not interpret statements based in science as they were intended. Research, such as that by Roe, Levy, and Derby described earlier in this Supporting Statement, shows that claims may have “halo” effects that lead consumers to misattribute health benefits with a claim. The proposed experiment is designed to help understand whether carbohydrate claims are associated with misattribution of health benefits. In this experiment, disclosure statements would be used to understand whether such information could redress misattribution of benefits. This understanding is not intended to challenge nutritional science, but rather to provide the Agency with more complete information to assess the effect of carbohydrate content claims on food labels.

The comment suggests that the Agency develop specific “decision criteria” for the results of the study. Consumer research does not set policy, but rather helps to inform policy. Data from this study would help to inform the Agency’s response to the carbohydrate content claim petitions. These data would be used in conjunction with data from many other sources. The results from this experiment are designed to help the Agency understand whether there are different consumer effects for different signals.

The comment proposed that all consumers have access to the Nutrition Facts Panel to “more closely approximate real-life conditions.” The Agency disagrees that this proposal would better emulate shopping or food use conditions. Research suggests that many consumers do not look at the Nutrition Facts Panel when they shop for foods. However, when asked direct questions about a product’s nutritional value, these same consumers may look at the Panel, if it were available. The study is designed to capture the understanding of consumers who do and do not evaluate the Nutrition Facts Panel when shopping and using foods. By comparing the front-panel only conditions to conditions that include the Nutrition Facts, the Agency will better

understand whether the Nutrition Facts could help to redress any possible confusion or misattribution associated with the claim.

The comment disagrees with the Agency's use of a "good source" claim with a "see nutrition information for sugar content" disclosure. The Agency was including this high sugar product with a "good source" claim to better understand the boundaries for any possible misattribution effects of the claim. The Agency is interested in understanding the effect of sugar disclosures, for which there is no precedent.

However, the comment's concern over the condition has made the Agency decide to use a juice drink in the study, rather than soda. Juice drinks can be high in sugar, but unlike soda, may include other nutrients than sugars.

## **9. Payment or Gift**

Members of Synovate's Internet panel will not be paid specifically for their participation in this study. However, as part of the firm's incentive to recruit and maintain membership, panelists are offered rewards by the firm for their general participation in surveys sent out by the panel. The reward takes the form of entries into the panel's monthly sweepstakes. Each time a member completes a study, the individual is automatically entered into the current month's drawing to win one of the following cash prizes: one cash prize of \$1000, 10 prizes of \$100, 15 prizes of \$50, 30 prizes of \$25, and 150 prizes of \$10.

## **10. Confidentiality Provisions**

All respondents would be provided with the assurance of confidentiality. The experiment would include information explaining to respondents that their information will be kept confidential. An independent contractor for the FDA would collect these data and would not provide FDA identifying information on the respondents.

The contractor, Synovate, has procedures in place to prevent unauthorized access to respondent information. The firm stores members' personal identifiable information on separate servers from survey response data, uses firewalls to secure its servers, maintains audit records of log-ins, file accesses and other security incidents, and conducts its work in a high security building.

Synovate reassesses security protocols each month. Access to all data collected by Synovate is limited to the internal Chief Privacy Officer and designated staff members only. Synovate staff members are

trained in their privacy policy. Each staff person who requires access to system data must sign a confidentiality agreement each year.

All electronic data would be maintained in a manner which 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 would also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

## 11. Privacy

This data collection would not include sensitive questions. The complete list of questions is attached in attachment F.

## 12. Burden of Information Collection

The total annual estimated burden imposed by this collection of information is 2,888 hours for this one-time collection (Table 1).

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

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interviews	9	1	9	1	9
Pretest	150	1	150	0.17	26
Screener	173,000	1	173,000	0.01	1,730
Experiment	9,360	1	9,360	0.12	1,123
Total					2,888

<sup>1</sup>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 cognitive interviews are designed to ensure that the questions are worded as clearly as possible to consumers. The cognitive interviews would take each respondent no more than an hour to complete. The pretest of the final questionnaire is designed to minimize potential problems in the administration of the interviews. The pretest is predicted to take each respondent 10 minutes to complete.

The screener was administered to the entire 600,000 Internet panel, with over 173,000 responses. To include diet status as a covariate, the screener was designed to identify respondents who are diabetic, non-diabetics who are limiting their carbohydrates, those who are trying to consume foods high in carbohydrate, and consumers in none of the previous categories. The screener was estimated to take respondents 36 seconds to complete.

The experiment would be conducted with 9,360 panel members. The experiment is predicted to take each respondent seven minutes to complete.

### **13. Costs to Respondents**

There are no costs to respondents.

### **14. Costs to Federal Government**

The estimated cost to the federal government is \$200,000. 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. This cost also includes FDA staff time to design and manage the study, to analyze the resultant data, and to draft a report.

### **15. Reason for Change**

This is a new data collection.

### **16. Statistical Reporting**

Conventional statistical techniques for experimental data, such as descriptive statistics, analysis of variance, and regression models would be used to analyze the data. Covariates used in the analysis would include diet status, age, race/ethnicity, gender, and education.

Table 2 outlines the time plan for data collection and analysis.

Table 2. Project Schedule for the Carbohydrate Content Claim Experiment

<b>Date</b>	<b>Activity</b>
Within 5 days after receipt of OMB approval of collection of information	Notification to contractor to proceed with data collection activities
Within 45 days after notification to contractor	Completion of data collection and delivery of data by contractor
Within 180 days after notification to contractor	Completion of preliminary analyses
Within 240 days after notification to contractor	Completion of final analyses and report

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.

**17. Display of OMB Approval Date**

No exemption is requested.

**18. Exceptions to “Certification for Paperwork Reduction Act Submissions”**

No exceptions are requested.

## B. Collections of Information Employing Statistical Methods

### **1. Potential Respondent Universe and Sampling Selection**

The universe for this experimental study is members of the Synovate Internet panel. Synovate's Internet panel consists of 600,000 households that are recruited by a variety of means to reflect all segments of the U.S. population and have agreed to participate in Internet research studies. Typical panel members receive three or four invitations per month to participate in research projects.

The 600,000 panel members were emailed a screener, as part of a regular Synovate omnibus study, to collect information on diet status. By separating the screener questions from the experiment rather than combining them, respondents should be less focused on their diets and carbohydrate issues when answering the study questions.

The 9,360 participant sample for this study would be drawn from the pool of over 173,000 panel members for whom we have information on diet status from the screener. Quotas will be used so that the overall sample is in proportion to the U.S. adult population on age, gender, education, race/ethnicity, and diabetes status. Because there are no national estimates for carbohydrate consumption behavior, quotas for high-and low-carbohydrate diet status would be in proportion to the panelists responding to the screener.

The Agency does not intend to generate nationally or locally representative results or precise estimates of population parameters from this study. The sample used is a convenience sample, rather than a probability sample. Despite the attempt to match between the study's sample and known population characteristics, matching is used solely to produce samples with a reasonable degree of diversity in key demographic characteristics. Furthermore, no legitimate weights can be constructed from non-probability samples such as the one used here. Hence, the Agency does not construe this sample or the results generated from this sample as nationally or locally representative. Rather, the strength of the experimental study lies in its internal validity, on which meaningful estimates of differences across conditions can be produced and generalized.

The sample size for this study is a reflection of the number of conditions, the number of products proposed for the study, and the assumptions described in the power analysis below. The experimental conditions in the study design include claims contained in the carbohydrate petitions and claims already found in the marketplace.

These experimental conditions are required to test the study hypotheses described in section A2. These hypotheses reflect the information needed by the Agency to respond to the carbohydrate content claim petitions. The 2005 Dietary Guidelines highlight components of carbohydrate that consumers should include in their diet and those that they should limit. If authorized, carbohydrate content claims could appear on products that are high or low in the carbohydrates consumers are encouraged to choose (e.g., fiber) or those consumers are encouraged to limit (e.g., added sugars). The Agency, therefore, believes that it is important to understand consumer reaction to claims on products with more and less healthful nutrition profiles.

In addition, the Agency believes that it is important to evaluate how consumers react to carbohydrate claims in the absence of other nutrition information, and also to assess how the availability of additional nutrition information affects consumers' judgments and inferences about the claim and the product. For each of the carbohydrate content claims tested, some respondents will see the front panel only, while others will see the front panel and the nutrition facts.

The Agency is also interested in whether disclosure statements that accompany a front panel claim affect consumers' judgments about the claim. This study tests three different disclosures for sugars, fat, or calorie content.

A very wide variety of food products could be eligible for carbohydrate content claims. The Agency, therefore, believes that it is important to include different types of products in the study to make certain that the cause-effect relationships found are not product-specific. This study will thus evaluate consumers' reactions to carbohydrate content claims for three different types of products.

#### *Power*

To test the hypotheses identified in section A2, the following assumptions were made in deriving the sample size: (1) 0.05 alpha and 0.80 power, (2) two-tailed mean tests, and (3) an effect size between small and medium, roughly 0.30. Based on these assumptions, the per group sample size needed to detect a difference should be 180<sup>6</sup>. The table below describes the study conditions (label(s) which respondents would view), the number of products relevant to the condition, and the total number of respondents needed for each condition (180 multiplied by the number of products, one to three, relevant to the condition).

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<sup>6</sup> Cohen, Jacob (1988). *Statistical Power Analysis for the Behavioral Sciences*, Second Edition. Hillsdale, NJ: Lawrence Erlbaum Associates.

<i>Groups</i>	<i>Products</i>	<i>180 x products</i>
1. Low carb front	(180x) x3 products	=540
2. Net carb front	x2 products	=360
3. CarbConscious front	x3 products	=540
4. No claim front	x3 products	=540
5. Low carb w/ disclosure front	x3 products	=540
6. CarbConscious w/ disclosure front	x3 products	=540
7. Good Source front	x3 products	=540
8. Good Source w/ disclosure front	x1 product	=180
9. Low carb front w/ healthier low carb NFP	x2 products	=360
10. CarbConscious front w/ healthier low carb NFP	x2 products	=360
11. Net carb front w/ healthier low carb NFP	x2 products	=360
12. Low carb front w/ less healthful low carb NFP	x3 products	=540
13. CarbConscious front w/ less healthful low carb NFP	x3 products	=540
14. Net carb front w/ less healthful low carb NFP	x1 products	=180
15. Low carb front w/ disclosure w/ less healthful low carb NFP	x3 products	=540
16. CarbConscious front w/disclosure w/less healthful low carb NFP	x3 products	=540
17. No claim front with healthier low carb NFP	x3 products	=540
18. No claim front with healthier high carb NFP	x3 products	=540
19. Good Source front w/ less healthful high carb NFP	x3 products	=540
20. Good Source front w/ disclosure w/ high carb NFP	x1 products	=180
21. Good Source front w/ healthier high carb NFP	x2 products	=360
<b>TOTAL SAMPLE SIZE</b>		<b>9,360</b>

Below please find a list of the alternative hypotheses for the study followed by a table indicating which condition is included in the study to test which hypothesis or hypotheses.

Hypothesis 1: Among respondents who see the front panel only, those who see a “low carb,” “net carb,” or “carbconscious” claim will evaluate products differently than those who view the no claim, control label.

Hypothesis 2: Among respondents who see the front panel only, those who see a “low carb” or “carbconscious” claim with a fat or calorie disclosure will evaluate the product differently than those who view the “low carb” or “carbconscious” claim without the fat disclosure or calorie disclosure, respectively.

Hypothesis 3: Among respondents who see the front panel only, those who see a “good source of carb” claim will evaluate the product differently than those who view the no claim, control label.

Hypothesis 4: Among respondents who see the front panel only, those who see a “good source of carb” claim with a sugar disclosure will evaluate the product differently than those who view the “good source of carb” claim without the sugar disclosure.

Hypothesis 5: Among respondents who view the front and back labels, those who view a “low carb,” “carbconscious” or “net carb” claim with a *healthier low carb* Nutrition Facts Panel (NFP) will evaluate the product differently than those who view the same front panel with a *less healthful low carb* NFP.

Hypothesis 6: Among respondents who view the front and back labels, those who view a “low carb” or “carbconscious” claim with a fat disclosure and a *less healthful low carb* NFP will evaluate the product differently than those who view a “low carb” or “carbconscious” claim with a *less healthful low carb NFP*, but without a fat disclosure.

Hypothesis 7: Among respondents who view the front and back labels, those who view a “low carb,” “carbconscious,” or “net carb” claim with a *healthier, low carb* NFP will evaluate the product differently than those who view a no claim, control front panel with a *healthier low carb* NFP.

Hypothesis 8: Among respondents who view the front and back labels, those who view a “good source of carb” claim with a sugar disclosure and a *high carb* NFP will evaluate the product differently than those who view a “good source of carb” claim with a *high carb* NFP, but without a sugar disclosure

Hypothesis 9: Among respondents who view the front and back labels, those who view a “good source of carb” claim with *healthier high carb* NFP will evaluate the product differently than those who view a “good source of carb” claim with a *less healthful high carb* NFP.

Hypothesis 10: Among respondents who view the front and back labels, those who view a “good source of carb” claim with a *healthier, high carb* NFP will evaluate the product differently than those who view a no claim control with a *healthier, high carb* NFP.

The 21 conditions for the study are necessary to address the 10 hypotheses described above.

<u>Groups</u>	<u>Hypothesis number(s)</u>
1. Low carb front	1 and 2
2. Net carb front	1
3. CarbConscious front	1 and 2
4. No claim front	1 and 3
5. Low carb w/ disclosure front	2
6. CarbConscious w/ disclosure front	2
7. Good Source front	3 and 4
8. Good Source w/ disclosure front	4
9. Low carb front w/ healthier low carb NFP	5 and 7
10. CarbConscious front w/ healthier low carb NFP	5 and 7
11. Net carb front w/ healthier low carb NFP	5 and 7
12. Low carb front w/ less healthful low carb NFP	5 and 6
13. CarbConscious front w/ less healthful low carb NFP	5 and 6
14. Net carb front w/ less healthful low carb NFP	5
15. Low carb front w/ disclosure w/ less healthful low carb	6
16. CarbConscious front w/disclosure w/less healthful low carb NFP	6
17. No claim front with healthier low carb NFP	7
18. No claim front with healthier high carb NFP	10
19. Good Source front w/ less healthful high carb NFP	8 and 9
20. Good Source front w/ disclosure w/ high carb NFP	8
21. Good Source front w/ healthful high carb NFP	9 and 10

## **2. Procedures for the Collection of Information**

The key dependent measures collected in the experiment to test each hypothesis stated in sections A2 and B1 are (1) purchase intent (Q1); (2) overall healthfulness (Q2); (3) appropriateness for a given objective (Q3); and (4) perceived level of nutrients (Q4).

Purchase intent: Q1. If you were shopping for [FILL BREAD/A JUICE DRINK/A FROZEN BEEF DINNER], how likely would you be to purchase this [FILL BREAD/JUICE DRINK/FROZEN BEEF DINNER]?

Overall healthfulness: Q2. If you were going to [FILL EAT BREAD/HAVE A JUICE DRINK/EAT A FROZEN BEEF DINNER], how healthy of a choice would this [FILL BREAD/JUICE DRINK/FROZEN BEEF DINNER] be?

Appropriateness for a given objective: Q3. Based on what you see on this label, how likely is it that [FILL EATING THIS BREAD/HAVING THIS JUICE DRINK/EATING THIS FROZEN BEEF DINNER] as a regular part of one's diet would help someone [FILL manage their weight, strengthen their bones, have more energy for sports]?

Perceived level of nutrients: Q4. Based on what you see on this label, how high or low do you consider this [FILL BREAD/JUICE DRINK/FROZEN BEEF DINNER] to be in each of the following nutrients? Calories, Total Fat, Total Carbohydrate, Sugars, Fiber, Protein.

Each of the dependent measures will be used to test each of the hypotheses. Subjects across all of the conditions will be asked to answer all of these questions. For all of the alternative hypotheses in the study, differences are expected in the likelihood of purchasing the product, ratings of healthfulness of the product, measures of the nutrients, and the likelihood of helping someone to manage their weight and have more energy for sports, in the case of low and high carbohydrate claims, respectively.

Covariates will be used to account for differences in responses related to the characteristics of the respondent. To help understand non-label factors that may relate to participants' responses to the dependent measures, the following information has been or will be collected.

- a. Interest in nutrition information (Q5).  
Q5. When you buy a food product for the **FIRST TIME**, how often do you read the nutrition facts label that lists ingredients and provides nutrition information?
- b. Purchase experience (Q6).  
Q6. How often do you buy [FILL WITH THE PRODUCT RESPONDENT SAW]?
- c. Consumption experience (Q7).  
Q7. How often do you [EAT BREAD/HAVE JUICE DRINKS/EAT FROZEN DINNERS]?
- d. Diabetes status (Screener1)  
Screener1: Have you been diagnosed with any type of diabetes?
- e. Carbohydrate consumption behavior (Screener2)  
Screener2: In the past 30 days have you....?  
Tried to **limit** the amount of carbohydrate you eat  
Tried to choose foods that are **low** in carbohydrate  
Tried to **increase** the amount of carbohydrate you eat  
Tried to choose foods that are **high** in carbohydrate  
None of the above
- f. Demographics, age, race/ethnicity, gender, education (panel enrollment demographic questionnaire).

It is hypothesized that: (1) Respondents who are interested in nutrition or who are diabetic are more likely to respond to the content of nutrition profile, when available (e.g. judge a more healthful profile more favorably). (2) In the absence of nutrition information, respondents who buy and consume the product regularly are more likely to indicate that they would purchase the product and rate it as healthful. (3) Respondents who have recently limited carbohydrate or chosen foods low in carbohydrate are more likely to rate the products with a low carbohydrate or a carbconscious claim favorably, while respondents who try to

increase carbohydrate or choose foods high in carbohydrate are more likely to rate these products unfavorably.

All information would be collected via the Internet. The three products in this experiment are (1) a loaf of bread, (2) bottled juice drink, and (3) a frozen beef dinner. These products were selected to understand whether consumer perception of carbohydrate content claims varies when the claim is on a label for a traditionally high-carbohydrate and ubiquitous staple (bread), a beverage (juice drink), and a complete meal (frozen dinner).

Forty percent of the participants (3,780) would see only a front panel with one of the carbohydrate content claims or a no claim, control label. The remaining participants would see both a front panel and corresponding Nutrition Facts Panel. For those with a condition that includes nutrition information, both the front and Nutrition Facts Panel would be shown side by side on the screen to respondents before they answer any questions.

On the Nutrition Facts Panel for the bread and frozen dinner, carbohydrate would be held constant at two levels, while the calories, fat, and fiber content vary to create more and less healthful product profiles. On the Nutrition Facts Panel for the juice drink, the sugar content, and therefore calories and total carbohydrate content, would vary. For example, one group of respondents would see the bread with a “low carb” claim on the front panel and the nutrition facts would indicate the product is low in total fat, saturated fat, and calories. Another group of respondents would see the exact same front panel, but the nutrition facts would indicate that the product is substantially higher in calories, total fat, and saturated fat. Comparisons between groups would help the Agency understand the extent of the possible misattribution of health benefits.

The carbohydrate content claims and carbohydrate-related statements that would be tested in the proposed study include “low carb,” “x grams net carbs,” “carbconscious,” and “good source of carb.” The value of “net carb” will be calculated as total carbohydrate less fiber and sugar alcohols. The appropriate Nutrition Facts will include information on this calculation in a “carb facts” box. Where relevant, this study would test claims with and without the following disclosure statements: (1) “see nutrition information for fat content”; (2) “see nutrition information for sugar content”; and (3) “not a low-calorie food.”

FDA has several regulations in part 101 (21 CFR part 101) that apply to the use of disclosures. See § 101.13(h)(1) for disclosures on total fat, saturated fat, cholesterol and sodium; § 101.62(c) for disclosures

related specifically to total fat and cholesterol on products with a saturated fat content claim; and § 101.60(c)(1)(iii)(B) and § 101.60(c)(2)(v) for a calorie disclosure used with a sugar-free claim.

If consumers are misled by carbohydrate content claims on food labels, the Agency would like to know whether disclosure statements could help to redress this problem. The disclosure statements for this study are appropriate to the products that might bear carbohydrate content claims. The fat disclosure statement or the “not a low-calorie food” statement, for example, may be necessary in light of the fact that low-carbohydrate foods are sometimes marketed for weight-loss. Consumers might select low-carbohydrate foods for this objective. However, these foods may be higher in calories due to a higher fat content resulting from a manufacturer’s reformulation of a food. (While carbohydrates have four calories per gram, fat has nine calories per gram.) Also, low-carbohydrate foods tend to be higher in fat, naturally.

The sugar disclosure information in the study would be useful to determine, if “good source” claims are permitted, whether these claims should be required to be accompanied by a disclosure to alert consumers to the sugar content in that food. The issue of disclosures and disqualifying amounts for sugar on products bearing a “good source” of carbohydrate content claim is a key issue of disagreement in the petitions that FDA has received. A sugar disclosure does not currently appear on packages. The Agency is concerned that foods that would be eligible to bear “good source” claims based on total carbohydrate content could include those foods that are high in added sugars, which would be contrary to current dietary recommendations to limit the intake of added sugars.

### **3. Methods to maximize response rates and to deal with issues of non-response**

This experimental study would use an existing Internet panel to draw a sample. The panel includes people who have expressed interest in sharing their opinions via the Internet and do so regularly. The expected participation rate for the Internet panel is 55 percent when responding to a specific study. To help ensure that the participation rate is as high as possible, the Agency will:

- Design an experimental protocol that minimizes burden (short in length, clearly written, and with appealing graphics);
- Test the draft protocol in cognitive interviews and pretests to ensure that the protocol does minimize burden and refine the protocol as appropriate;

- Administer the experiment over the Internet, allowing respondents to answer questions at a time and location of their choosing;
- Administer the experiment to individuals who have expressed interest in participating in Internet studies;
- Email a reminder to the respondents who do not complete the protocol four days after the original invitation to participate is sent;
- Provide contact information on where to get help for respondents who may have questions as they complete the experiment.

#### **4. Test Procedures**

A series of up to nine cognitive interviews would be conducted in three waves. At the end of each the first two waves, any necessary refinements to the questions would be made and tested in the successive wave. Cognitive interviews would help ensure that the questions are as clear and as minimally burdensome as possible.

Pretests of the questionnaire would be conducted prior to the main experimental study. The 150 pretest participants would be drawn from the sample population, Synovate's Internet Panel. The pretest would be completed in at most three waves of 50 interviews. Like the cognitive interview schedule, any refinements identified in one wave would be made and tested in the next. The pretest would help ensure that any potential problems in sample selection, administration, and data collection are addressed before the experiment is in the field.

#### **5. Individuals Involved in Statistical Consultation and Information Collection**

The contractor, Synovate, would collect the information on behalf of the FDA as a task order under the Quick-Turn-Around Research Services contract. Leigh Seaver, Ph.D., is the Senior Study Director for Synovate, telephone (703) 790-9099. Analysis of the information would be conducted primarily by staff on the Consumer Studies Staff, Division of Social Science, Office of Regulations and Policy, CFSAN, FDA, and coordinated by Judith Labiner-Wolfe, PhD, telephone (301) 436-2443.