

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0083]

Agency Information Collection Activities; Proposed Collection; 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 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 voluntary consumer study entitled "Gluten-Free Labeling of Food Products Experimental Study."

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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.

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FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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.

Gluten-Free Labeling of Food Products Experimental Study

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic 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.

The data will 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. Participation in the study is voluntary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

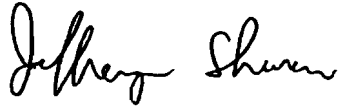
Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screeners	6,000	1	6,000	0.0055	33
Pretest	140	1	140	.167	23.38
Experiment	5,000	1	5,000	.167	835
Total					891.38

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

Approximately 6,000 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 33 hours. A pretest will be conducted with 140 participants; we estimate that it will take a respondent 10 minutes (0.167 hours) to complete the pretest, for a total of 23.38 hours. Five thousand adults 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 835 hours. Thus, the total estimated burden is 891.38 hours. FDA's burden estimate is based on prior experience with consumer experiments that are similar to this proposed experiment.

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Dated: February 23, 2009.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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