GLUTEN-FREE LABELING OF FOOD PRODUCTS EXPERIMENTAL STUDY

OMB No. 0910-NEW

SUPPORTING STATEMENT

PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2)), the Food and Drug Administration (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 proposing to define the term gluten-free for voluntary use in the labeling of foods in response to the Food Allergen Labeling and Consumer Protection Act of 2004. The act directs the Secretary of Health and Human Services (HHS), in consultation with appropriate experts and stakeholders, to issue a rule to define, and permit use of, the term gluten-free on the labeling of foods. FDA's Center for Food Safety and Applied Nutrition (CFSAN), Division of Social Sciences, will conduct consumer research to assist CFSAN's Office of Nutrition, Labeling, and Dietary Supplements in this information collection by conducting an experimental study to test the effects of a variety of gluten-free claims on consumers' ability to make product choices in their best interest. Results of this study will be used to help FDA define how gluten-free terms can be used on food product labels.

2. Purpose and Use of the Information Collection

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 consumers who have celiac disease or a 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.

The agency does not intend to generate nationally representative results or precise estimates of population parameters from the experimental studies. The studies will use convenience samples rather than probability samples.

3. Use of Improved Information Technology and Burden Reduction

The study will mainly use web-based surveys, with the option of mail surveys available upon request. Web-based surveys not only reduce the burden on respondents, but also minimize possible administration errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, Web-based surveys are less intrusive and less costly.

4. Efforts to Identify Duplication and Use of Similar Information

In 2007, the American Celiac Disease Association (ACDA) conducted a 15-question online survey on the subject of gluten-free labeling. Responses were collected from 5,022 consumers and health care professionals. The survey found strong support for regulation defining the term "gluten-free" for use on the food label and support for a limit of less than 20ppm gluten in order to carry the claim. Consumers were not concerned about statements such as "may contain. . . " or "produced in a facility . . ." if they could rely on the "gluten-free" claim on products meeting the FDA criteria. The ACDA study is the only available consumer research study focusing on gluten-free labeling, other consumer research on gluten-free focuses on difficulties of implementing and maintaining a gluten-free diet. FDA's proposed study focuses on regulatory aspects of gluten-free related issues. Therefore, there is no duplicative collection of this information. No comparable data have been collected by any other entities. The experimental study proposed here will provide valuable information specific to consumer reaction to certain specific gluten-free claims on the food label.

5. Impact on Small Businesses or Other Small Entities

This collection of information will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. If this information is not collected, FDA will not know how consumers with celiac disease, gluten intolerances, and other consumers will react to a variety of gluten-free statements on the food label or how they will respond to a number statements made on foods that are naturally free of gluten. This lack of information would impede FDA's ability to define under what circumstances certain gluten-free statements can be used on the food label.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus two copies of the information; or retain records for more than 3 years. The design of the experimental study will not produce results that cannot be generalized to the response universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of March 6, 2009 (74 FR 9822), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received thirty-four letters in response to the notice, each containing one or more comments. The comments, and the agency's responses, are

discussed in the following paragraphs. Some of the comments received were not responsive to the comment request on the four specified aspects of the collection of information. These non-responsive comments will not be addressed in this document.

(**Comment)** 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 proposed gluten-free labeling rule (See 72 FR 2795).

(**Comment)** 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)** 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 phone number for potential respondents to call and request a paper version. The phone number will be included in a flyer about the study that FDA will disseminate to celiac disease treatment and research centers to post for patients to view and in the e-mail invitations the centers will forward to their patients.

(**Comment)** 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)** 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 Pub. L. 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)** 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)** 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)** 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 US 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) One comment suggested including natural food storeowners in the study.

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

(**Comment)** 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)** 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)** 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.

9. Explanation of Any Payment or Gift to Respondents

Synovate, the firm that owns the consumer panel from which we will select participants who do not have adverse health effects due to gluten, routinely sends inexpensive gifts to panel members to show appreciation for participants' efforts in answering the questionnaires. Other participants will not be compensated.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study questionnaire and screener contain a statement that responses will be kept confidential. Confidential information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

We will assure confidentiality by using independent contractors (Synovate and RTI) to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. Synovate's and RTI's privacy policy adheres to the professional standards of the Council of American Survey Research Organizations (casro.org). Neither Synovate nor RTI will share personal information regarding panel members with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in the data files delivered to the agency.

All electronic data will be maintained in a manner that 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 will 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. Justification for Sensitive Questions

The survey does not include any questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Participants will be adults with celiac disease, adults with a gluten intolerance, adults who do not have either of these conditions but follow a gluten-free diet and adults who purchase and prepare foods for individuals with celiac disease or gluten intolerance or who follow a gluten-free diet. Participants will also include adults for whom gluten poses no adverse health effects and who do not follow a gluten-free diet who are members of a web-based consumer panel. These adults will serve as a control group.

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
Online Screener	9,800	1	9,800	.05	490
Telephone Screener	200	1	200	.083	17
Online Pre-Test[2]	140	1	140	.167	23
Paper Experiment	200	1	200	.33	66
Online Experiment with panel	3,400	1	3,400	.167	568
Online Experiment with Convenience Sample	3,400	1	3,400	.25	850
Total					2014

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

[2] There is no paper pretest

Approximately 9,800 respondents will be screened online. We estimate that it will take a respondent 3 minutes (0.05 hours) to complete the online screening questions, for a total of 490 hours. Approximately 200 respondents will be screened over the telephone. We estimate that it will take a respondent 5 minutes (0.083 hours) to complete the telephone screener, for a total of 17 hours. An online pre-test 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 23 hours. We estimate that about 200 respondents will request to complete the experimental study on paper instead of online. We estimate that it

will take a respondent about 20 minutes (.33 hours) to complete the study on paper, for a total paper experiment time of 66 hours. Approximately 3,400 online panel respondents will complete the online experiment. We estimate that it will take a respondent 10 minutes (0.167 hours) to complete the entire online experiment, for a total of 568 hours. Approximately 3,400 convenience sample respondents will complete the online experiment. We estimate that it will take a respondent 15 minutes (0.25 hours) to complete the entire online experiment, for a total of 850 hours. Thus, the total estimated burden is 2014 hours. FDA's burden estimate is based on prior experience with consumer experiments that are similar to this proposed experiment.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital, operating, or maintenance costs associated with this collection.

14. Annualized Cost to Federal Government

The total estimated cost of this research is $159,000. This includes $150,000 paid to the contractor to program the study, draw the sample, collect the data, create a database of the results, deliver oral and written preliminary summaries, and deliver a written final report of summaries and analytical findings. In addition, FDA estimates the cost of salaries for the FDA staff involved in the project development, implementation and monitoring to be $9,000, for a total estimated cost of $159,000.

15. Explanation for Program Changes or Adjustments

This is a new data collection. The new burden hours are due to a one-time data collection and its related pre-test and screener.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to help inform proposed regulations for the gluten-free labeling of food products. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. Final results of the study may be summarized for publication in a peer-reviewed scientific journal. The planned schedule for project activities is shown in Table 2.

Table 2. *Project Schedule*

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to the contractor to proceed with data collection activities	Not applicable
Within 135 days after notification to contractor	Completion of data collection	Not applicable
Within 180 days after notification to contractor	Delivery by the contractor of final data files	Not applicable
Within 6 months after receipt of final data files	Delivery of oral and written preliminary summaries	FDA
Within 18 months after receipt of final data files	Delivery of a written final report of summaries and analytical findings	FDA
Within 18 months after receipt of final data files	Response to information requests	FDA and public
Within 24 months after receipt of final data files	Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	Public

Activities associated with the outcomes of this research will primarily consist of written and oral presentations as well as a written final report. In addition, journal manuscripts and oral and/or poster presentations will be planned to disseminate the information to the public, including professionals, academics, and industry and consumer organizations. The dialogues will help improve the effectiveness of the agency's regulatory and education initiatives in promoting and protecting the public health.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.