4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

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

Menu Labeling: Supplemental 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 guidance for industry entitled "Menu Labeling: Supplemental Guidance for Industry." The guidance addresses stakeholder concerns regarding the implementation of nutrition labeling required for foods sold in covered establishments, includes expanded and new examples of alternatives to aid in compliance, identifies places where we intend to be more flexible in our approach, and advises of our intent to exercise enforcement discretion regarding nutrient declaration for "calories from fat" as part of the additional written nutrition information. The guidance also includes many graphical depictions to convey our thinking on various topics and to provide examples of options for implementation, and addresses calorie disclosure signage for self-service foods, including buffets and grab-and-go foods; reasonable basis, and the criteria for considering the natural variation of foods, when determining nutrition labeling for such foods; various methods for providing calorie disclosure information, including those for pizza; compliance and enforcement; and criteria for distinguishing between menus and other information presented to the consumer.

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-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.

- 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 (HFS-800), 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: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Menu Labeling: Supplemental Guidance for Industry." 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.

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)). The menu labeling requirements are codified at Title 21 of the Code of Federal Regulations, § 101.11 (21 CFR 101.11).

In the *Federal Register* of May 4, 2017 (82 FR 20825), we published an interim final rule extending the compliance date to May 7, 2018. Our goals are to ensure that consumers are provided with consistent nutrition information they can use to make informed choices for themselves and their families, and to guide industry in clearly understanding the flexible ways in which the requirements can be implemented.

In the *Federal Register* of November 9, 2017 (82 FR 52036), we made available a draft guidance for industry entitled "Menu Labeling: Supplemental Guidance for Industry" and gave interested parties an opportunity to submit comments by January 8, 2018, for us to consider before beginning work on the final version of the guidance. The draft guidance addressed concerns raised by stakeholders regarding the implementation of nutrition labeling required for foods sold in covered establishments. It included expanded and new examples of alternatives to aid in compliance and identified places where we intend to be more flexible in our approach. The draft guidance also included many graphical depictions to convey our thinking on various topics and to provide examples of options for implementation. It addressed calorie disclosure signage for self-service foods, including buffets and grab-and-go foods; reasonable basis, and the

criteria for considering the natural variation of foods; various methods for providing calorie disclosure information, including those for pizza; compliance and enforcement; and criteria for distinguishing between menus and other information presented to the consumer.

We received numerous comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include adding new questions and answers 3.4, 3.5, and 8.3 and Figures 12, 13, 16, 17, and 18. In addition, we made editorial changes to improve clarity in questions and answers 4.1, 5.4, 6.2, 7.1, 8.1, 10.1, and 10.2 and clarified the headings for the graphics in Figures 3 and 14.

In addition, the final guidance announces our intent to exercise enforcement discretion regarding the "calories from fat" nutrient declaration requirement as part of the additional written nutrition information required in § 101.11(b)(2)(ii)(A). As discussed in the final guidance, we are taking this position because the current science supports a view that the type of fat is more relevant with respect to the risk of chronic disease than the overall caloric fat intake, and to align with the final rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (81 FR 33742, May 27, 2016). (Our current thinking on this issue is discussed in the preamble to the final rule titled, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (81 FR 33742 at 33780 through 33781) now codified primarily at 21 CFR 101.9 and 101.36). With respect to our enforcement discretion policy pertaining to "calories from fat" declarations, this part of the guidance is immediately effective because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). The guidance announced in this notice finalizes the draft guidance dated November 2017.

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. 3501-3520). The collections of information in § 101.11(b)(2), (c)(3), and (d) have been approved under OMB control number 0910-0783.

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: May 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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