



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2018-D-0075]

The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products:

Draft Guidance for Industry; Extension of Comment Period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The Food and Drug Administration (FDA or we) is extending the comment period for the notification of availability of a draft guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry" that appeared in the *Federal Register* of March 2, 2018. The draft guidance, when finalized, will advise food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol "†" immediately after the added sugars percent Daily Value information on certain foods. The symbol would lead the reader to truthful and non-misleading statements outside the Nutrition Facts label to provide additional information regarding the added sugars present in particular foods. 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 document that published in the *Federal Register* of March 2, 2018 (83 FR 8953). Submit either electronic or written comments by June 15, 2018.

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): 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-2018-D-0075 for "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: 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 Dockets Management Staff 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 <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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Blakely 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

In the *Federal Register* of March 2, 2018 (83 FR 8953), we published a document announcing the availability of a draft guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry." The draft guidance is intended to advise food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol "†" immediately after the added sugars percent Daily Value information on certain foods. The symbol would lead the reader to truthful and non-misleading statements outside the Nutrition Facts label to provide additional information regarding the added sugars present in particular foods. The draft guidance explains that we intend to consider exercising enforcement discretion for the use of this symbol on single ingredient packages and/or containers of pure honey or pure maple syrup, and certain dried cranberry and cranberry juice products that are sweetened with added sugars, and that

contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars. We provided a 60-day comment period that was scheduled to close on May 1, 2018.

We have received requests to extend the comment period for the draft guidance (Refs. 1 and 2). 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 for 45 additional days, until June 15, 2018. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

II. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. Letter from Margaret Lombard, Chief Executive Officer, National Honey Board, to FDA Dockets Management Staff (April 3, 2018).
2. Letter from Ray Bonenberg, President, International Maple Syrup Institute, to Dr. Scott Gottlieb, Commissioner of Food and Drugs, FDA (April 4, 2018).

Dated: April 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-08603 Filed: 4/24/2018 8:45 am; Publication Date: 4/25/2018]