



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0376]

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the revised draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," that appeared in the Federal Register of August 12, 2016. We are taking this action in response to requests to extend the comment period to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the draft guidance published August 12, 2016 (81 FR 53486). Submit either electronic or written comments by December 12, 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-2011-D-0376 for "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry." 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.

FOR FURTHER INFORMATION CONTACT: Cara Welch, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2333.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 12, 2016, we published a notice announcing the availability of a revised draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues." The revised draft guidance, when finalized, will help industry in evaluating whether to submit a premarket safety notification for a new dietary ingredient (NDI), or for a dietary supplement containing an NDI, and in preparing such premarket safety notifications (also referred to as NDI notifications). section III of the notice (81 FR 53486 at 53489), "Other Issues for Consideration," listed specific issues to be addressed.

The notice provided a 60-day period for the submission of comments pertaining to the revised draft guidance, including in particular (but not limited to) section III. Comments on these issues, the revised draft guidance, and the relevant portions of the 2011 draft guidance, will contribute to our final guidance on new dietary ingredient notifications and related issues. The comment period was scheduled to end on October 11, 2016.

We received requests for 30- and 90-day extensions of the comment period. In general, the requests conveyed concern that the current 60-day comment period does not allow sufficient time for interested parties to develop a meaningful or thoughtful response to the draft guidance. Some requests mentioned that the requests for comment may necessitate indepth research and/or require supporting data to provide meaningful responses.

We considered the requests and are extending the comment period for the draft guidance for 60 days until December 12, 2016. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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