4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2011-F-0172]

Menu Labeling: Supplemental Guidance for Industry (Edition 2); Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Menu Labeling: Supplemental Guidance for Industry (Edition 2)." The draft guidance, when finalized, will update the existing guidance to add new questions and answers to address voluntary declaration of added sugars and voluntary declaration of nutrition information for menus on third-party platforms.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-2011-F-0172 for "Menu Labeling: Supplemental 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, 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 draft 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 draft guidance.

FOR FURTHER INFORMATION CONTACT: Sonia Hudson, Office of Nutrition and Food Labeling (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2731; or Holli Kubicki,

Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of December 1, 2014 (79 FR 71156), we published a final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments to implement the menu labeling provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)) ("Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments"). The menu labeling requirements are codified at § 101.11 (21 CFR 101.11). Before these requirements, consumers could find nutrition information on most packaged foods; however, this labeling was not generally and consistently available in restaurants and similar retail food establishments that serve ready-to-eat, prepared food. Providing calorie and other nutrition information for ready-to-eat prepared foods in restaurants and similar retail food establishments enables consumers to make informed and healthful dietary choices.

In the *Federal Register* of May 5, 2018 (83 FR 20731), we announced the availability of a final guidance entitled "Menu Labeling: Supplemental Guidance for Industry" that addresses stakeholder questions regarding the implementation of nutrition labeling requirements for foods sold in covered establishments and includes examples of alternatives to aid in compliance. A "covered establishment" is a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that voluntarily registers with FDA to be covered by the Federal menu labeling requirements (§ 101.11(a); see 21 U.S.C. 343(q)(5)(H)(i)).

We are announcing the availability of a draft guidance for industry entitled "Menu Labeling: Supplemental Guidance for Industry (Edition 2)." The draft guidance is a revision to

the guidance issued in May 2018. We are including two new questions and answers regarding voluntarily declaring added sugars as part of additional written nutrition information and voluntarily providing nutrition information consistent with the menu labeling requirements through third-party platforms. The guidance, if finalized, will support further alignment of menu labeling with our Nutrition Facts label regulation at 21 CFR 101.9, because we recommend that covered establishments voluntarily include the declaration of "added sugars" as part of the additional written nutrition information under § 101.11(b)(2)(ii)(A). Additionally, with the popularity of using third-party platforms, such as third-party online ordering websites and delivery applications to order food for pickup and delivery from chain restaurants and similar retail food establishments, we recommend the voluntary disclosure of calorie information for standard menu items to help consumers make informed and healthful decisions when ordering their meals online using a third-party platform.

On November 6-8, 2023, FDA hosted a virtual public meeting and listening session to explore what Federal Agencies, communities, and private industry are doing to encourage the reduced consumption of added sugars. Issuing this draft guidance is one important step that FDA can take to make progress towards this goal.

FDA is issuing the draft guidance to receive comments on the new questions and answers, and, as appropriate, will move the questions and answers to the final guidance document, after reviewing comments and incorporating any changes to the questions and answers. For ease of reference, a question retains the same number when it moves from the draft guidance to the final guidance.

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.

II. Paperwork Reduction Act of 1995

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the *Federal Register* for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice of the proposed collection of information in a future issue of the *Federal Register*.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in § 101.11 have been approved under OMB control number 0910-0782.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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