a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the **Federal Register** of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.'' The guidance provides the agency's interpretation of terms central to the submission of a notification and the agency's views on the information that should be included in the notification. The agency believes that the guidance will enable food producers to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the act. In addition to the information specifically required by the act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications the agency receives to ensure that they comply with the criteria established by the act.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act/Basis of Burden	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(3)(C) (health claims)	2	1	2	450	900
Guidance for notifications	3	1	3	1	3
Total					1,153

[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 health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. Because the claims are based on an authoritative statement of certain scientific bodies of the Federal Government or the National Academy of Sciences or one of its subdivisions, FDA believes that the information submitted with a notification will either be provided as part of the authoritative statement, or readily available as part of the scientific literature to firms wishing to make claims. Presentation of a supporting bibliography and a brief balanced account or analysis of this literature should be fairly straightforward.

Dated: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7024 Filed 4–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0120]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a consumer experimental study of carbohydrate content claims on food labels.

DATES: Submit written or electronic comments on the collection of information by June 7, 2005.

ADDRESSES: Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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 three products: (1) A loaf of bread, (2) a can of soda, and (3) a frozen entrée. 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 entrée).

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 entrée, 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.

FDA estimates the burden of this 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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7026 Filed 4–7–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

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 May 9, 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 written 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.

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers (OMB Control Number 0910–0037)—Extension

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is authorized to prevent the interstate distribution of food products that may be injurious to health or that are otherwise adulterated, as defined in section 402 of the act (21 U.S.C. 342). Under the authority granted to FDA by section 404 of the act (21 U.S.C. 344), FDA regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit FDA to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum*. The spores of *C. botulinum* must be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, FDA regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with FDA using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2))). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (§ 13.87(a) (21 CFR 113.87(a))).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms are also required to document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any