Status: Meeting is open to the public, limited only by the space available.

Background: NIOSH has been conducting an occupational epidemiologic research program addressing potential long term health effects of working in the Department of Energy (DOE) nuclear weapons complex under a series of Memoranda of Understanding (MOUs) with DOE. Establishment of this research program began following recommendations of a Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) for the U.S. Department of Energy in 1990. Input from various stakeholders has been sought since the program's inception including organized labor, current and former workers, DOE site management and contractors, DOE headquarters, academic research partners, the occupational safety and health community, various governmental agencies, and the general public. A document entitled: Agenda for HHS Public Health Activities (For Fiscal Years 2005–2010) at U.S. Department of Energy Sites is accessible at *http://www.cdc.gov/niosh/pdfs/hhsdoe_2005–2010–2.pdf* and includes information on completed, ongoing, and proposed occupational epidemiologic research activities under the DOE–DHHS MOU.

Purpose: This meeting will provide an overview of recently completed work conducted under the MOU, outline ongoing research activities, summarize findings and follow-up from a NIOSH public meeting held July 2004 addressing chronic lymphocytic leukemia radiogenic research, and discuss plans for future research. Attendees will have opportunities for questions and oral commentary on this NIOSH research program. Stakeholder feedback and the opportunity to update stakeholders on this research program are two primary objectives of the meeting. Written comments will be accepted at the meeting and may also be sent to the address for the NIOSH Health-Related Energy Research Branch below.

The agenda for this meeting is currently being developed. Stakeholders interested in attending may request additional information from the contact person identified below. Written comments may also be submitted to the address below until November 1, 2005.

Contact Person for More Information: Ms. Patty Gudlewski may be contacted at 513–841–4419 or by e-mail at *PGudlewski@cdc.gov.*

Addresses: Written requests for meeting information may be sent to Ms. P. Gudlewski; NIOSH–HERB; Mailstop R–44; 4676 Columbia Parkway; Cincinnati, OH 45226. Written comments should be sent to the attention of Dr. Steven Ahrenholz at the same NIOSH mailing address or may be e-mailed to him at *SAhrenholz@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 10, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–16257 Filed 8–16–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0120]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Carbohydrate Content Claims on Food Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 16, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study of Carbohydrate Content Claims on Food Labels

The authority for FDA to collect the information for this experimental study derives from the Commissioner of Food and Drugs' authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)).

The Nutrition Labeling and Education Act of 1990 (Public Law 101–535) amended the act. Section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)) was added under these amendments. This section 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.

In 1993, FDA published regulations that implemented the 1990 amendments. Among these regulations, § 101.13 (21 CFR 101.13) sets forth general principles for nutrient content claims (see 56 FR 60421, November 27, 1991, and 58 FR 2302, January 6, 1993). Other regulations in subpart D of part 101 (21 CFR part 101, subpart D) 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, § 101.69 (21 CFR 101.69) establishes the procedures and requirements for petitioning the agency to authorize nutrient content claims.

The Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) amended section 403(r)(2) of the act by adding sections 403(r)(2)(G) and (r)(2)(H) to permit nutrient content claims based on published authoritative statements by a scientific body when FDA is notified of such claims in accordance with the requirements established in these sections.

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. FDA has been petitioned to amend existing food labeling regulations to define terms for use in nutrient content claims characterizing the level of carbohydrate in foods.

The purpose of this proposed data collection is to help enhance FDA's understanding of consumer response to carbohydrate content claims on food labels. More specifically, this experimental study will help answer the following research questions:

1. Does the presence of a given front panel carbohydrate content claim suggest to consumers that the product is lower or higher in total carbohydrate, calories, and other nutrients (i.e., total fat, fiber, and protein) than the same product without the claim or with a different claim?

2. Does the presence of a given front panel carbohydrate content claim suggest to consumers who do not view the Nutrition Facts panel that the food is healthier or otherwise more desirable than the same product without the claim or with a different claim?

3. Does the presence of a front panel carbohydrate content claim suggest to consumers that the product is healthier than the same product without a claim or with a different claim despite information to the contrary available on the Nutrition Facts panel?

4. Do disclosure statements help consumers to draw appropriate conclusions about products with carbohydrate content claims on the front panel?

The label claims that would be tested in the proposed study include ''carb-free,'' ''low carb,'' ''x g net carbs,'' ''carbconscious,'' ''good source of carb,'' and ''excellent source of carb.'' The study would also include control labels (labels not bearing a claim). Where relevant, this study would test carbohydrate content 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.''

Participants would see mock food label images for one of the following three products: (1) A loaf of bread, (2) a can of soda, and (3) a frozen entree. Three products were selected to understand whether consumer perception of carbohydrate content claims changes when the food is a traditionally high-carbohydrate, ubiquitous staple (bread), a beverage (soda), or a complete meal (frozen entree).

Half of the participants would see only a front panel with a carbohydrate content claim or a control label not bearing a claim. The other half of the participants would see both the front panel and the back panel, which includes the Nutrition Facts information. In the Nutrition Facts panel for the bread and frozen entree, the calorie, fat, and fiber content would vary to create more and less healthful product profiles. Total carbohydrate content would also vary. On the Nutrition Facts panel for the soda, the sugar content, and therefore total carbohydrate content and calories, would vary.

The proposed experimental study would be conducted online via the Internet. The sample would be drawn from an existing consumer opinion panel developed and maintained by the research firm Synovate. Synovate's Internet panel consists of 600,000 households that have agreed to participate in research studies conducted through the Internet.

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. Periodically, Synovate gives incentives of small monetary value to panel members for their participation. Studies begin with an e-mailed invitation to the sampled respondents.

For this proposed study, Synovate's Internet panel would be screened for diet status. Twenty-five percent of the households in the Internet panel (150,000 households) are expected to respond to the screening questions. Based on information gathered from the screening process, a sample would be drawn to allow for 2,500 participants in each of 4 groups: (1) Diabetic consumers, (2) consumers who try to eat a diet low in carbohydrate (but who are not diabetic), (3) consumers who try to eat a diet high in carbohydrate, and (4) consumers who are not part of any of the preceding three groups. Assignment to a condition would be random within each of the four groups of consumers. Of the members of the Internet panel who respond to the screening questions and are selected for the study (18,200 panel members), 55 percent (10,000 panel members) are expected to participate in the experiment.

In the **Federal Register** of April 8, 2005 (70 FR 18032), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received eight comments on this proposed data collection. The first comment was from a citizen; the second was from National Starch Food Innovation; the third was from The Sugar Association; the fourth was from the American Dietetic Association; the fifth was from the Grocery Manufacturers of America; the sixth was 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 were from the Calorie Control Council.

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. The sample size for the study is 10,000 consumers. FDA needs this sample size to conduct sub-analyses within four different groups: Consumers who are diabetic, nondiabetics who are limiting their carbohydrates, consumers who are trying to consume foods high in carbohydrate, and consumers in none of the previous categories. To identify an adequate number of consumers from each of these groups for meaningful sub-analyses, FDA will need to screen the full Synovate Internet panel, but will not be using the full panel for the study itself. The screening will be conducted in the context of a quarterly multi-topic survey that Synovate e-mails to all of its Internet panel members. This data collection proposes to include three very brief diet status screening questions on one of Synovate's multi-topic surveys. These questions would take no more than 36 seconds to complete. Based on Synovate's previous experience with this panel, 150,000 panel members should reply to the screening questions. The sample for this proposed data collection would be drawn from the estimated 150,000 responses to the screening questions. The sample would include roughly 18,000 consumers, of which FDA projects that 10,000 will complete the study.

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 as follows: (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;'' and (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 the following will occur: (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)); (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 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 (21 CFR 101.13(h)(1)). 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'' 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.

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 (soda), and a complete meal (frozen dinner). The agency does not agree that any of the 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.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive Interviews	9	1	9	0.5	5
Pretest	150	1	150	0.17	26
Screener	150,000	1	150,000	0.01	1,500
Experiment	10,000	1	10,000	0.12	1,200
Total					2,731

[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 cognitive interviews are designed to ensure that the questions are worded as clearly as possible to consumers. The cognitive interviews would take each respondent 30 minutes 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 approximately 10 minutes to complete.

The screener would be sent via the Internet to the entire 600,000-household Internet panel, of which 25 percent (150,000 households) are predicted to respond. The brief screener is predicted to take each respondent 36 seconds to complete.

The experiment would be conducted with 10,000 panel members. The experiment is predicted to take each respondent approximately 7 minutes to complete.

Dated: August 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16242 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005C–0302, 2005C–0303, and 2005C–0304]

CIBA Vision Corp.; Filing of Color Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that CIBA Vision Corp. has filed three petitions proposing that the color additive regulations be amended to