

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0871]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Studies on Consumer Responses to Nutrient Content Claims on Fortified Foods

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 23, 2013.

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: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Experimental Studies on Consumer Responses to Nutrient Content Claims on Fortified Foods." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, 301-796-5733, domini.bean@fda.hhs.gov.

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 Studies on Consumer Responses to Nutrient Content Claims on Fortified Foods—OMB Control Number 0910-New)

I. Background

The Nutrition Labeling and Education Act gave FDA the authority to issue regulations that require almost all packaged foods to bear nutrition labeling. The law also allows manufacturers to provide other nutrition

information on labels in the form of various types of statements, including claims, as long as such statements comply with the regulatory limits that govern the use of each type of statement. There are three types of claims that the food industry can voluntarily use on food labels: (1) Health claims, (2) nutrient content claims, and (3) structure/function claims. All claims must be truthful and not misleading (Ref. 1).

FDA's policy on fortification (21 CFR 104.20) establishes a set of principles that serve as a model for the rational addition of nutrients to foods. FDA has an interest in the American public achieving and maintaining diets with optimal levels of nutritional quality, wherein healthy diets are composed of foods from a variety of nutrient sources. FDA does not encourage the addition of nutrients to certain food products (including sugars or snack foods such as [cookies] candies, and carbonated beverages). FDA is interested in studying whether fortification of these foods could cause consumers to believe that substituting fortified snack foods for more nutritious foods would ensure a nutritionally sound diet.

Research suggests consumer product perceptions and purchase decisions can be influenced by labeling statements and different labeling statements may have different influences (Refs. 2 through 5). FDA, as part of its effort to promote public health, proposes to conduct a controlled, randomized experiment to explore consumer responses to expressed and implied nutrient content claims on the labels of snack foods such as cookies, carbonated beverages, and candy. The study will use a 15-minute Web-based questionnaire to collect information from 7,500 English-speaking adult members of an online consumer panel maintained by a contractor. Researchers will endeavor to collect samples that reflect the U.S. Census on gender, education, age, and ethnicity/race for both modes of administration.

Potential conditions for the study include the following: (1) A mock snack product with a claim similar to "[a]s much [nutrient] as a serving of [food product];" (2) a mock candy with the claim "[g]ood source of [nutrient];" and (3) a mock carbonated beverage with the claim, "product name] plus [nutrient]." Each participant in each study will be randomly assigned to view a label image. Each participant in each study will also be randomly allowed or disallowed to access the Nutrition Facts label of the product. All label images will be mock products resembling actual food labels found in the marketplace.

Participants will view label images and answer questions about their perceptions and reactions to the label. Product perceptions (e.g., healthiness, potential health benefits, levels of nutrients), label perceptions (e.g., helpfulness and credibility), and purchase/choice questions will constitute the measures of response in the experiment. To help understand the data, the study will also collect information about participants' background, such as purchase and consumption of similar products; nutrition knowledge; dietary interests; motivation regarding label use; health status and demographic characteristics.

The study is a part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will be used primarily to inform the Agency's understanding of how claims on the packages of fortified food may affect how consumers perceive a product or a label, which may in turn affect their dietary choices. The results of the study will not be used to develop population estimates.

In accordance with 5 CFR 1320.8(d), in the **Federal Register** of August 15, 2012 (77 FR 48988), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received six 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. One of the comments received was not responsive to the comment request on the four specified aspects of the collection of information. This non-responsive comment will not be addressed in this document. We respond to the remaining comments in this document. For ease of reading, we preface each comment with a numbered "Comment" and each response by a corresponding numbered "Response." We have numbered each comment to help distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, or importance, or the order in which it was received.

(Comment 1) Four comments expressed support of the utility of the study for FDA's mission, stating that use of the study results will help FDA: (1) Fulfill its role as a steward of the public health; (2) continue to help consumers use the food label to make informed consumption decisions; and (3) help FDA to continue the policy against fortifying sugars or snack foods such as cookies, candies, and carbonated beverages.

(Response 1) FDA agrees with the comments.

(Comment 2) Reacting to FDA's declaration in the 60-day notice (77 FR 48988), that it intends to use "a mock snack product" to study nutrient content claims on fortified foods, one comment requested that FDA limit testing of such claims to sugars, cookies, candy, and carbonated beverages.

(Response 2) FDA agrees with the comment. FDA will limit testing of nutrient content claims on fortified

snack foods to mock cookies, candy, and carbonated beverages.

(Comment 3) One comment requested that FDA use images of actual commercially available labels for fortified snack products in the study instead of the proposed mock snack food labels, claiming that use of actual labels will increase the external validity of the studies.

(Response 3) FDA disagrees with the comment. Actual labels will increase the external validity of the findings but actual labels also are highly likely to

introduce brand effects, a bias that may be difficult to separate from effects of the claims themselves, which is the focus of the studies.

Recent study design decisions have indicated that the Agency needs a larger sample size for Study 1 than originally expected; therefore, the Agency will not conduct Study 2 (a shopping simulation study) which was described in the 60-day notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1 hour (60 minutes)	9
Pretest invitation	1,600	1	1,600	0.033 (2 minutes)	53
Pretest	400	1	400	0.25 (15 minutes)	100
Survey invitation	32,000	1	32,000	0.033 (2 minutes)	1,056
Survey	7,500	1	7,500	0.25 (15 minutes)	1,875
Total					3,099

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

II. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration. Claims That Can Be Made for Conventional Foods and Dietary Supplements. September 2003. Available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm>.

2. Drichoutis, A.C., P. Lazaridis, and R.M. Nayga, "Consumers' Use of Nutritional Labels: A Review of Research Studies and Issues," *Academy of Marketing Science Review*, 2006(9), 2006. Available at <http://www.amsreview.org/articles/drichoutis09-2006.pdf>.

3. Lähteenmäki, L., P. Lampila, and K. Grunert, et al., "Impact of Health-Related Claims on the Perception of Other Product Attributes," *Food Policy*, 23: 230-239, 2010.

4. Labiner-Wolfe, J., C.-T. J. Lin, and L. Verrill, "Effect of Low Carbohydrate Claims

on Consumer Perceptions about Food Products' Healthfulness and Helpfulness for Weight Management," *Journal of Nutrition Education and Behavior*, 42(5): 315-320, 2010.

5. Roe, B., A.S. Levy, and B.M. Derby, "The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Evidence from FDA Experimental Data," *Journal of Public Policy and Marketing*, 18(1): 89-105, 1999.

Dated: August 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0745]

Request for Comments on the Food and Drug Administration Safety and Innovation Act Section 907 Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket for comments pertaining to the report issued as required by section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA). This notice is intended to solicit input from all relevant stakeholders before FDA issues an action plan to address issues raised in the report and to announce that such information submitted to FDA is available to all interested persons in a timely fashion.

DATES: Submit electronic or written comments by November 20, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments 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: Pamela E. Scott, Office of Women's Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2320, Silver Spring, MD 20903,