District Office, as appropriate. If sending information directly to the manager of the Boston ACO Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact Maureen Maisttison, Aerospace Engineer, AIR–7B1, FAA, 1200 District Ave, Massachusetts, 01803; phone: 781–238–7076; fax: 781–238–7151; email: *maureen.maisttison@faa.gov.*

(2) Refer to European Aviation Safety Agency AD 2017–0220, dated November 10, 2017, for more information. You may examine the EASA AD in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2018–0281.

(3) For service information identified in this proposed AD, contact Hoffmann Propeller GmbH & Co. KG, Sales and Service, Küpferlingstrasse 9, 83022 Rosenheim, Germany; phone: +49 (0) 8031 1878 0; fax: +49 (0) 8031 1878 78; email: *info@hoffmann-prop.com.* You may view this referenced service information at the FAA, Engine & Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7759.

Issued in Burlington, Massachusetts, on July 6, 2018.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–14862 Filed 7–11–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2011–F–0171]

RIN 0910–AH83

Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) proposes to revise the type size labeling requirements for front of package (FOP) calorie declarations for packaged food sold from glass front vending machines. We are taking this action in response to requests from the vending and packaged foods industries to reduce the regulatory burden and increase flexibility, while continuing to provide calorie declarations for certain articles of food sold from vending machines.

DATES: Submit either electronic or written comments on the proposed rule by September 25, 2018. Please note that late, untimely filed comments will not be considered.

ADDRESSES: You may submit comments as follows:

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 No. FDA–2011–F–0171 for ''Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size.'' 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 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: *http://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: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, *Marjan.Morravej@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of This Proposed Rule

We are proposing to amend our vending machine labeling regulations in 21 CFR part 101 by revising § 101.8(b)(2) (21 CFR 101.8(b)(2)), in order to revise the type size requirement when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from certain vending machines. When using FOP labeling, our existing regulations at § 101.8(b)(2) require that the type size of the calorie declaration for articles of food sold from certain vending machines be at least 50 percent of the size of the largest printed matter on the label. We propose, instead, to require that the type size of the calorie declaration on the front of the package be at least 150 percent (one and one-half times) the size of the net quantity of contents (*i.e.,* net weight) declaration on the package of the vended food. We are proposing this change to reduce regulatory burdens that the vending and packaged foods industries shared with us after the final rule implementing the vending machine labeling requirements (79 FR 71259, December 1, 2014) was issued, while continuing to provide calorie declarations for certain articles of food sold from vending machines. Electronic comments must be submitted on or before September 25, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 25, 2018. 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.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule would revise the type size requirement for calories labeled on the front of the package of vended foods in § 101.8(b)(2). We are proposing that the type size be anchored to the net quantity of contents statement, such that the minimum type size is 150 percent (one and one-half times) the size of the net quantity of contents, instead of being based on the largest printed matter on the label. The proposed rule would only apply when calories are displayed on the front of the package of foods sold in glass front vending machines.

C. Legal Authority

This action is consistent with our authority in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(5)(H)). The FD&C Act, at section 403(q)(5)(H), requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines. In addition, we are issuing this proposed rule consistent with our authority in sections 201(n), 403(a)(1), and 403(f), of the FD&C Act (21 U.S.C. 321(n), 343(a)(1), and 343(f)). Further, we are issuing this proposed rule under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. We discuss our legal authority in greater detail in Section III, ''Legal Authority.''

D. Costs and Benefits

In response to requests from the vending and packaged foods industries to reduce the regulatory burden and increase flexibility, FDA is proposing to revise the existing type size requirements when calories are displayed on the front of the package of foods sold in glass front vending machines. Because this rule only proposes minor revisions to FOP calorie labeling type size requirements, we estimate there are no costs to vending machine operators and potential costs savings to vending machine operators and packaged food manufacturers. We welcome data that would help us to better estimate these impacts.

II. Background

A. Requirements for Calorie Labeling of Articles of Food in Vending Machines and Our Consideration of Front of Package Labeling Issues

Section 403(q)(5)(H) of the FD&C Act requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines. Under section 403(q)(5)(H)(viii) of the FD&C Act, if an article of food is sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts label before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase; and is operated by a person who is engaged in the business of owning or operating 20 or more vending machines, the vending machine operator must ''provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.''

In the **Federal Register** of December 1, 2014 (79 FR 71259), we issued a final rule to implement the vending machine labeling requirements in section 403(q)(5)(H) of the FD&C Act. The final rule, which became effective on December 1, 2016, requires vending machine operators that own or operate 20 or more vending machines (or that voluntarily register with us to be subject to the final rule) to provide calorie declarations for certain articles of food sold from vending machines. The final rule describes which foods are subject to the calorie declaration requirement. The final rule also establishes type size, color, and contrast requirements for calorie declarations in, or on, the vending machines and for calorie declarations on signs adjacent to the vending machines. The final rule also clarifies that vending machine operators do not have to provide calorie information for a food if a prospective purchaser can view certain calorie information on the front of the package, in the Nutrition Facts label on the food, or in a reproduction of the Nutrition Facts label for the food, subject to certain requirements. The calorie declaration requirements covered in the final rule are codified at § 101.8.

In the **Federal Register** of August 1, 2016 (81 FR 50303), we issued a final rule that extended the compliance date for final calorie declaration requirements for certain food products sold from glass-front vending machines to July 26, 2018. The extended compliance date applies only to those products in glass front vending machines that provide FOP calorie disclosures and that comply with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label.

In the preamble of the proposed rule (published in the **Federal Register** of April 6, 2011 (76 FR 19237 at 19244)), we stated that FOP labeling could be a

way to provide ''visible nutrition information,'' as long as the criteria for color, font, and type size are met, and total calories contained in the vended food are included. We also tentatively concluded that the visible nutrition information must be in a type size reasonably related to the most prominent printed matter on the labeling, among other things, such that a purchaser is able to notice and read the information. The preamble to the proposed rule (76 FR 19237 at 19244) explained that we considered ''reasonably related'' to mean a type size at least 50 percent of the size of the largest print on the label. This type size as specified in the preamble to the proposed rule is consistent with interpretations we have used in food labeling guidance when determining the type size of the statement of identity on packaged foods (Ref. 1).

In the preamble to the final rule (79 FR 71259 at 71269), we noted that many comments supported the idea that FOP labeling could provide visible nutrition information; these comments said that FOP labeling is the most efficient way to satisfy section 403(q)(5)(H)(viii) of the FD&C Act. Other comments stated that vending machine operators are likely to prefer food products with FOP labeling because operators selling such food products in their vending machines would not have to provide calorie declarations in compliance with section 403(q)(5)(H)(viii)(I)(bb) of the FD&C Act.

We also discussed several comments that said that interpreting ''reasonably related'' to mean a type size that is at least 50 percent of the size of the largest print on the label would require a type size that is too large. One comment suggested revising the rule to specify a ratio for the size of the FOP calorie disclosure relative to other printed material on the label. The comment stated that ''reasonably related'' would be hard to enforce, and we should require the FOP calorie disclosure to be at least two-thirds the size of the largest type size of any other writing on the package, with a minimum size of one-half square inch. Other comments stated we should omit type size or prominence requirements for the FOP calorie disclosure.

In response to comments to the proposed rule, we revised the rule by removing the words ''reasonably related'' at § 101.8(b)(2) and instead required the calorie labeling print to be ''at least 50 percent of the size of the largest printed matter on the label.'' We also noted that vending machine operators had other options for satisfying section 403(q)(5)(H)(viii) of the FD&C Act, including using a vending machine that provides electronic reproductions of Nutrition Facts labels, as provided in § 101.8(b)(1), or posting signs with calorie declarations, as provided in § 101.8(c).

B. Challenges of Existing Type Size Requirement, and Proposed Change to ''150 Percent of the Size of the Net Quantity of Contents Declaration''

Since the publication of the final rule, several industry representatives indicated that the 50 percent type size requirement for FOP calorie labeling presents significant technical challenges to the packaged foods industry (Refs. 2 and 3). They said it would make the calorie declaration very large on some products and would make label redesign difficult or not practical. They explained that, for glass front vending machines without electronic displays, FOP labeling assures that consumers will get accurate calorie information for vended foods. The industry representatives also said that many packaged food manufacturers who wish to help vending machine operators comply with the regulations by providing packaged foods with FOP labeling will have to redesign their labels at great expense. They noted the existence of several voluntary FOP labeling programs where calorie information is presented in a FOP type size that ranges from 100 to 150 percent of the size of the net quantity of contents statement on the principal display panel. They acknowledged these labeling programs do not meet our type size requirements, and said that complying with the type size requirement for calorie labeling would significantly disrupt their FOP nutrition labeling programs because there would no longer be enough room on the label to accommodate both the voluntary FOP information and our calorie labeling requirement. Thus, they said that the nutrition information beyond calorie labeling that is presently provided under industry FOP programs may no longer be included. Additionally, they said that, while the existing FOP labeling may not be at least 50 percent of the size of the largest printed matter on the label, as required by our rule, the calorie information is nonetheless visible to consumers. Finally, they stated that, in most cases, industry would be able to comply with a rule that linked the FOP type size for calorie labeling if it were no larger than 150 percent of the type size of the net quantity of contents statement. Other industry representatives also have expressed support for using the 150 percent standard for purposes of the FOP type size requirement (Refs. 4–7).

Consequently, the proposed rule would remove the requirement specifying the FOP labeling be at least 50 percent of the size of the largest printed matter on the label and instead link the type size to the size of the net quantity of contents statement. Specifically, the proposed rule would revise § 101.8(b)(2) pertaining to ''articles of food not covered'' to state that the visible nutrition information must be in a type size at least 150 percent of the size of the net quantity of contents declaration on the front of the package.

This revision, if finalized, would allow for greater flexibility for the use of FOP calorie labeling in glass front vending machines, while still ensuring that a FOP calorie declaration would be visible for the consumer, regardless of the size of the package. It also would minimize the need for label changes for foods that currently have voluntary FOP calorie declarations that are 150 percent of the size of the net quantity of content statement provided the calorie declarations meet the other criteria in the final rule. It is our understanding that many packaged food products sold in glass front vending machines that currently bear FOP calorie labeling would meet the 150 percent requirement that we are proposing. However, to more fully understand the current marketplace, we specifically invite comment and data on the percentage of food products commonly sold in glass front vending machines bearing voluntary FOP calorie labeling, and for those products that currently bear voluntary FOP calorie labeling, the type size of the FOP calorie labeling used on the products.

C. Other Approaches

Data and information currently available to FDA indicate that the proposed rule is consistent with some existing voluntary FOP calorie declarations currently used on food product labels and it is feasible for other foods that may be sold in vending machines. We also evaluated two other approaches for providing visible nutrition information that would meet the criteria in section 403(q)(5)(H)(viii) of the FD&C Act, such that the food would not be subject to the vending machine calorie labeling requirements. We invite comment on these two alternative approaches, described more fully below.

1. Alternative Approach A—At Least 100 Percent of the Size of the Net Quantity of Contents Declaration

The first alternative approach would be to require the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration. Our existing food labeling regulations for packaged foods, at 21 CFR 101.7(i), require that the declaration of net quantity be in letters and numerals in a type size that is established in relation to the area of the principal display panel of the package and that the declaration be uniform for all packages of substantially the same size. The regulation prescribes the following size specifications for net quantity declarations:

- Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less;
- Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches;
- Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches; and
- Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than ½ inch in height if the area is more than 400 square inches.

If the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, then the lettering sizes are to be increased by one-sixteenth of an inch.

We considered requiring the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration on the front of the package; in other words, the visible nutrition information would, at a minimum, be the same size as the net quantity of contents declaration. We invite comment on the impact of meeting the visible nutrition information criteria, required under section 403(q)(5)(H)(viii) of the FD&C Act, especially on food in smaller packages, such as small candy bars or single serve bags of nuts, that are sold in glass front vending machines under this alternative approach where the FOP calorie declaration is at least the same size as the net quantity of contents declaration.

FDA invites comment on the advantages and disadvantages of this alternative.

2. Alternative Approach B—Not Specifying Any Size

The second alternative approach would be to not specify any size for the visible nutrition information. This option would give the packaged food industry considerable flexibility in deciding how large—or how small—voluntary FOP calorie labeling could be, and may reduce the need for packaging changes for some manufacturers. We note that in developing the final vending machine labeling rule, we considered, but disagreed with comments asking that we omit requirements for prominence or type size of FOP calorie disclosures. As we discussed in the preamble to that final rule, ''When a vending machine food is in a vending machine, a prospective purchaser cannot handle the product to make it easier for the purchaser to read the nutrition information. Therefore, 'visible nutrition information' on the front of package must be large enough, and prominent enough, for prospective purchasers to see and use the information'' (79 FR 71259 at 71269).

We invite comment on the advantages and disadvantages of this alternative.

III. Legal Authority

We are proposing to revise the labeling requirements for providing calorie declarations for food sold from certain vending machines, as set forth in this proposed rule, consistent with our authority in section 403(q)(5)(H) of the FD&C Act. Under section 403(q)(5)(H), certain vending machine operators must provide calorie declarations for certain articles of food sold from vending machines. Under section 403(a)(1) of the FD&C Act, such information must be truthful and non-misleading. Under section 403(f) of the FD&C Act, any word, statement, or other information required by or under the FD&C Act to appear on the label or labeling of an article of food must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Under section 403(a), (f), or (q) of the FD&C Act, food to which these requirements apply is deemed misbranded if these requirements are not met. In addition, under section 201(n) of the FD&C Act, the labeling of food is misleading if it fails to reveal facts that are material in light of representations made in the labeling or with respect to consequences that may result from use. Thus, we are issuing this proposed rule under sections 201(n), 403(a)(1), 403(f), and 403(q)(5)(H) of the FD&C Act, as well as under section 701(a) of the FD&C Act, which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Description of the Proposed Rule (Proposed § 101.8(b)(2))

The proposed rule would make a change to the existing rule for calorie labeling of food sold from vending machines, in order to reduce the regulatory burden and increase flexibility while continuing to provide calorie declarations for certain articles of food sold from vending machines. We propose to revise § 101.8(b)(2) to remove the requirement that the type size of the visible calorie declaration for articles of food be at least 50 percent of the size of the largest printed matter on the label and, instead, to require the type size to be at least 150 percent (one and one-half times) the size of the net quantity of contents (*i.e.,* net weight) declaration on the package of the vended food. We also would make a minor editorial correction to the same sentence in § 101.8(b)(2), substituting the word ''prospective'' in place of ''perspective.''

We also would revise the first sentence of § 101.8(b)(2) by inserting a comma after the word ''minimum.'' This change corrects a punctuation error.

V. Proposed Effective and Compliance Dates

We are proposing that any final rule resulting from this rulemaking have an effective date of 30 days after the date of its publication in the **Federal Register**. We also are proposing that covered vending machine operators comply with any final rule resulting from this rulemaking by January 1, 2020. We are proposing this compliance date in order to provide sufficient time for the packaged food industry to revise their labels, as appropriate, consistent with any new requirements.

As discussed in section II.A., by July 26, 2018, vending machine operators with glass front vending machines will have to comply with all vending machine requirements of the final rule issued in 2014. However, it is unlikely that we will be able to complete the current rulemaking to revise the type size labeling requirements for FOP calorie declarations before the July 26, 2018 compliance date. Therefore, pending completion of this rulemaking, FDA intends to exercise enforcement discretion with respect to the July 26, 2018 compliance date for products sold in glass front vending machines that provide a FOP calorie disclosure and

the product complies with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label.

Further, as previously noted, vending machine operators with glass front vending machines will have to comply by July 26, 2018, with all vending machine requirements, including complying with calorie disclosure requirements in 21 CFR 101.8(c)(2). Although these requirements cover gums, mints, and roll candy products sold in glass front machines, FDA intends to exercise enforcement discretion, at least until January 1, 2020, with respect to gums, mints, and roll candy products sold in glass front machines in packages that are too small to bear FOP labeling. FDA intends to consider this issue further.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the 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.'' This proposed rule has been designated as a significant regulatory action as defined by Executive Order 12866. This proposed rule is expected to be an Executive Order 13771 deregulatory action. Additional details can be found in the proposed rule's preliminary economic analysis.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The vending machine final rule does not impose burdens to the suppliers of vending machine foods. While suppliers are not obliged to engage in FOP calorie labeling, this proposed rule, if finalized, would allow for greater flexibility for the use of FOP calorie labeling in glass front vending machines than the existing regulations, potentially reducing the burden on covered vending machine operators of providing additional calorie labeling. Thus, we propose to certify that the proposed 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 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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits and Costs of the Proposed Rule

FDA proposes to revise the type size labeling requirements for providing FOP calorie declarations for packaged food sold from certain vending machines. We are taking this action in response to requests from the vending and packaged foods industries to reduce the regulatory burden and increase flexibility. The proposed rule would revise the type size requirements for FOP calorie labeling on packaged foods displayed for sale in glass front vending machines.

There are currently several voluntary FOP labeling programs where calorie information is presented. If finalized, this proposal may provide an increased incentive for packaged food manufacturers to add new or amend current FOP calorie labeling to foods in order to comply with the updated standard. If so, glass front vending machine operators carrying exclusively those products will not have to provide signs with calorie information for the food, providing an opportunity to reduce operator costs. To the extent this occurs, some costs may shift from the vending machine operator to the manufacturer. Packaged food manufacturing firms may choose to incur additional costs associated with amending the FOP label in order to retain revenue streams from current customers, including vending machine operators. If total revenue is greater than total cost, this proposed rule will provide cost savings for packaged food manufacturing firms. We expect the potential cost savings to both vending machine operators and packaged food manufacturers to outweigh the costs to packaged food manufacturers and thus the net effect to be positive, but lack the data to quantify this effect. We welcome data that would help us to better estimate these impacts.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 8) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. 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.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no new collection of information beyond what was described in the December 2014 final rule and approved under OMB control number 0910–0782. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. 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. Federal law includes an express preemption provision that preempts any nutrition labeling requirement of food that is not identical to the requirement of section 403(q) of the FD&C Act, except that this provision does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment elects to comply voluntarily with the nutrition information requirements under section 403(q)(5)(H)(ix) of the FD&C Act. The proposed rule would create requirements for nutrition labeling of food under section 403(q) of the FD&C

Act that would preempt certain non-identical State and local nutrition labeling requirements.

Section 4205 of the Patient Protection and Affordable Care Act (ACA), which amended the FD&C Act to require certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines, also included a Rule of Construction providing that nothing in the amendments made by section 4205 of the ACA shall be construed: (1) To preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the FD&C Act and is expressly preempted under subsection (a)(4) of such section; (2) to apply to 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; or (3) except as provided in section 403(q)(5)(H)(ix) of the FD&C Act, to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of the FD&C Act (see Pub. L. 111–148, section 4205(d) of the ACA, 124 Stat. 119, 576 (2010)).

We interpret the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold from vending machines that must comply with the Federal requirements of section 403(q)(5)(H) of the FD&C Act, unless the State or local requirements are identical to the Federal requirements. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either: (1) From vending machines that are operated by a person engaged in the business of owning or operating 20 or more vending machines subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act; or (2) from vending machines operated by a person not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act who voluntarily elects to be subject to those requirements by registering biannually under section 403(q)(5)(H)(ix) of the FD&C Act.

Otherwise, for food sold from vending machines not subject to the nutrition labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, States and localities may impose nutrition labeling requirements. Under our interpretation of section 4205(d)(1) of the ACA, nutrition labeling for food sold from these vending machines would not be nutrient content disclosures of the type required under section 403(q)(5)(H)(viii) of the FD&C Act and, therefore, would not be preempted. Under this interpretation, States and localities would be able to continue to require nutrition labeling for food sold from vending machines that are exempt from nutrition labeling under section 403(q)(5) of the FD&C Act. This interpretation is consistent with the fact that Congress included vending machine operators in the voluntary registration provision of section 403(q)(5)(H)(ix) of the FD&C Act. There would have been no need to include vending machine operators in the provision that allows opting into the Federal requirements if States and localities could not otherwise require non-identical nutrition labeling for food sold from any vending machines.

In addition, the express preemption provisions of 21 U.S.C. 343–1(a)(4) do 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. This is clear from both the literal language of 21 U.S.C. 343–1(a)(4) with respect to the scope of preemption and from the Rule of Construction at section 4205(d)(2) of the ACA.

X. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are 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. FDA, ''Guidance for Industry: A Food Labeling Guide (4. Name of Food)'', last updated January 2013. Retrieved from *https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf.*
2. Letter from Karin F. R. Moore, Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, dated March 31, 2016.
3. Letter from Karin F. R. Moore, Senior Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, dated June 28, 2016.
4. Letter from Karin F. R. Moore, Senior Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Scott Gottlieb, M.D., Commissioner of Food and Drugs, FDA, dated July 19, 2017.
5. Letter from Jason Eberstein, Director, State & Federal Government Affairs, National Automatic Merchandising Association, to Scott Gottlieb, M.D., Commissioner of Food and Drugs, FDA, dated November 21, 2017.
6. Letter from Brad G. Figel, Vice President, North America Public Affairs, Mars, Inc., to Mick Mulvaney, Director, Office of Management and Budget, dated January 30, 2018.
7. Letter from Elizabeth Avery, President and CEO, SNAC International, to Dockets Management Staff, FDA, dated February 12, 2018.
8. FDA, ''Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Preliminary Small Entity Analysis,'' dated June 2018. Also available at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.8 is amended by revising paragraph (b)(2) to read as follows:

§ 101.8 Vending machines.

* * * * *

(b) * * *

(2) The prospective purchaser can otherwise view visible nutrition information, including, at a minimum, the total number of calories for the article of food as sold at the point of purchase. This visible nutrition information must appear on the food label itself. The visible nutrition information must be clear and conspicuous and able to be easily read on the article of food while in the

vending machine, in a type size at least 150 percent of the size of the net quantity of contents declaration on the front of the package, and with sufficient color and contrasting background to other print on the label to permit the prospective purchaser to clearly distinguish the information.

* * * * *

Dated: July 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14906 Filed 7–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 328

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401

[EPA–HQ–OW–2017–0203; FRL–9980–52–OW]

RIN 2040–AF74

Definition of ''Waters of the United States''—Recodification of Preexisting Rule

AGENCY: Department of Defense, Department of the Army, Corps of Engineers; Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The purpose of this supplemental notice is for the Environmental Protection Agency (EPA) and the Department of the Army (agencies) to clarify, supplement and seek additional comment on an earlier proposal, published on July 27, 2017, to repeal the 2015 Rule Defining Waters of the United States (''2015 Rule''), which amended portions of the Code of Federal Regulations (CFR). As stated in the agencies' July 27, 2017 Notice of Proposed Rulemaking (NPRM), the agencies propose to repeal the 2015 Rule and restore the regulatory text that existed prior to the 2015 Rule, as informed by guidance in effect at that time. If this proposal is finalized, the regulations defining the scope of federal Clean Water Act (CWA) jurisdiction would be those portions of the CFR as they existed before the amendments promulgated in the 2015 Rule. Those preexisting regulatory definitions are the ones that the agencies are currently implementing in light of the agencies' final rule published on February 6, 2018, adding a February 6, 2020 applicability date to the 2015 Rule, as well as judicial decisions preliminarily enjoining and staying the 2015 Rule.

DATES: Comments must be received on or before August 13, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2017–0203, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The agencies may publish any comment received to the public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The agencies will generally not consider comments or comment content located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets.commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Michael McDavit, Office of Water (4504–T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–2428; email address: *CWAwotus@epa.gov;* or Stacey Jensen, Regulatory Community of Practice (CECW–CO–R), U.S. Army Corps of Engineers, 441 G Street NW, Washington, DC 201314; telephone number: (202) 761–6903; email address: *USACE_CWA_Rule@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The agencies propose to repeal the Clean Water Rule: Definition of ''Waters of the United States,'' 80 FR 37054, and recodify the regulatory definitions of ''waters of the United States'' that existed prior to the August 28, 2015 effective date of the 2015 Rule. Those preexisting regulatory definitions are the ones that the agencies are currently implementing in light of the agencies' final rule (83 FR 5200, February 6, 2018), which added a February 6, 2020 applicability date to the 2015 Rule. Judicial decisions currently enjoin the 2015 Rule in 24 States as well. If this proposal is finalized, the agencies would administer the regulations promulgated in 1986 and 1988 in portions of 33 CFR part 328 and 40 CFR parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401, and would continue to interpret the statutory term ''waters of the United States'' to mean the waters covered by those regulations, as the agencies are currently implementing those regulations consistent with Supreme Court decisions and longstanding practice, as informed by applicable guidance documents, training, and experience.

State, tribal, and local governments have well-defined and established relationships with the federal government in implementing CWA programs. Those relationships are not affected by this proposed rule, which would not alter the jurisdiction of the CWA compared to the regulations and practice that the agencies are currently applying. The proposed rule would permanently repeal the 2015 Rule, which amended the longstanding definition of ''waters of the United States'' in portions of 33 CFR part 328 and 40 CFR parts 110, 112, 116, 117, 122, 230, 232, 300, 302, and 401, and restore the regulations as they existed prior to the amendments in the 2015 Rule.[1]

The agencies are issuing this supplemental notice of proposed rulemaking (SNPRM) to clarify, supplement and give interested parties an opportunity to comment on certain important considerations and reasons for the agencies' proposal. The agencies clarify herein the scope of the solicitation of comment and the actions proposed. In response to the July 27, 2017 NPRM, (82 FR 34899), the agencies received numerous comments on the impacts of repealing the 2015 Rule in its entirety. Others commented in favor of retaining the 2015 Rule, either as written or with modifications. Some commenters interpreted the proposal as restricting their opportunity to provide such comments either supporting or opposing repeal of the 2015 Rule. In this SNPRM, the agencies reiterate that this regulatory action is intended to permanently repeal the 2015 Rule in its entirety, and we invite all interested persons to comment on whether the 2015 Rule should be repealed.

[1] While EPA administers most provisions in the CWA, the Department of the Army, Corps of Engineers (Corps) administers the permitting program under section 404. During the 1980s, both agencies adopted substantially similar definitions of ''waters of the United States.'' *See* 51 FR 41206, Nov. 13, 1986, amending 33 CFR 328.3; 53 FR 20764, June 6, 1988, amending 40 CFR 232.2.