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]

A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with the Patient Protection Affordable Care Act of 2010); 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 "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with FDA's Food Labeling regulations)." The guidance will help certain restaurants and similar retail food establishments comply with the menu labeling requirements, including the requirements to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. In addition, we note that enforcement of the Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments final rule will commence 1 year after the date on which this document publishes in the Federal Register.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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." The Agency will review this copy, including the claimed confidential information, in its 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., 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: Ashley Rulffes, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry, entitled "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)." 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.

In the Federal Register of September 16, 2015 (80 FR 55564), we announced the availability of a draft guidance for industry entitled "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods--Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)." We invited comment on the draft guidance by November 2, 2015.

We received many comments on the draft guidance and have modified the guidance as appropriate by revising several questions and answers and adding new questions and answers. (The new questions and answers are at 5.5, 5.7, 5.11, 5.17, 5.35, 7.11, and 7.12.) Changes to the guidance include additional examples and explanations to clarify how the provisions of the rule would apply to various situations. The guidance announced in this document finalizes the draft guidance dated September 2015.

II. Enforcement

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016 (Pub. L. 114-113). Section 747 of the Consolidated Appropriations Act states that none of the funds made available under the Consolidated Appropriations Act may be used to implement, administer, or enforce the final rule entitled "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" until 1 year after the date we publish a Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments. As a result, enforcement of the final rule published December 1, 2014 (79 FR 71156), will commence **[INSERT DATE 1 YEAR AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

III. 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(d), (c)(3), and (b)(2) have been approved under OMB control no. 0910-0783.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: April 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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