DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0083]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Gluten-Free Labeling of Food Products Experimental Study

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 December 17, 2009.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Gluten-Free Labeling of Food Products Experimental Study.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Gluten-Free Labeling of Food Products Experimental Study—(OMB Control Number 0910–NEW)

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393 (b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. FDA is planning to conduct an experimental study about gluten-free labeling of food products. The Gluten-Free Labeling of Food Products Experimental Study will collect information from both consumers who have celiac disease or gluten intolerance and those who do not have either condition. The purpose of the study is to gauge perceptions of characteristics related to claims of ''gluten-free'' and allowed variants (e.g., ''free of gluten,'' ''without gluten,'' ''no gluten''), in addition to other types of statements (e.g., ''made in a gluten-free facility'' or ''not made in a facility that processes gluten-containing foods'') on the food label. The study will also assess consumer understanding of ''gluten-free'' claims on foods that are naturally free of gluten, and gauge consumer reaction to a product carrying a gluten claim concurrently with a statement about the amount of gluten the product contains.

In a 60-day **Federal Register** notice, which published on March 6, 2009 (74 FR 9822), FDA stated that the data would be collected over the Internet from samples derived from two sources: (1) A membership list from a celiac disease special interest organization and (2) an online consumer panel. FDA will not utilize the membership list of a celiac disease special interest organization. Instead, FDA will obtain participants through the assistance of major celiac disease and research centers around the United States. Participation in the study is voluntary.

Also in the March 6, 2009, sixty-day **Federal Register** notice, FDA requested public comment on the proposed information collection provisions. FDA received 34 letters in response to the notice, each containing 1 or more comments. The comments, and the agency's responses, are discussed in the following paragraphs. Some of the comments received were beyond the scope of the collection of information. Those comments are not addressed in this document.

(Comment 1) Several comments cited the importance of doing the gluten-free study and commended FDA for doing it.

(Response) FDA agrees that the study will help FDA learn how consumers react and respond to the gluten-free labeling options presented in the gluten-free labeling proposed rule (See 72 FR 2795, January 23, 2007).

(Comment 2) One comment suggested using software tools such as *surveymonkey.com* to minimize the costs associated with creating online surveys. This comment also suggested using a survey program that allowed for both closed-ended (choose a response) and open-ended (write a response) response options.

(Response) FDA agrees that using existing software to collect data online will minimize the costs. The contractor hired to collect the data has a long history of online data collection and has existing software for this type of data collection. This software allows for multiple types of questions and response options.

(Comment 3) Several comments recommended that FDA expand the data collection method from using the Internet only to also include paper surveys. One comment said that computer access is difficult for people who live in rural areas. Another comment said that elderly people and those with lower incomes are less likely to have access to computers.

(Response) FDA agrees that a paper version should be available for people who might have difficulties in accessing the internet. FDA plans to make a paper version available by providing a telephone number for potential respondents to call and request a paper version. The telephone number will be included in a flyer about the study FDA will disseminate to celiac disease treatment and research centers to post for patients to view.

(Comment 4) One comment said that many children have access to computers only at school so they suggested that FDA offer a paper survey so that respondents can include children.

(Response) FDA disagrees. The study is limited to adults age 18 and above. This age group includes individuals who regularly shop for and prepare foods. FDA acknowledges that children can shop for and prepare foods but the likelihood that they do is far less than their caregivers, who will be included in the study.

(Comment 5) One comment recommended FDA to test gluten-free statements that say, ''Testing meets FDA standards for gluten'' and ''Testing meets FDA standards of less than 20ppm of gluten present.''

(Response) FDA disagrees with the comment. Section 206 of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of Public Law No. 108–282) requires FDA to issue a rule to define and permit use of the term ''gluten-free'' on the labeling of foods. In the proposed rule (72 FR 2795), FDA proposed a regulation to define the term ''gluten-free'' and to establish uniform conditions for its use in the voluntary labeling of foods. FDA will not test these statements because they are not consistent with FALCPA or with our proposed rule.

(Comment 6) One comment suggested having an open-ended question where respondents can describe the type of labeling that they believe is the best and most understandable.

(Response) FDA agrees and will provide an open-ended question at the end of the questionnaire to allow respondents to comment on the study and to make suggestions for labeling preferences.

(Comment 7) One comment asked that the questions be very clear.

(Response) FDA agrees that it is important that the study questions be unambiguous. To achieve this goal, FDA will conduct cognitive interviews prior to administering the main study, in which a trained interviewer goes through the questionnaire with adults with celiac disease and discusses whether the questions are understandable and valid.

(Comment 8) Several comments had recommendations for groups of people that should be included in the study. One comment said that the control group, the people for whom gluten poses no adverse health-effects, should be comprised of individuals who are ''avid label readers,'' on the theory that their label-reading behavior would make them most like people who use label information to help them avoid gluten. One comment said it was essential to get participants who are in various stages of a gluten-free diet because labeling needs are different depending on how long one has been diagnosed with celiac disease. One comment said it was important to recruit participants from various ethnic and socio-economic backgrounds because these factors may have impacts on what people eat. One comment said the FDA should consider that many people who have celiac disease or gluten sensitivities also have other food intolerances and the survey should be constructed with these people in mind.

(Response) FDA agrees that the control group should consist of respondents who frequently read the food label in making purchase decisions. FDA will identify and recruit such individuals by including a question in the study screener to gauge such efforts. FDA will also identify and recruit individuals who report in the study screener that they follow gluten free diets for reasons other than that they have celiac disease. FDA will include a question for individuals with celiac disease and for caregivers to such individuals that asks how long they have been diagnosed with celiac disease. FDA expects that individuals from various ethnic and socio-economic backgrounds will respond to the invitation to participate in the study. Working through major celiac disease and research centers around the United States will also help to reach a diverse population. FDA will include a question in the study asking individuals with celiac disease if they have other food intolerances or food allergies.

(Comment 9) One comment suggested including natural food store owners in the study.

(Response) FDA disagrees with the comment that natural food store owners should be included in the study. The study population in this research is consumers. Store owners may participate if they meet the study criteria.

(Comment 10) One comment suggested that instead of recruiting participants from celiac disease special interest groups that might introduce interest-based biases, FDA should contact celiac disease and research centers to ask them to distribute the survey to their mailing lists.

(Response) FDA agrees with the comment and has contacted major celiac disease and research centers around the United States to ask them to distribute an invitation to participate in the study to their mailing lists, if they have one, and to put up a flyer at their centers inviting patients to participate online or call to request a paper copy.

(Comment 11) Several comments suggested making the survey available in more than one language.

(Response) FDA disagrees. Although making the questionnaire available in more than one language increases public access, FDA plans to administer the study only in English because existing research and information on individuals with celiac disease and gluten-intolerances does not suggest that gluten-free labeling issues vary by culture.

(Comment 12) One comment suggested that the survey results should be made available to the public.

(Response) FDA agrees with the comment and will make the study results available when they are ready.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	10,000	1	10,000	0.0055	55
Pretest	140	1	140	.167	24
Experiment	7,000	1	7,000	.167	1,169
Total					1,248

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

In the March 6, 2009, sixty-day notice, FDA estimated the total annual reporting burden to be 892 hours. FDA has made several changes to its burden estimate as reflected in table 1 of this document. The agency increased: (1) The number of screeners from 6,000 to 10,000 and (2) the number of completed questionnaires from 5,000 to 7,000.

Approximately 10,000 respondents will be screened. We estimate that it will take a respondent 20 seconds (0.0055 hours) to complete the screening questions, for a total of 55 hours. A pretest will be conducted with 140 respondents; we estimate that it will take a respondent 10 minutes (0.167 hours) to complete the pretest, for a total of 24 hours. Seven thousand (7,000) respondents will complete the experiment. We estimate that it will take a respondent 10 minutes (0.167 hours) to complete the entire experiment, for a total of 1,169 hours. Thus, the total estimated annual reporting burden is 1,248 hours. FDA's burden estimate is based on prior experience with consumer experiments that are similar to this proposed experiment.

Dated: November 9, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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