



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Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a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 (21 CFR 10.30)." The draft guidance, when finalized, will describe our views on the scientific evidence needed and the approach to evaluating the scientific evidence on the physiological effects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.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on this document by [INSERT DATE 60 DAYS AFTER DATE OF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-3401 for "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)."

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-830), 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: 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:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. 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.

In the Federal Register of May 27, 2016 (81 FR 33741), we published a final rule amending our Nutrition and Supplement Facts label regulations. The final rule provides a definition of dietary fiber as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health § 101.9(c)(6)(i) (21 CFR 101.9(c)(6)(i)). One mechanism by which a manufacturer could request an amendment to the dietary fiber definition is by using the citizen petition process in § 10.30. If an isolated or synthetic nondigestible carbohydrate meets the dietary fiber definition, then it would be added to the list of dietary fibers in the definition in § 101.9(c)(6)(i).

The draft guidance document represents our current thinking regarding the type of scientific evidence on which we will rely and the scientific evaluation process we plan to use in determining the strength of the evidence for the relationship between an isolated or synthetic non-digestible carbohydrate that is added to food and a physiological effect that is beneficial to human health.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 101.9 have been approved under OMB control number 0910-0813.

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.

Dated: November 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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