4164-01-P

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, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products; 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 final guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products." This guidance provides clarification on the labeling requirements for single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups, which are not required to bear the words "Includes Xg Added Sugars," but must still include the percent Daily Value for added sugars on their labels. This guidance is also intended to advise food manufacturers of our intent to exercise enforcement discretion related to the use of a "†" symbol immediately following the percent Daily Value for added sugars on single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups; the "†" symbol would lead the consumer to a statement that is truthful and not misleading in a footnote at the bottom of the Nutrition Facts label. The guidance also advises food manufacturers of our intent to exercise enforcement discretion with respect to the use of a "†" symbol immediately after the added sugars percent Daily Value information that leads the consumer to a statement

that is truthful and not misleading outside of the Nutrition Facts label on certain dried cranberry and cranberry beverage products that are made up of cranberry juice sweetened with added sugars and that contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars. Further, this guidance advises of our intent to exercise enforcement discretion regarding compliance with Nutrition Facts label final rule and Serving Size final rule requirements until July 1, 2021, for the single-ingredient sugars and syrups as well as the cranberry products discussed in the guidance document.

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-2018-D-0075 for "The Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, 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." 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.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.

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, Nutrition Programs Staff, 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, Office of Nutrition and Food Labeling, 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 Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products." 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 alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

This guidance provides clarification on the labeling requirements for single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups, which are not required to bear the words "Includes Xg Added Sugars" but must still include the percent Daily Value for added sugars on their labels. This guidance is also intended to advise food manufacturers of our intent to exercise enforcement discretion related to use of a "†" symbol on single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups immediately following the percent Daily Value for the contribution of added sugars to the diet obtained from these products. This would lead the consumer to a statement that is truthful and not misleading in a footnote at the bottom of the Nutrition Facts label. We also intend to exercise our enforcement discretion with respect to the use of a "†" symbol immediately after the added sugars percent Daily Value information that would lead the

consumer to a statement outside of the Nutrition Facts label on certain dried cranberry and cranberry beverage products that are made up of cranberry juice sweetened with added sugars and that contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars.

In the *Federal Register* of May 27, 2016, FDA issued a final rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (81 FR 33742; the "Nutrition Facts label final rule"). The Nutrition Facts label final rule amended the regulations for the nutrition labeling of conventional foods and dietary supplements to provide updated nutrition information and to improve how the nutrition information is presented to consumers. The Nutrition Facts label final rule also revised the Nutrition Facts label to replace "sugars" with "total sugars" and to include the declaration of added sugars. The Nutrition Facts label final rule defines "added sugars," in part, to include sugars that are either added during the processing of foods or are packaged as such. The definition includes free sugars (free mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. The Nutrition Facts label final rule requires added sugars to be declared on the food label by stating "Includes Xg Added Sugars" indented directly below "Total Sugars," where X represents the amount, in grams, of added sugars (see 21 CFR 101.9(c)(6)(ii)).

On December 20, 2018, the President signed into law the Agriculture Improvement Act of 2018 (Pub. L. 115-334) ("the Farm Bill"). Section 12516 of the Farm Bill states that the food labeling requirements under section 403(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)) shall not require that the Nutrition Facts label of any single-ingredient sugar, honey, agave, or syrup, including maple syrup, that is packaged and offered for sale as a single-

ingredient food bear the declaration "Includes Xg Added Sugars." Therefore, single-ingredient sugars, honey, agave, and syrups, including maple syrup, do not need to have the statement "Includes Xg Added Sugars" on their label. At the same time, the Farm Bill did not change the requirement under the final rule to include the percent Daily Value for the contribution of added sugars to the diet obtained from these products.

In the *Federal Register* of March 2, 2018 (83 FR 8953), we made available a draft guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products" (hereafter referred to as "the draft guidance") and gave interested parties an opportunity to submit comments by May 1, 2018. In response to requests for more time to comment on the draft guidance, we issued a notice in the *Federal Register* of April 25, 2018 (83 FR 17961) extending the comment period to June 15, 2018. We received over 3,600 comments to the draft guidance from industry, consumer advocacy groups, trade associations, members of Congress, State governments, and private citizens.

After consideration of the comments to the draft guidance, as well as Pub. L. 115-334, we have made changes in the final guidance to clarify the requirements for the labeling of added sugars on packages and/or containers of single ingredient honey, maple syrup, and other single ingredient sugars and syrups. The final guidance clarifies that the line representing added sugars on the Nutrition Facts label, as well as the percent Daily Value on that line, are retained for single-ingredient sugars and syrup, however these products do not need to have the statement "Includes Xg Added sugars" on that line. The final guidance also explains our intent to exercise enforcement discretion for all single ingredient sugars and syrups with respect to the inclusion of a "†" symbol after the percent Daily Value, which leads the reader to a truthful and not misleading statement within a footnote at the bottom of the Nutrition Facts label that includes a

description of the gram amount of sugar added to the diet by one serving of the product and its contribution to the percent Daily Value for added sugars in the diet.

We are finalizing the guidance without any changes with respect to our intent to exercise enforcement discretion for the use of a "†" symbol that would direct consumers to truthful and not misleading statements on the package outside the Nutrition Facts label on certain cranberry products sweetened with added sugars that provide an amount of total sugars in a serving that does not exceed the level of total sugars in a serving of a comparable product with no added sugars.

At this time, we are not aware of products, other than the cranberry products discussed in the guidance document, for which the addition of sugars is intended to increase palatability, and for which the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars. Therefore, at this time we do not intend to exercise enforcement discretion with respect to the use of the "†" that would direct consumers to truthful and not misleading statements on the package outside the Nutrition Facts label on products, including dairy products and whole grain products, other than the cranberry products discussed in the guidance document. We specifically note that we do not intend to exercise enforcement discretion with respect to beverages made from açaí berries because it appears that açaí berry beverages are made, at least in part, from açaí berries combined with water. Therefore, we do not consider açaí berry beverages to be a comparable product to other naturally sweet juices. Furthermore, we do not have sufficient evidence to show that sugars are added to açaí berries to increase palatability like the naturally tart fruit described in the 2015-2020 Dietary Guidelines for Americans (available at https://www.dietaryguidelines.gov/current-dietary-guidelines). We note that we would consider whether the same type of enforcement

discretion discussed with respect to certain cranberry products might be warranted for other products for which the addition of sugars is intended to increase palatability, such as naturally tart fruits, and for which the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars.

Further, the final guidance announces our intent to exercise enforcement discretion, until July 1, 2021, regarding the compliance with the Nutritional Facts Label final rule and Serving Size final rule (81 FR 33742 and 81 FR 34000 (May 27, 2016)) requirements for single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups, as well as certain dried cranberry and cranberry beverage products. We recognize the importance of giving manufacturers of such products additional time to make appropriate label changes consistent with the Farm Bill and this final guidance. With respect to our enforcement discretion policy pertaining to compliance with updated Nutrition Facts label and serving size requirements, this part of the guidance is being implemented without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

II. Paperwork Reduction Act of 1995

This 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. 3501-3521). The collections of information in 21 CFR part 101 have been approved under OMB control number 0910-0813.

III. 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: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-12983 Filed: 6/18/2019 11:15 am; Publication Date: 6/20/2019]