



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Draft Guidance for Industry; Reopening of the Comment Period.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice, published in the Federal Register of September 9, 2016 (81 FR 62509), announcing the availability of the draft guidance for industry entitled "Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling." We are reopening the comment period in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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." We will review this copy, including the claimed confidential information, in our 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.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 9, 2016 (81 FR 62509), we published a notice announcing the availability of a draft guidance entitled, "Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling." Although you can comment on any guidance at any time, to ensure that we consider comments on this draft guidance before we begin work on the final version, interested persons were originally given until November 8, 2016, to comment on the draft guidance.

Following publication of the September 9, 2016, notice of availability, we received a request for a 90-day extension of the comment period. The request expressed concern that the current 60-day comment period does not allow sufficient time to develop a thoughtful and comprehensive response to the draft guidance. We have considered the request and are reopening the comment period for an additional 90 days, until [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. We believe that this reopening allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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