



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2016-D-3401]

Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of availability of a draft guidance entitled "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition" that appeared in the Federal Register of November 23, 2016.

The draft guidance, when finalized, will describe our views on the scientific evidence needed and the approach to evaluating the scientific evidence on the physiological effects of isolated or synthetic non-digestible carbohydrates that are added to foods that are beneficial to human health. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the notice that published in the Federal Register of November 23, 2016 (81 FR 84516). Submit either electronic or written comments by [INSERT DATE 30 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: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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-3401 for "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://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 <https://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 <https://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: Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2579.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 23, 2016 (81 FR 84516), we published a notice announcing the availability of a draft guidance entitled "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition." The draft guidance explains the scientific review approach we plan to use for evaluating scientific evidence submitted to us in citizen petitions to determine whether a particular isolated or synthetic non-digestible carbohydrate that is added to food should be added to our definition of "dietary fiber" that is found in the Nutrition and Supplement Facts label final rule, which appeared in the Federal Register of May 27, 2016 (81 FR 33742). Only those isolated or synthetic non-digestible carbohydrates that meet the definition can be declared as a dietary fiber on a Nutrition and Supplement Facts label. We provided a 60-day comment period that was scheduled to close on January 23, 2017.

Elsewhere in this issue of the Federal Register, we have published a notice to reopen the comment period for a related notice that appeared in the Federal Register of November 23, 2016 (81 FR 84595). We requested scientific data, information and comments in the related November 23, 2016, notice to help us evaluate the potential beneficial physiological effects on human health of 26 specific isolated or synthetic non-digestible carbohydrates that are added to food so that we may determine whether any of them should be added to our definition of dietary fiber in our Nutrition Facts and Supplement Facts label final rule. The November 23, 2016, notice also announced the availability of a document entitled "Science Review of Isolated and Synthetic Non-Digestible Carbohydrates," which summarizes a scientific literature review that we conducted of clinical studies associated with the 26 specific isolated or synthetic non-digestible carbohydrates. The original comment period for this notice closed on January 9, 2017.

We have received requests to extend the comment period for the isolated or synthetic non-digestible carbohydrates draft guidance. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful comments to the draft guidance.

We have considered the requests and are extending the comment period for the draft guidance until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance. The extended comment period deadline [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for the draft guidance also coincides with the reopened comment period for our related request for scientific data, information, and comments for the November 23, 2016, notice.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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