§ 421.152 Time limits to provide evidence supporting a request for relief.

(a) An applicant has 30 days after the date on which he or she submits a request for relief under § 421.150 to provide us with the evidence required under § 421.151(b)(1) through (3).

(b) An applicant may ask us for more time to submit evidence under paragraph (a) of this section. The request for an extension of time must be in writing and must give the reasons why the applicant cannot give us the required evidence within the 30-day period. If the applicant shows us that he or she had good cause for missing the deadline, we will extend the 30-day period. To determine whether good cause exists, we use the standards explained in § 404.911 of this chapter.

(c) If the applicant does not submit the evidence required under § 421.151 within the 30-day period provided under paragraph (a) of this section, or within the extended period provided under paragraph (b) of this section, we will dismiss the request for relief.

§ 421.155 Burden of proof in requests for relief.

An applicant who requests relief under § 421.150 must prove that he or she is not likely to act in a manner dangerous to public safety and that granting relief from the prohibitions imposed by 18 U.S.C. 922(d)(4) and (g)(4) will not be contrary to the public interest.

§ 421.160 Granting a request for relief.

(a) We may grant an applicant's request for relief if the applicant establishes, to our satisfaction, that the circumstances regarding the disability, and the applicant's record and reputation, are such that the applicant will not be likely to act in a manner dangerous to public safety, and that the granting of the relief would not be contrary to the public interest.

(b) We will not grant an applicant's request for relief if the applicant is prohibited from possessing firearms by the law of the State in which the applicant resides.

§ 421.165 Actions on a request for relief.

(a) After the applicant submits the evidence required under § 421.151 and any other evidence he or she wants us to consider, we will review the evidence, which will include any evidence from our records that we determine is appropriate. A decision maker who was not involved in making the finding that the applicant's benefit payments be made through a representative payee will review the evidence and act on the request for relief. We will notify the applicant in writing of our action regarding the request for relief.

(b) If we deny an applicant's request for relief, we will send the applicant a written notice that explains the reasons for our action. We will also inform the applicant that if he or she is dissatisfied with our action, he or she has 60 days from the date he or she receives the notice of our action to file a petition seeking judicial review in Federal district court.

(c) If we grant an applicant's request for relief, we will send the applicant a written notice that explains the reasons for our action. We will inform the applicant that we will notify the Attorney General, or his or her delegate, that the individual's record should be removed from the NICS database. We will also notify the applicant that he or she is no longer prohibited under 18 U.S.C. 922(g)(4) from purchasing, possessing, receiving, shipping, or transporting firearms or ammunition based on the prohibition that we granted the applicant relief from. We will notify the Attorney General, or his or her delegate, that the applicant's record should be removed from the NICS database after we grant the applicant's request for relief.

(d) The NIAA requires us to process each application for relief not later than 365 days after the date we receive it. If we fail to resolve an application for relief within that period for any reason, including a lack of appropriated funds, we will be deemed to have denied the relief request without cause. In accordance with the NIAA, judicial review of any petition brought under this paragraph shall be de novo.

§ 421.170 Judicial review following a denial of a request for relief.

(a) Judicial review of our action denying an applicant's request for review is available according to the standards contained in 18 U.S.C. 925(c). An individual for whom we have denied an application for relief may file a petition for judicial review with the United States district court for the district in which he or she resides.

(b) If, on judicial review, a Federal court grants an applicant's request for relief, we will notify the Attorney General that the individual's record should be removed from the NICS database.

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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 May 5, 2017.

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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