



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]

RIN 0910-ZA48

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

Food Establishments; Extension of Compliance Date; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; extension of compliance date; request for comments.

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. In the Federal Register of December 30, 2016, we stated that the compliance date for the final rule would be May 5, 2017. We are extending the compliance date to May 7, 2018. We are taking this action to enable us to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration's policies.

DATES: Compliance date: As of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the compliance date for covered establishments set out in the final rule published December 1, 2014 (79 FR 71156), and extended in final rules published on July 10, 2015 (80 FR 39675) and December 30, 2016 (81 FR 96364), is further extended. Covered establishments must comply with the rule published December 1, 2014 (79 FR 71156), by May 7, 2018.

Comment date: Submit either electronic or written comments regarding this compliance date extension, implementation of the December 2014 final rule, and the various topics flagged in the SUPPLEMENTARY INFORMATION section of this document, by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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): 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 “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments.” Received comments, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://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.” 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 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 docket, 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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Felicia B. Billingslea, 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

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. Extension of the Compliance Date and Request for Comments

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.

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016 (Pub. L. 114-113). Section 747 of that law 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 the later of December 1, 2016 or 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). In the Federal Register of December 30, 2016 (81 FR 96364), we confirmed that the compliance date would be May 5, 2017.

This interim final rule extends the compliance date to May 7, 2018. We are taking this action consistent with Executive Orders 13777, 13771, and 13563, as well as in response to the diverse and complex set of stakeholders affected by the rule and continued, numerous, and fundamental questions they raise regarding the final rule and its implementation. The continued, fundamental questions and concerns with the final rule suggest that critical implementation issues, including some related to scope, may not have been fully understood and the agency does not want to proceed if we do not have all of the relevant facts on these matters. Retailers with many different and diverse business models have raised concerns about how the rule lacks flexibility to permit them to provide meaningful nutrition information to consumers given their type of business and different operations. Moreover, we continue to receive many questions about calorie disclosure signage for self-service foods, including buffets and grab-and-go foods. We do not want to proceed with a rule that might turn out to be too inflexible to support innovation in delivering information to consumers. In addition, we have received questions regarding how to distinguish a menu, which requires the posting of calorie information, from advertisements and other marketing pieces, which do not require calorie information. Many of these menu questions are complex and have highlighted for the agency the need for further

consideration and clarification. How to address the natural calorie variations for foods has also been raised by stakeholders as an issue that needs additional guidance and clarity. Finally, some entities with certain business models have stated that they continue to have questions about what provisions of the final rule are applicable to them. We believe questions like this still need to be addressed.

The previous extensions, as well as Congressional concern regarding implementation expressed through letters and appropriations law, are a reflection of the challenge in implementing this rule for a diverse industry of approximately 298,600 covered establishments, organized under 2,130 chains, that we estimated to be covered by the 2014 final rule. Executive Order 13777, “Enforcing the Regulatory Reform Agenda” (82 FR 12285, March 1, 2017), sets forth a policy to alleviate unnecessary regulatory burdens. Given the principles and policies set forth in these executive orders, particularly with respect to reducing burdens, reducing costs, maintaining flexibility, and improving effectiveness, we have decided to extend the compliance date to May 7, 2018. The additional time will allow us to consider what opportunities there may be to address these fundamental and complex questions and reduce the cost and enhance the flexibility of these requirements beyond those reflected in the final rule. Given our decision to reconsider the rule consistent with these Executive Orders, it would not make sense to require establishments covered by our final rule to come into compliance with the rule (for which compliance is not yet required), as well as incur additional ongoing costs to maintain or update compliance, when these requirements may change as a result of our reconsideration of the rule. We solicit comment on the extension of the compliance date.

To assist us in our review, we invite interested parties to submit comments on how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our

regulatory objectives to provide consumers with nutrition information so that they can make informed choices for themselves and their families. In particular, and in light of the issues we have noted above, we are interested in hearing about approaches to reduce the regulatory burden or increase flexibility with respect to:

(1) Calorie disclosure signage for self-service foods, including buffets and grab-and-go foods;

(2) methods for providing calorie disclosure information other than on the menu itself, including how different kinds of retailers might use different methods; and

(3) criteria for distinguishing between menus and other information presented to the consumer.

(See ADDRESSES for instructions on submitting comments.) These questions have been identified by stakeholders as among the fundamental issues that continue to pose significant implementation challenges. As of April 7, 2017, we have received five requests for an extension of the compliance period, which we will add to the docket. In addition, on April 5, 2017, a request to stay the effective date was submitted to FDA (see Docket No. FDA-2017-P-2164); this request is currently under consideration.

To the extent that 5 U.S.C. 553 applies to this extension of the compliance date, the action is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, to the extent that the notice-and-comment and delayed effective date requirements set forth in 5 U.S.C. 553 applies to this action, the implementation of this action without opportunity for public comment, effective immediately upon publication today in the Federal Register, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Given the imminence of the compliance date (May 5, 2017), and the fact that, as

discussed above, a number of regulated establishments continue to raise numerous, complex questions about applicability of the menu labeling requirements and about how to implement them, we have decided that providing an opportunity for public comment would be impracticable and contrary to the public interest. This is because providing immediate notice to covered establishments of the additional time to come into compliance allows for more efficient planning and accounting for implementation of requirements, thus reducing regulatory burden and costs on affected entities. In addition, providing immediate notice that there will be additional time to comply is necessary so that affected entities can avoid incurring immediate costs and efficiently plan and account for implementation of the requirements by the imminent compliance date. Good cause exists to delay the compliance date without comment and effective immediately. In accordance with 21 CFR 10.40(e)(1), however, we note that interested parties may provide comment on the compliance date extension, including whether it should be modified or revoked. In addition, interested parties may submit comments on how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives with respect to providing consumers with nutrition information so that they can make informed choices for themselves and their families. In addition, as we have done throughout this complex rulemaking process, we will continue to work with stakeholders as we go forward.

III. Economic Analysis of Impacts

We have examined the impacts of the interim final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with new regulations shall “be offset by the elimination of existing costs associated with at least two prior regulations.” We have developed an Economic Analysis of Impacts that assesses the impacts of the interim final rule, including cost savings to industry and foregone benefits to consumers. We estimate at least one type of impact in at least one year to be greater than \$100 million. Thus, we believe that this interim final rule is an economically 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 reduces the burden on covered establishments 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, December 1, 2014 (final rule); 80 FR 39675, July 10, 2015 (extending the compliance date to December 1, 2016); 81 FR 96364, December 30, 2016 (clarifying extension of the compliance date to May 5, 2017)), we certify the interim 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 \$148 million, using the most current (2016) Implicit Price Deflator for the Gross

Domestic Product. This interim final rule would not result in an expenditure by industry in any year that meets or exceeds this amount.

This interim final rule extends the compliance date to May 7, 2018, for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and similar retail food establishments. The principal benefit of this interim final rule will be the reduction in costs to covered establishments associated with extending the compliance date by one year. The total annualized benefit (i.e., cost savings) of this interim final rule, using a 3-percent discount rate over 20 years, would be from \$2 to \$6 million; with a 7-percent discount rate, the annualized benefit would be \$3 to \$8 million. The principal cost of this interim final rule will be the reduction in benefits to consumers associated with extending the compliance date by one year. The total annualized cost (i.e., foregone benefits) of this interim final rule, using a 3-percent discount rate over 20 years, would be from \$5 to \$15 million; with a 7-percent discount rate, the annualized cost would be \$6 to \$19 million.

Extending the compliance date of the “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” final rule by one year reduces the annualized net benefits (discounted at 3 percent) approximately 1 percent, from \$506 million to \$501 million. While average annualized net benefits decrease by \$5 million, they are still positive. We recognize that there may be additional costs and benefits to both consumers and covered establishments that we do not have the data to quantify here. We are presenting the estimated benefits and costs of the menu labeling final rule, which takes effect according to the dates in this interim final rule. These quantitative estimates reflect an assumed baseline in which the menu labeling regulation eventually goes fully into effect. If statutory or other changes that are separate from FDA rulemaking were to impact full implementation, the quantitative benefits

estimates would be lower and the quantitative cost estimates higher than shown here. We invite comment on both this Regulatory Impact Analysis and the Regulatory Impact Analysis for the December 2014 final rule.

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

IV. Paperwork Reduction Act

This interim 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 (see ADDRESSES) 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, interim economic impact analysis for “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comment,” April 2017. Available at: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses>.

Dated: May 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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