



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2019-D-0725]

The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels; 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 final guidance for industry entitled "The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels." The guidance describes FDA's views on the declaration of allulose on Nutrition Facts and Supplement Facts labels and the caloric content of allulose. The guidance also announces our intent to exercise enforcement discretion for the exclusion of allulose from the amount of Total Sugars and Added Sugars declared on the Nutrition Facts and Supplement Facts label and use of a general factor of 0.4 calories per gram (kcal/g) for allulose when calculating declarations on Nutrition and Supplement Facts labels.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time 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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2019-D-0725 for "The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts

Labels." 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 Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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 Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, 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 guidance.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1450.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents 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 April 18, 2019 (84 FR 16272), we published a notice announcing the availability of a draft guidance for industry entitled "The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels." The draft guidance: (1) described our tentative views on the declaration of allulose on Nutrition Facts and Supplement

Facts labels and on the caloric content of allulose; and (2) announced our tentative intent to exercise enforcement discretion for the exclusion of allulose from the amount of Total Sugars and Added Sugars declared on the label and use of a general factor of 0.4 kcal/g for allulose when calculating declarations on Nutrition and Supplement Facts labels pending review of the issues in a rulemaking.

The draft guidance gave interested parties an opportunity to submit comments by June 17, 2019, for us to consider before beginning work on the final version of the guidance. We received approximately 30 comments from industry, health professionals, consumer advocacy groups, scientists, trade associations, and consumers. We are finalizing the positions in the draft guidance and have made technical corrections and editorial changes throughout the guidance to improve clarity. We also added language clarifying that allulose must still be declared in the ingredient statement even if it is excluded from certain label declarations. Finally, we reorganized the section detailing our consideration of allulose as a sugar.

The guidance announced in this notice finalizes the draft guidance with respect to: (1) our views on the declaration of allulose on Nutrition Facts and Supplement Facts labels and on the caloric content of allulose; and (2) our intent to exercise enforcement discretion for the exclusion of allulose from the amount of Total Sugars and Added Sugars declared on the label and use of a general factor of 0.4 kcal/g for allulose when calculating declarations on Nutrition and Supplement Facts labels pending review of the issues in a rulemaking.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910-0381.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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