



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

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

RIN 0910-AG57

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail

Food Establishments; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The final rule appeared in the Federal Register of December 1, 2014, and on May 5, 2016, we stated in the Federal Register that the enforcement of the final rule would begin on May 5, 2017. We are taking this action to clarify and confirm that the compliance date for the final rule is May 5, 2017.

DATES: Effective date: This final rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Compliance date: Covered establishments must comply with the rule published December 1, 2014 (79 FR 71156) by May 5, 2017.

FOR FURTHER INFORMATION CONTACT: Ashley Rulffes, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371, email: ashley.rulffes@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 1, 2014 (79 FR 71156), we published a final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The final rule, which is now codified at § 101.11 (21 CFR 101.11), implements provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)) and:

- Defines terms, including terms that describe criteria for determining whether an establishment is subject to the rule;
- establishes which foods are subject to the nutrition labeling requirements and which foods are not subject to these requirements;
- requires that calories for standard menu items be declared on menus and menu boards that list such foods for sale;
- requires that calories for standard menu items that are self-service or on display be declared on signs adjacent to such foods;
- requires that written nutrition information for standard menu items be available to consumers who ask to see it;
- requires, on menus and menu boards, a succinct statement concerning suggested daily caloric intake (succinct statement), designed to help the public understand the significance of the calorie declarations;
- requires, on menus and menu boards, a statement regarding the availability of the written nutrition information (statement of availability);
- establishes requirements for determination of nutrient content of standard menu items;

- establishes requirements for substantiation of nutrient content determined for standard menu items, including requirements for records that a covered establishment must make available to FDA within a reasonable period of time upon request; and
- establishes terms and conditions under which restaurants and similar retail food establishments not otherwise subject to the rule could elect to be subject to the requirements by registering with FDA.

In the preamble to the final rule (79 FR 71156 at 71239 through 71241), we stated that the rule would be effective on December 1, 2015, and also provided a compliance date of December 1, 2015, for covered establishments. The final rule (at § 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 is voluntarily registered to be covered under § 101.11(d).

II. Extending the Compliance Date

In the Federal Register of July 10, 2015 (80 FR 39675), in response to requests from affected entities, we announced our decision to extend the compliance date for the final rule to December 1, 2016. The final rule requirements are intended to ensure that consumers are provided accurate, clear, and consistent nutrition information for foods sold in covered establishments in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. We stated in that extension that allowing adequate time for covered establishments to fully implement the final rule’s requirements, as described in the requests, would help accomplish the primary objective of the final rule and is in the public interest.

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.

In the Federal Register of May 5, 2016 (81 FR 27067), we announced the availability of the Level 1 guidance document and stated that enforcement of the final rule published December 1, 2014, would commence on May 5, 2017 (81 FR 27067 at 27068). While FDA made clear that we would not begin enforcing menu labeling requirements prior to May 5, 2017, we did not at that time formally make a change to the compliance date through rulemaking.

Therefore, through this final rule, we are clarifying and confirming that the compliance date for the final rule entitled “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” codified at § 101.11, is May 5, 2017.

III. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final

rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule provides more flexibility by further extending the compliance date for the “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” final rule (79 FR 71156) (menu labeling final rule), we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule extends the compliance date of the menu labeling final rule by approximately 5 months: From December 1, 2016, to May 5, 2017. The estimated costs and benefits accrued in any given year that the menu labeling rule is in effect, relative to the first year of compliance, does not change; however, because the compliance date is being extended by 5 months, the discounted value of both total costs and total benefits decreases. The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date by 5 months. The principal cost of this final rule will be the reduction in benefits associated with

extending the compliance date by 5 months. Extending the compliance date of the menu labeling final rule by 5 months reduces the annualized net benefits (discounted at 3 percent) approximately 3 percent, from \$457 million to \$442 million. While average annualized net benefits decrease by \$15 million, they are still positive. We note that this extension of the compliance date will not have an actual effect on the cost or benefits of the menu labeling rule, because, under section 747 of the Consolidated Appropriations Act, 2016, FDA was not authorized to spend funds to “implement, administer, or enforce” the rule until May 5, 2017, a year after the date on which published a Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments. We are presenting the benefits and costs of the menu labeling final rule, which takes effect according to the dates in this rule.

The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

IV. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Reference

The following reference is on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. FDA, "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date," 2015. Available at:
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/>.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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