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.

[FR Doc. 2012–19991 Filed 8–14–12; 8:45 am]

BILLING CODE 4160–01–P

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

entitled ''Suicidality: Prospective Assessment of Occurrence in Clinical Trials'' issued in September 2010.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 15, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT: Thomas Laughren, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4114, Silver Spring, MD 20993–0002, 301–796–2260.

SUPPLEMENTARY INFORMATION:

I. Background

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. Specifically, this guidance addresses FDA's current thinking regarding the importance of suicidal ideation and behavior assessment in psychiatric and nonpsychiatric drug trials and the general principles for how best to accomplish this assessment during drug development.

Prospective assessment of suicidal ideation and behavior involves actively querying patients about the occurrence of suicidal thinking and behavior, rather than relying on patients to report such occurrences spontaneously, followed by retrospective classification of events into appropriate categories. This guidance recommends a specific suicidal ideation and behavior assessment instrument that can be used to conduct such prospective assessments and offers guidance on the use of alternative instruments.

This guidance is intended to serve as a focus for continued discussions among FDA, pharmaceutical sponsors, the academic community, and the public. This guidance does not address the complex analytic issues involved in the analysis of the suicidal ideation and behavior data that will be derived from prospective assessments of suicidal ideation and behavior; these issues will be addressed in separate guidances.

This guidance is a revision of the draft guidance for industry entitled ''Suicidality: Prospective Assessment of Occurrence in Clinical Trials'' issued September 9, 2010 (75 FR 54889). Comments we received on the draft guidance have been considered and the guidance has been revised. The revision: (1) Replaces the term ''suicidality'' with the terms ''suicidal ideation and behavior''; (2) provides an expanded set of the Columbia Classification Algorithm for Suicide Assessment (C–CASA) categories, along with definitions and explanations; (3) revises the advice on which trials and patients would need assessments of suicidal ideation and behavior and the timing of such assessments; (4) addresses concerns about the time burden of assessments; (5) addresses questions about the possible value of the assessments providing protection for patients in the trials themselves; (6) makes it clear that use of an assessment instrument that directly classifies relevant thoughts and behaviors into C–CASA categories eliminates the need for any additional coding; (7) provides multiple additional references; and (8) revises advice on evaluation of alternative instruments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on prospective assessment of occurrence of suicidal ideation and behavior in clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19993 Filed 8–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0585]

Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories; 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 ''Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories.'' The draft guidance identifies additional food categories to be included in food facility registrations as determined appropriate by FDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 14, 2012.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Compliance, Division of Field Programs