Menu Labeling: Supplemental Guidance for Industry (Edition 2)

Draft Guidance

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Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comment on the draft guidance within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2011-F-0172 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2372.

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

1. Introduction

This guidance document addresses stakeholder questions regarding the implementation of nutrition labeling required for foods sold in covered establishments,² including examples of alternatives to aid in compliance. We are proposing to update this guidance document to include new questions and answers regarding voluntarily declaring added sugars as part of the additional written nutrition information for standard menu items provided to a customer upon request and voluntarily providing nutrition information consistent with the menu labeling requirements through third-party platforms.

This is a revision of the first edition of the guidance document entitled, "Menu Labeling: Supplemental Guidance for Industry." FDA is adding new Questions and Answers 5.8 and 7.5 to this guidance in response to frequently asked questions regarding the menu labeling requirements. Specifically, to support further alignment with the final rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels," we address the voluntary declaration of "added sugars" as part of the additional written nutrition information under 21 CFR 101.11(b)(2)(ii)(A). Additionally, we discuss the voluntary use of the menu labeling requirements to help consumers make informed and healthful decisions when ordering their meals online using a third-party platform. FDA expects to continue to issue subsequent editions of this guidance document, as appropriate, by revising existing questions and answers and by adding new questions and answers.

FDA's guidance documents, including this guidance, do not establish legally enforceable

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² 21 CFR 101.11(a) defines "covered establishment" as 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. See generally 21 U.S.C. 343(q)(5)(H)(i).

responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

2. Background

On December 1, 2014, we published a final rule in the *Federal Register* (79 FR 71156) 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 (FD&C Act). The menu labeling requirements are codified at Title 21 of the Code of Federal Regulations, section 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 helps enable consumers to make informed and healthful dietary choices.

5. Methods for Providing Calorie Disclosure Information

5.8 I am a covered establishment that uses third-party platforms (TPPs), such as third-party online ordering websites and delivery applications. Can I choose to provide nutrition information for standard menu items ordered through a TPP?

Answer: Yes. Calorie labeling on menus for standard menu items can help consumers make informed and healthful decisions about meals and snacks when eating out. We recognize that using TPPs for online food ordering has increased since the menu labeling requirements were finalized, and we encourage covered establishments to provide important nutrition information for the standard menu items offered on a TPP, especially for chains that already provide this information on their own websites and for which this information is readily available. Providing nutrition information for standard menu items on TPPs would help ensure consumers have greater access to information to identify healthier choices.

Covered establishments offering online ordering directly through their websites are subject to our menu labeling requirements, including providing calorie declarations for standard menu items on their online menus (21 CFR 101.11(b)(2)(i)(A)).

7. Determining Nutrient Content for Standard Menu Items

7.5 Added sugars is a required nutrient in the Nutrition Facts label for packaged foods (21 CFR 101.9) but it is not required nutrition information under the menu labeling requirements (21 CFR 101.11(b)(2)(ii)). Can I choose to declare added sugars as part of my additional written nutrition information for standard menu items?

Answer: Yes, you may voluntarily provide the gram amount of added sugars for standard menu items. When we issued the final menu labeling rule in 2014, the additional written nutrition information required for standard menu items was aligned with the nutrition information required in the Nutrition Facts label regulations at that time, except for most vitamins and minerals. However, when we amended the Nutrition Facts label regulations in 2016 to include, in part, "added sugars" as a required nutrient, we did not update the menu labeling regulations at the same time (see 21 CFR 101.9(c)(6)(iii)).

The Dietary Guidelines for Americans recommends limiting calories from added sugars to less than 10 percent of total calories per day. Consuming too much added sugars can make it difficult to meet nutrient needs while staying within calorie limits. Including the amount of added sugars for standard menu items could help consumers meet current dietary recommendations. Therefore, we encourage covered establishments to voluntarily disclose the gram amount of added sugars for standard menu items as part of their written nutrition information to help consumers make more informed dietary choices.