Dated: August 10, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–20051 Filed 8–14–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0871]

Agency Information Collection Activities; Proposed Collection; 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 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 study entitled ''Experimental Studies on Consumer Responses to Nutrient Content Claims on Fortified Foods.''

DATES: Submit either electronic or written comments on the collection of information by October 15, 2012.

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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

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 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 promulgate regulations which 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).

The 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. The 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. The 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). The FDA, as part of its effort to promote public health, proposes to conduct two related studies to explore consumer responses to expressed and implied nutrient content claims on the labels of snack foods such as cookies, carbonated beverages, and candy. Both studies will be controlled, randomized experiments. Study 1 will use a 15-minute Web-based questionnaire to collect information from 4,000 English-speaking adult members of an online consumer panel maintained by a contractor. Study 2 will use the same questionnaire and draw a sample of 1,000 English-speaking adult participants from the same online consumer panel to test a subset of the experimental conditions employed in Study 1. Participants in Study 2 will also access the survey on the Web but will use a grocery-shopping simulation software program to participate in the study. Study 2 is expected to last 15 minutes as well.

The purpose for using both the regular Web-based application and the simulated shopping program is to be able to compare the two modes of data collection. One critique of experimental studies is that they may lack external validity—the ability to generalize the findings beyond the study setting because the study is very different from real life (Ref. 6). The grocery-shopping simulation software program may more closely mimic consumers' real-life shopping experiences compared to the regular Web-based application and would therefore be expected to elicit survey responses similar to real-life food shopping. One study comparing simulated shopping with actual behavior concluded that consumers' simulated purchase behaviors are highly predictive of their actual behavior (Ref. 7). If proposed Study 1 and Study 2 results are comparable, this will lend support to the external validity of online experimental study results. 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 studies 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 survey 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 studies are part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the studies 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 studies will neither be used to develop population estimates nor be directly used to inform policy.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of Responses per respondent	Total annual responses	Average burden per response	Total hours
Study 1 Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Study 2 Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Study 1 Cognitive interview	9	1	9	1 hour (60 minutes)	9
Study 2 Cognitive interview	9	1	9	1 hour (60 minutes)	9
Study 1 Pretest invitation	1,600	1	1,600	0.033 (2 minutes)	53
Study 2 Pretest invitation	800	1	800	0.033 (2 minutes)	26
Study 1 Pretest	200	1	200	0.25 (15 minutes)	50
Study 2 Pretest	100	1	100	0.25 (15 minutes)	25
Study 1 Survey invitation	32,000	1	32,000	0.033 (2 minutes)	1,056
Study 2 Survey invitation	8,000	1	8,000	0.033 (2 minutes)	264
Study 1 Survey	4,000	1	4,000	0.25 (15 minutes)	1,000
Study 2 Survey	1,000	1	1,000	0.25 (15 minutes)	250
Total					2,754

[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 (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (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/LabelingNutrition/LabelClaims/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, 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.
6. Campbell, D.T. and J.C. Stanley, ''Experimental and Quasi-Experimental Designs for Research,'' Chicago: Rand McNally. 1966.
7. Sharpe, KM., R. Staelin, and J. Huber, ''Using Extremeness Aversion to Fight Obesity: Policy Implications of Context Dependent Demand,'' *Journal of Consumer Research,* 35:406–422, 2008.

Dated: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0849]

Draft Guidance for Industry on Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials.'' The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidal ideation and behavior in clinical trials of drug and biological products, including drugs for psychiatric and nonpsychiatric indications. This guidance revises and replaces a previous draft guidance