public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 2, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–21688 Filed 9–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–D–2241]**

### Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.'' The draft guidance, when finalized, will describe the type and quality of evidence that we recommend that infant formula manufacturers and distributors have to substantiate structure/function claims in infant formula labels and labeling. This draft guidance is intended to help infant formula manufacturers making structure/function claims comply with the statutory requirement that all claims in infant formula labeling must be truthful and not misleading under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 8, 2016.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2016–D–2241 for ''Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:**

*With regard to this draft guidance:* Gillian Robert-Baldo, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1451.

*With regard to the information collection issues:* 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:**

## I. Background

We are announcing the availability of a draft guidance for industry entitled ''Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.'' We are issuing this draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current

thinking on substantiation of structure/function claims in infant formula labels and labeling. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance, when finalized, will describe the type and quality of evidence we recommend that infant formula manufacturers and distributors have in their records to substantiate their structure/function claims in the labeling of infant formulas. It will describe what we believe to be competent and reliable scientific evidence to substantiate structure/function claims in the context of infant formulas.

**II. Paperwork Reduction Act of 1995**

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). ''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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, we invite 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 collected; and (4) ways to minimize the burden of the information collected on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Recommended Recordkeeping to Substantiate Structure/Function Claims Made in Infant Formula Labels and Labeling (OMB Control Number 0910—NEW).

*Description of respondents:* This new collection of information would be performed by infant formula manufacturers and distributors. The records recommended, to the extent practicable, in this draft guidance would include one-time and annual information collection burdens pertaining to substantiation of structure/function claims made by infant formula manufacturers and distributors. In addition, we have estimated the information collection burden for any future structure/function claims that would involve controlled studies to generate data to support those structure/function claims.

The draft guidance document for industry entitled ''Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling'' addresses only structure/function claims in infant formula labeling. It describes the type and quality of evidence we recommend infant formula manufacturers and distributors have to substantiate their structure/function claims in labeling of both nonexempt and exempt infant formulas under section 403(a) of the FD&C Act (21 U.S.C. 343(a)(1)).

*Analysis of Burden Estimates Resulting From Substantiation for Infant Formula Structure/Function Claims:* Infant formula manufacturers and distributors would only collect information to substantiate their product's structure/function claim if they choose to place a structure/function claim on their product's label or labeling. Gathering evidence on a currently existing claim is estimated to be a one-time burden; the respondents would collect the substantiating information for their product pursuant to section 403(a) of the FD&C Act. We recommend that infant formula manufacturers and distributors accurately maintain the substantiating materials for these claims in their files. We estimate that infant formula manufacturers and distributors would seek substantiation for their claims in intervention studies and the scientific literature and that this burden will likely be comparable to the time needed to assemble information for a new infant formula submission (16 hours). In addition, we estimate, based on information available to FDA, that there are currently 10 existing structure/function claims for which infant formula manufacturers would gather substantiation data. Therefore, the total one-time estimated burden imposed by this collection of information would be 160 hours (16 estimated information collection hours × 10 estimated existing structure/function claims), as shown in table 1.

We have estimated the annual information collection burdens for maintenance of records related to substantiation of existing structure/function claims. We estimate that respondents would spend 1 hour annually maintaining records for each of the 10 estimated currently existing structure/function claims. Therefore, 1 hour × 10 claims = 10 annual hours, as presented in table 1.

It is possible that an infant formula manufacturer or distributor would want to make a structure/function claim for which there is equivocal or insufficient evidence or no substantiating evidence. In this case, we estimate that an infant formula manufacturer or distributor would conduct a controlled study in order to gather data to substantiate the structure/function claim. It is not possible to know the frequency with which this may occur; however, we assume that an infant formula manufacturer or distributor would engage in a controlled study only if the benefits to the infant formula manufacturer or distributor were larger than the costs of performing the study. To account for the possibility that infant formula manufacturers or distributors would choose to conduct a controlled study for the purpose of generating data to substantiate a new structure/function claim, in table 2 we estimate an information collection burden based on one hypothetical annual controlled study. The burdens of this hypothetical controlled study are based on averages taken from three sample controlled studies (Refs. 1, 2, and 3) and estimates an average test subject size of 153 infants.

We estimate that a hypothetical controlled study would involve, on average, four recordkeepers: A principal investigator (*e.g.,* a physician), a sample collector, one nurse or other health care professional with similar experience, and a microbiological laboratory technologist. We estimate that the principal investigator would work, on average, 3 hours annually to assemble and interpret the data collected per study period. We estimate that one sample collector would work an average of 38.25 hours annually (153 infants × 0.25 hours per infant = 38.25 hours) to collect and record stool samples from infants. We estimate that one nurse or other health care professional with similar experience would work an average of 38.25 hours annually (153 infants × 0.25 hours per infant = 38.25 hours) to complete questionnaires on the samples collected from the infants in the study. We estimate that a

microbiological laboratory technologist would work an average of 76.5 hours annually (153 infants × 0.5 hours per infant = 76.5 hours) to prepare and analyze fecal samples taken from infants in the controlled study. All estimates are shown in table 2. Therefore, a total of 156 additional annual burden hours (3 + 38.25 + 38.25 + 76.5 = 156) are estimated to account for the information collection burden resulting from the need to conduct a controlled study in order to gather data to substantiate a new structure/function claim, or a structure/function claim that lacks sufficient prior evidence, for a total of 166 total annual hours (156 + 10 = 166) for the upkeep and generation of information used to substantiate structure/function claims. Including the one-time burden of 160 hours annualized over 3 years (160/3 = 53.3), the total annual record keeping burden is 219.3 hours (166 + 53.3 = 219.3). There are no estimated capital costs or operating and maintenance costs associated with this information collection.

TABLE 1—ESTIMATED ONE-TIME HOURLY RECORDKEEPING BURDEN

| Recordkeeping activity | Number of respondents | First year frequency of recordkeeping | Total records | Hours per record | Total hours |
|---|---|---|---|---|---|
| **First Year Hourly Burden** | | | | | |
| Assembling Records Related to Substantiation of Existing Structure/Function Claims | 10 | 1 | 10 | 16 | 160 |
| Total First Year Only Recordkeeping Burden | | | | | *160 |

TABLE 2—RECORDKEEPING BURDEN

| Recordkeeping activity | Number of respondents | Annual frequency of recordkeeping | Total records | Hours per record | Total hours |
|---|---|---|---|---|---|
| **Recurring Hourly Burden** | | | | | |
| *Annualized Recordkeeping Burden from Table 1 | 10 | 1 | 5.3 | 1 | 53.3 |
| Maintaining Records Related to Substantiation of Structure/Function Claims. | 10 | 1 | 10 | 1 | 10 |
| Controlled Study—Principal Investigator | 1 | 1 | 1 | 3 | 3 |
| Controlled Study—Sample Collector | 1 | 153 | 153 | 0.25 (15 minutes) | 38.25 |
| Controlled Study—Nurse/Heath Care Professional. | 1 | 153 | 153 | 0.25 (15 minutes) | 38.25 |
| Controlled Study—Lab Tech | 1 | 153 | 153 | 0.5 (30 minutes) | 76.5 |
| Total Recordkeeping Burden | | | | | 219.3 |

Before the proposed information collection provisions contained in this draft guidance become effective, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the proposed information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

### III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

### IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.*

1. Moro, G., F. Mosca, V. Miniello, *et al.,* ''Effects of a New Mixture of Prebiotics on Faecal Flora and Stools in Term Infants.'' *Acta Paediatrica,* 2003. Supplement September 1991(441): pp. 77–79.
2. Boehm, G., M. Lidestri, P. Casetta,, *et al.,* ''Supplementation of a Bovine Milk Formula with an Oligosaccharide Mixture Increases Counts of Faecal Bifidobacteria in Preterm Infants.'' *Archives of Disease in Childhood Fetal and Neonatal Edition,* 2002. 86(3): pp. F178–181.
3. Pickering, L.K., D.M. Granoff, J.R. Erickson, *et al.,* ''Modulation of the Immune System by Human Milk and Infant Formula Containing Nucleotides.'' *Pediatrics,* 1998. 101(2): pp. 242–249.

Dated: August 29, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–21725 Filed 9–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Maternal, Infant, and Early Childhood Home Visiting Program Cost Reporting Pilot Study

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from