lists as explained in 21 CFR 10.115(f)(5). FDA has established Docket No. FDA–2012–N–1021 where comments on the FY 2021 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted and shared with the public (see **ADDRESSES**). FDA believes this docket is a valuable tool for receiving information from interested persons. FDA anticipates that feedback from interested persons will allow CDRH to better prioritize and more efficiently draft guidances to meet the needs of the Agency and our stakeholders.

In addition to posting the lists of prioritized device guidance documents, CDRH has identified as a priority, and has devoted resources to, finalization of draft guidance documents. To assure the timely completion or reissuance of draft guidances, in FY 2015 CDRH committed to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH committed to finalize, withdraw, reopen the comment period, or issue new draft guidance on the topic for 80 percent of the documents within 3 years of the close of the comment period and for the remaining 20 percent, within 5 years. As part of MDUFA IV commitments, FDA reaffirmed this commitment, as resources permit.

Fulfillment of these commitments will be reflected through the issuance of updated guidance on existing topics, withdrawal of guidances that no longer reflect FDA's current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

II. CDRH Guidance Development Initiatives

A. Metrics for FY 2020 A-List and B-List Publication

Stakeholder feedback on guidance priorities is important to ensure that the CDRH guidance program meets the needs of stakeholders. The feedback received on the FY 2020 list was mostly in agreement, and CDRH continued to work toward issuing the guidances on this list. Some guidances requested for inclusion in the FY2020 list by stakeholders have been included as part of the FY 2021 list. In FY 2020, CDRH published 14 of 27 guidances on the FY 2020 list (12 from the A-list, 2 from the B-list). In addition, FDA is committed to providing timely guidance to support response efforts to the Coronavirus Disease 2019 (COVID–19) pandemic. As such, FDA has shifted resources to issue 23 guidances and 11 guidance revisions in FY 2020.

B. Finalization of Draft Guidance Documents

Of the 23 draft guidances issued in FY 2015, CDRH finalized 91 percent within 3 years of the comment period close and 91 percent within 5 years. In addition, in FY 2020, two draft guidances issued prior to October 1, 2014, remain for which no action has been taken yet, and CDRH has been continuing to work towards taking an action on these remaining draft guidances.

Looking forward, in FY 2021, CDRH will strive to finalize, withdraw, or reopen the comment period for 50 percent of existing draft guidances issued prior to October 1, 2015.

C. Applicability of Previously Issued Final Guidance

At the website where CDRH has posted the ''A-list'' and ''B-list'' for FY 2021, CDRH has also posted a list of final guidance documents that issued in 2011, 2001, 1991, and 1981 for our annual review of previously issued final guidances. CDRH is interested in external feedback on whether any of these final guidances should be revised or withdrawn. In addition, for guidances that are recommended for revision, information explaining the need for revision, such as the impact and risk to public health associated with not revising the guidance, would also be helpful as the Center considers potential action with respect to these guidances. CDRH will consider the comments received from this retrospective review when determining priorities for updating guidance documents and will revise these as resources permit.

Consistent with the Good Guidance Practices regulation at 21 CFR 10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting feedback on the list of previously issued final guidances located in the annual agenda website, feedback on any guidance is appreciated and will be considered.

In FY 2020, CDRH received comments regarding guidances issued in 2010, 2000, 1990, and 1980 and has withdrawn 52 guidance documents in response to comments received and because these guidance documents were determined to no longer represent the Agency's current thinking. The revision of several guidance documents is also being considered as resources permit.

III. Website Location of Guidance Lists

This notice announces the website location of the document that provides the A- and B-lists of guidance documents, which CDRH is intending to publish during FY 2021. To access these two lists, visit FDA's website at *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidance-development.* We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (*e.g.,* newly identified safety issues). The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

Dated: October 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23104 Filed 10–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1359]

Sugars that Are Metabolized Differently Than Traditional Sugars

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or we) is establishing a docket and invites information about and comments on the nutrition labeling of sugars that are metabolized differently than traditional sugars. We are taking this action to inform our regulatory approach to these distinctly metabolized sugars to promote the public health and help consumers make informed dietary decisions.

DATES: Submit either electronic or written comments on the notice by December 18, 2020.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. Electronic comments must be submitted on or before December 18, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 18, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2020–N–1359 for ''Sugars that are Metabolized Differently than Traditional Sugars.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Office of Nutrition and Food Labeling, 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 general, under section 403(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)) (FD&C Act), a food is deemed misbranded unless its label or labeling bears nutrition information for certain nutrients. To implement section 403(q) of the FD&C Act, we have issued regulations related to:

- The declaration of nutrients on food labeling, including nutrients that are required or permitted to be declared and the format for such declaration;
- Daily Values (DVs) for nutrients, which are used to declare nutrient contents as percent DVs (%DVs) on the Nutrition Facts label; and
- Exemptions for certain specified products.

These regulations are at § 101.9 (21 CFR 101.9). Additionally, section 403(q)(2)(A) of the FD&C Act provides discretion to the Secretary of Health and Human Services, and, by delegation, to FDA, to determine whether providing nutrition information regarding a nutrient will assist consumers in maintaining healthy dietary practices.

In the **Federal Register** of May 27, 2016 (81 FR 33742), we issued a final rule titled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (''Nutrition Facts final rule''). The Nutrition Facts final rule revised the Nutrition Facts label to reflect new scientific information by, among other things: (1) Requiring the declaration of the gram amount of ''Added Sugars'' in a serving of a product, establishing a Daily Reference Value (DRV), and requiring the %DV declaration for ''Added Sugars'' and (2) changing ''Sugars'' to ''Total Sugars'' and requiring that ''Includes 'X'g Added Sugars'' be indented and declared directly below ''Total Sugars'' on the label. We discussed our rationale for the required declaration of ''Added Sugars'' in the preamble to both the Nutrition Facts final rule (81 FR 33742 at 33799 through 33801) and the proposed rule in the **Federal Register** of March 3, 2014 (79 FR 11880 at 11902 through 11905), and explained our establishment of a DRV of 10 percent of total energy intake from ''Added Sugars'' and requirement of a %DV for ''Added Sugars'' in the preamble to the supplemental proposed rule in the **Federal Register** of July 27, 2015 (80 FR 44303 at 44307 through 44309).[1]

In the Nutrition Facts final rule, we confirmed that our definition of ''Total Sugars'' remains the same as the previously existing definition of ''Sugars'' at § 101.9(c)(6)(ii)—

[1] We also recognize that with the requirement for the mandatory declaration of added sugars on the label, there is an interest in the use of nutrient content claims that convey to consumers information about the amount of sugars or added sugars in a product. In the Nutrition Facts final rule, we said that we plan to revisit our nutrient content claims regulations as appropriate and as time and resources permit (81 FR 33742 at 33751). We intend to address nutrient content claims related to sugars and added sugars at a later date.

specifically, as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). We defined ''Added Sugars,'' in part, as sugars that are either added during the processing of foods or are packaged as such. We codified this definition in our regulations at § 101.9(c)(6)(iii).

In determining which sugars should be included in the definition of ''Added Sugars'' in the Nutrition Facts final rule, we considered the presence of added sugars as a component of dietary intake and whether it was consistent with the concept of ''empty calories'' (81 FR 33742 at 33835). (The Scientific Report of the 2015 Dietary Guidelines Advisory Committee noted that sugars that are added to foods either by the consumer or by food manufacturers are referred to as ''empty calories'' because they provide calories, but few or no nutrients. See United States Department of Agriculture and HHS, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 2015, Part D. ''Chapter 1: Food and Nutrient Intakes, and Health: Current Status and Trends,'' pg. 69, available at *https://health.gov/dietaryguidelines/2015-scientific-report/pdfs/scientific-report-of-the-2015-dietary-guidelines-advisory-committee.pdf*.) We noted, in the preamble to the Nutrition Facts final rule, that it would be extremely difficult for individuals consuming large amounts of empty calories from sugar-sweetened foods and beverages to be able to consume enough other components of a healthy dietary pattern (81 FR 33742 at 33807). In part because of this, current dietary recommendations include limiting the consumption of added sugars in the diet, which we explained in the preamble to the supplemental proposed rule (80 FR 44303 at 44308).

We are aware that some members of the food industry are looking for ways to reformulate products to reduce the sugar content of foods while still providing products that meet consumer preferences. The use of sugars that provide fewer calories, that are not associated with dental caries, and that result in a lower glycemic and insulinemic response than other sugars could be one way for industry to provide products that meet both current dietary recommendations and consumer preferences.

There are several sugars that are not metabolized by the body like other substances that are traditionally known as sugars. The sugars that many consumers are most familiar with (''traditional sugars''), such as sucrose, are associated with an increased risk of dental caries, have 4 calories per gram, and cause an increase in blood glucose and insulin levels after consumption. Some sugars (*e.g.,* allulose, D-tagatose, isomaltulose) do not have all of the same effects in the body as traditional sugars. Because of that, we have received multiple requests from industry to treat these sugars that are metabolized differently than traditional sugars as distinct from traditional sugars for purposes of nutrition labeling. For example, some asked that we exempt certain sugars from inclusion as a carbohydrate, sugar, or added sugar on the Nutrition Facts label for foods and beverages (see, *e.g.,* Citizen Petition Submitted by Tate & Lyle Ingredients Americas LLC requesting that Allulose be Exempt From Being Included As a Carbohydrate, Sugar, or Added Sugar in the Nutrition Facts Label on Foods and Beverages, April 10, 2015, Docket Number FDA–2015–P–1201); some asked that we use a lower general factor for the caloric value of certain sugars (see, *e.g.,* Citizen Petition Submitted by The Food Lawyers Requesting the Use of a General Factor of 0.4 Calories Per Gram of Allulose on the Nutrition Facts Label, July 12, 2016, Docket Number FDA–2016–P–2030); and others asked that we define ''Total Sugars'' as the sum of all free mono- and disaccharides that contain at least one unit of glucose or fructose (see, *e.g.,* Citizen Petition Submitted by Bonumose LLC for Consideration of D-tagatose as Dietary Fiber, November 19, 2018, Docket Number FDA–2018–P–4454).

In the preamble to the Nutrition Facts final rule, we stated that we needed additional time to fully consider certain information provided about one of these sugars that is metabolized differently than traditional sugars—specifically, allulose (81 FR 33742 at 33796). Therefore, we did not reach a decision as to whether allulose should be excluded from the declaration of ''Total Carbohydrate,'' ''Total Sugars,'' or ''Added Sugars.'' We stated that allulose, as a monosaccharide, must be included in the amount of the declaration of ''Total Carbohydrate,'' ''Total Sugars,'' and ''Added Sugars'' pending any future rulemaking that would otherwise consider excluding allulose from the declarations. We also noted that D-tagatose and isomaltulose are chemically sugars. Because these sweeteners are chemically sugars, and other substances are included or excluded from the definition of ''Total Sugars'' and ''Added Sugars'' based on whether they are a free mono- or disaccharide rather than on their physiological effects, including D-tagatose and isomaltulose in the declaration of added sugars is consistent with how we have characterized other sugars. As such, we did not exclude D-tagatose and isomaltulose from the ''Added Sugars'' declaration in the Nutrition Facts final rule (81 FR 33742 at 33837).

In the **Federal Register** of April 18, 2019 (84 FR 16272), we announced the publication of a draft guidance that provided our view on the declaration of allulose on Nutrition and Supplement Facts labels, as well as on the caloric content of allulose. We announce our final guidance elsewhere in this edition of the **Federal Register**. The guidance states 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 the use of a general factor of 0.4 calories per gram (kcal/g) for allulose when determining ''Calories'' on the Nutrition and Supplement Facts labels pending review of the issues in a rulemaking.

We are interested in learning more about the kinds of sugars that are metabolized differently than traditional sugars and that are used in foods, any distinct physiological effects in the body caused by those sugars, and how we should treat those sugars for purposes of food labeling.

II. Request for Comments and Information

We invite comment, particularly scientific data and other evidence, about the following topics:

A. General Information About Sugars That Are Metabolized Differently Than Traditional Sugars

1. We are aware of three sugars that are metabolized differently in the body than traditional sugars: allulose, D-tagatose, and isomaltulose. What other sugars are metabolized differently in the body than traditional sugars? Please provide any studies that examine the chemical properties or physiological effects of these other sugars.

2. What research on consumer awareness or understanding of the differences between sugars that are metabolized differently than traditional sugars and traditional sugars is available? Please provide any data or other information that supports your response.

B. Declaration of Total Sugars

1. We could take one of various approaches to account for sugars that are metabolized differently than traditional sugars in the declaration of ''Total Sugars.'' For example, we could require them to be declared within the

''Total Sugars'' declaration, we could exclude them from the ''Total Sugars'' declaration, or we could adjust the gram amount of the ''Total Sugars'' declaration based on their caloric contribution to the diet. What considerations could inform our approach? Please explain your reasoning, and provide data or other information that would support these considerations and any recommended approach.

2. In the guidance regarding allulose, we discuss factors that we considered when determining whether a sugar should be excluded from the declaration of ''Total Sugars,'' including pH of dental plaque after consumption, caloric value, and glycemic and insulinemic response. What, if any, other factors impact whether a sugar should be excluded from the declaration of ''Total Sugars''? Please provide any data or other information that supports your response.

C. Declaration of Added Sugars

1. We could take one of various approaches to account for sugars that are metabolized differently than traditional sugars in the declaration of ''Added Sugars.'' For example, we could require them to be declared within the ''Added Sugars'' declaration, we could exclude them from the ''Added Sugars'' declaration, or we could adjust the gram amount of the ''Added Sugars'' or the %DV declaration based on their caloric contribution to the diet. What considerations could inform our approach? Please explain your reasoning, and provide data or other information that would support these considerations and any recommended approach.

2. In the guidance regarding allulose, we discuss factors that we considered when determining whether a sugar should be excluded from the declaration of ''Added Sugars,'' including caloric value and glycemic and insulinemic response. What other factors, if any, impact whether a sugar should be excluded from the declaration of ''Added Sugars''? Please provide any data or other information that supports your response.

3. We might adjust the %DV for ''Added Sugars'' for the U.S. population 4 years of age and older based on the caloric contribution of the sugar. For example:

Assume a product contains 5 g of sucrose and 10 g of another sugar with a caloric value of 2 kcal/g per serving.

Step 1. Calculate the Total Caloric Contribution of Sugars (amount of sucrose (g/serving) × caloric value (kcal/g)) + (amount of other sugar (g/serving) × caloric value (kcal/g))

a. Sucrose: 5 g/serving × 4 kcal/g (caloric value of sucrose) = 20 kcal/serving

b. Other sugar: 10 g/serving × 2 kcal/g (caloric value of other sugar) = 20 kcal/serving

c. Total Caloric Contribution = 20 kcal/serving (sucrose) + 20 kcal/serving (other sugar) = 40 kcal/serving

Step 2. Calculate Total Amount of Sugars Adjusted for the Total Caloric Contribution (Total Caloric Contribution of Sugars (kcal/serving) ÷ 4 kcal/g))

Amount of Sugars Adjusted for Caloric Contribution = 40 kcal/serving ÷ 4 kcal/g = 10 g-equivalent/serving

Step 3. Calculate %DV for Added Sugars (Amount of Sugars Adjusted for Caloric Contribution (g-equivalent) ÷ 50 g/day (DV for Added Sugars for the general U.S. population 4 years of age and older) × 100))

%DV = (10 g-equivalent ÷ 50 g/day) × 100 = 20%

What considerations are there with respect to adjusting the %DV declaration based on the caloric contribution of the sugar?

D. Label Declarations

1. We currently require the disclosure of sugar alcohols and sugars that are metabolized differently than traditional sugars in the ingredient statement in accordance with § 101.4(a), but also allow for the voluntary declaration of sugar alcohols on the Nutrition Facts label (§ 101.9(c)(6)(iv)). Please provide any data or other information that we could consider when determining whether we should allow for the voluntary declaration on the Nutrition Facts label of sugars that are metabolized differently than traditional sugars.

2. Sugar alcohols fall into a separate category of labeling and are excluded from the ''Total Sugars'' and ''Added Sugars'' declarations. Please provide any data or other information that we could consider when determining whether sugars that are metabolized differently than traditional sugars should be combined with sugar alcohols into one declaration within the Nutrition Facts label.

3. If sugars that are metabolized differently than traditional sugars are excluded from the ''Total Sugars'' and ''Added Sugars'' declarations and are combined with sugar alcohols in a separate labeling category within the Nutrition Facts label, what names would be scientifically appropriate for such a category? Please provide any data or other information that supports your recommendation.

Dated: October 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22900 Filed 10–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute