



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. FDA-2012-N-1210 and FDA-2004-N-0258]

RIN 0910-ZA49

Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods that Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Proposed Extension of Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to extend the compliance dates by approximately 1.5 years for the final rules providing updated nutrition information on the label of food, including dietary supplements; defining a single-serving container; requiring dual-column labeling for certain containers; updating, modifying, and establishing certain reference amounts customarily consumed (RACCs); and amending the label serving size for breath mints. The final rules appeared in the *Federal Register* of May 27, 2016. We are taking this action because, after careful consideration, we have tentatively determined that additional time would help ensure that all manufacturers covered by the final rules have guidance from FDA to address, for example, certain technical questions we received after publication of the final rules, and that they are able to complete and print updated Nutrition Facts

labels for their products before they are expected to be in compliance with the final rules.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on the extension of the compliance period as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 30 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): 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 Nos. FDA-2012-N-1210 and FDA-2004-N-0258 for “Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods that Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Date.” Received comments, those filed in a timely manner (see ADDRESSES), 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.

FOR FURTHER INFORMATION CONTACT: Paula Trumbo, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2579.

SUPPLEMENTARY INFORMATION:

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I. Background

In the *Federal Register* of May 27, 2016 (81 FR 33742 and 81 FR 34000), we published two final rules entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (the Nutrition Facts Label Final Rule) and “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (the Serving Size Final Rule). The Nutrition Facts Label Final Rule revises the Nutrition Facts label by:

- Removing the declaration of “Calories from fat” because current science supports a view that the type of fat is more relevant than overall total fat intake in increased risk of chronic diseases;
- Requiring the declaration of the gram amount of “Added Sugars” in a serving of a product, establishing a Daily Reference Value (DRV), and requiring the percent Daily Value (DV) declaration for added sugars;

- Changing “Sugars” to “Total Sugars” and requiring that “Includes 'X' g Added Sugars” be indented and declared directly below “Total Sugars” on the label;
- Updating the list of vitamins and minerals of public health significance. For example, the Nutrition Facts Label Final Rule requires the declaration of vitamin D and potassium and permits, rather than requires, the declaration of vitamins A and C;
- Updating certain reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplement Facts labels;
- Revising the format of the Nutrition Facts and Supplement Facts labels to increase the prominence of the term “Calories;”
- Removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets; and
- Requiring the maintenance of records to support the declarations of certain nutrients under specified circumstances.

The Serving Size Final Rule requires all containers, including containers of products with “large” RACCs (i.e., products with RACCs of at least 100 grams (g) or 100 milliliters (mL)), containing less than 200 percent of the RACC to be labeled as a single-serving container. Except for when certain exceptions apply, the Serving Size Final Rule further requires that containers and units that contain at least 200 percent and up to and including 300 percent of the RACC be labeled with a column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire container, in addition to the required column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (i.e., the serving size derived from the RACC). The Serving Size Final Rule also

updates, modifies, and establishes RACCs for certain foods and product categories.

II. Description of the Proposed Rule

We are proposing to extend the compliance date for manufacturers with \$10 million or more in annual food sales in the final rules published on May 27, 2016, from July 26, 2018, to January 1, 2020, and the compliance date for manufacturers with less than \$10 million in annual food sales in the final rules published on May 27, 2016, from July 26, 2019, to January 1, 2021.

We emphasize that this proposed rule would only extend the compliance dates. Therefore, comments to this proposed rule should pertain to the extension of the compliance dates only. We are proposing to extend the compliance dates for the Nutrition Facts Label Final Rule and the Serving Size Final Rule, consistent with our authority in sections 403(q) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q) and 371(a), respectively).

III. Proposed Compliance Dates

This proposed rule would extend the compliance date for manufacturers with \$10 million or more in annual food sales in the final rules published on May 27, 2016, from July 26, 2018, to January 1, 2020, and the compliance date for manufacturers with less than \$10 million in annual food sales in the final rules published on May 27, 2016, from July 26, 2019, to January 1, 2021. We are taking this action because, after careful consideration, we have tentatively determined that additional time would help ensure that all manufacturers covered by the rules have guidance from FDA to address, for example, certain technical questions we received after publication of the final rules (see Docket No. FDA-2016-D-4414 (pertaining to a draft guidance entitled “Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and

Minerals: Guidance for Industry”)), and that they are able to complete and print updated Nutrition Facts labels for their products before they are expected to be in compliance with the rules. Companies and trade associations with members covered by the rules have informed us that they have significant concerns about their ability to update all their labels by the compliance dates due to issues regarding (among other things) the need for upgrades to labeling software, the need to obtain nutrition information from suppliers, the number of products that would need new labels, and a limited time for reformulation of products. Consequently, we are proposing to extend the compliance dates to provide more time to comply with the Nutrition Facts Label and the Serving Size Final Rules. We propose extending the compliance date by approximately 1.5 years for both categories of manufacturers as a means to balance the importance of ensuring that industry has sufficient time to comply with complex new requirements, and the importance of decreasing costs, against the importance of minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace.

We are taking this action consistent with Executive Orders 13771 and 13563 and in response to the continued concern that companies and trade associations have shared with us regarding the time needed for implementation of the final rules and the need for FDA to provide further guidance to manufacturers subject to the final rules. Consistent with the policies set forth in these executive orders with respect to reducing burdens, reducing costs, maintaining flexibility, and improving effectiveness, we are therefore proposing to extend the compliance date for manufacturers with \$10 million or more in annual food sales to January 1, 2020, and the compliance date for manufacturers with less than \$10 million in annual food sales to January 1, 2021.

Our goal is to complete this rulemaking as quickly as possible. However, we are aware

that firms are working under the current compliance dates to come into compliance. Pending completion of this rulemaking, we intend to exercise enforcement discretion with respect to the current July 26, 2018, and July 26, 2019, compliance dates.

IV. Economic Analysis of Impacts

We have examined the impacts of this proposed 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 significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an Agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the Agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This proposed rule is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule’s economic analysis.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities when “the agency publishes a general notice of proposed rulemaking” (5 U.S.C. 601(2)). We have analyzed the proposed rule under the Regulatory Flexibility Act and propose to certify that, because the proposed rule only would extend the compliance dates for the Nutrition Facts Label and Serving Size Final Rules, the proposed rule would 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 proposing “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 2016 Implicit Price Deflator for the Gross Domestic Product. We have determined that the proposed rule would not result in any expenditure by industry in any year that meets or exceeds this amount.

The principal benefit of this proposed rule to extend the compliance dates is the reduction in the costs to industry of meeting the compliance dates of the Nutrition Facts Label Final Rule and the Serving Size Final Rule. This reduction in costs can be attributed to a reduction in the relabeling and reformulation costs of the Nutrition Facts Label and Serving Size Final Rules. We estimate that, at the mean, the present value of the benefits (i.e., cost savings) of this proposed rule to extend the compliance dates over the next 20 years is \$1.0 billion using either a 3 percent or 7 percent discount rate (2016\$). This is illustrated in table 1. Extending the compliance dates by approximately 1.5 years would reduce the estimated benefits of the

Nutrition Facts Label and Serving Size Final Rules because it would delay the realization by consumers of the full annual welfare gains of the Nutrition Facts Label and Serving Size Final Rules. More specifically, an extension of the compliance dates would delay the incorporation of the provisions of the Nutrition Facts Label and Serving Size Final Rules by food manufacturers into their products. We estimate that, at the mean, the present value of the forgone benefits of this proposed rule to extend the compliance dates over the next 20 years is \$0.9 billion using either a 3 percent or 7 percent discount rate (2016\$). This is also presented in table 1. We estimate that, at the mean, the present value of the net benefits (that is, cost savings minus forgone benefits) of this proposed rule to extend the compliance dates over the next 20 years is \$0.1 billion using either a 3 percent or 7 percent discount rate (2016\$). This is shown in table 1.

Table 1.--Summary of the Cost Savings to Industry and Foregone Benefits to Consumers of this Proposed Rule to Extend the Compliance Dates (in billions of 2016\$)

	Discount Rate	Cost Savings	Foregone Benefits	Net Benefits (Cost Savings - Foregone Benefits)
Present Value	3%	\$1.0	\$0.9	\$0.1
	7%	\$1.0	\$0.9	\$0.1
Annualized Amount	3%	\$0.07	\$0.06	\$0.01
	7%	\$0.09	\$0.08	\$0.01

Notes: Cost savings to industry, forgone benefits to consumers, and net benefits reflect mean estimates. This proposed rule to extend the compliance dates would extend the compliance dates of the Nutrition Facts Label and Serving Size Final Rules by approximately 1.5 years. Annualized Amount = Amount / Annualizing Factor. 3 percent annualizing factor = 14.88. 7 percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

For purposes of this analysis, we use the same methodology for estimating costs and benefits that we used in the original Regulatory Impact Analysis for the Final Rules. We previously acknowledged potential shortcomings with that approach (see 2016 Regulatory Impact Analysis at 79 n.34) but have not received comments about ways to improve that analysis. We thus follow the same basic approach here.

The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and at

<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses>.

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. Paperwork Reduction Act of 1995

This proposed 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.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 403A of the FD&C Act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: “* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce--(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) * * *.” The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning

the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353, 2364 (1990)). If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

VIII. References

The following reference is on display in the Dockets Management Staff (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 website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. United States Department of Health and Human Services. United States Food and Drug Administration. Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis for Proposed Rule on “Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates.” September 2017. Available from <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses>.

Dated: September 26, 2017.

Anna K. Abram,

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

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