

this Web site. Registrants must use this form to ensure that complete information is submitted.

(i) Information should be submitted by email by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by email to menulawregistration@fda.hhs.gov.

(ii) If email is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301-436-2804 or mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, Rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(5) *When to renew the registration.* To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

(e) *Signatures.* Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

(f) *Misbranding.* A standard menu item offered for sale in a covered establishment shall be deemed misbranded under sections 201(n), 403(a), 403(f) and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity with paragraph (b) or (c) of this section.

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-27833 Filed 11-25-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA-2011-F-0171]

RIN 0910-AG56

Food Labeling; Calorie Labeling of Articles of Food in Vending Machines

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: To implement the vending machine food labeling provisions of the

Patient Protection and Affordable Care Act of 2010 (ACA), the Food and Drug Administration (FDA or we) is establishing requirements for providing calorie declarations for food sold from certain vending machines. This final rule will ensure that calorie information is available for certain food sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article, or does not otherwise provide visible nutrition information at the point of purchase. The declaration of accurate and clear calorie information for food sold from vending machines will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. This final rule applies to certain food from vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines. Vending machine operators not subject to the rules may elect to be subject to the Federal requirements by registering with FDA.

DATES:

Effective Date: December 1, 2016.

Compliance Date: Covered vending machine operators must comply with the rule by December 1, 2016. See section III.E for more information on the effective and compliance dates.

Comment Date: Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 31, 2014 (see section V, the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910—New and title "Information Collection Provisions of the final rule on Food Labeling: Calorie Labeling of Articles of Food in Vending Machines." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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Executive Summary

Purpose and Coverage of the Final Rule

To help make calorie information for vending machine foods available to prospective purchasers in a direct, accessible, and consistent manner to enable them to make informed and healthful dietary choices, section 4205 of the ACA and the rule require that vending machine operators who own or operate 20 or more vending machines, or who voluntarily elect to be covered, must provide calorie declarations for those vending machine foods for which the Nutrition Facts label cannot be examined prior to purchase or for which visible nutrition information is not otherwise provided at the point of purchase.

Summary of the Major Provisions of the Final Rule

- The final rule requires vending machine operators who own or operate 20 or more vending machines (or who voluntarily register with FDA to be subject to the final rule) to provide calorie declarations for certain articles of food sold from vending machines.
 - The final rule defines a vending machine operator as a person or entity that controls or directs the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, and is compensated for the control or direction of the function of the vending machine.
 - Through biannual registration, vending machine operators who are not covered by the final rule can voluntarily elect to become subject to it.
 - The final rule describes which foods are subject to the calorie

declaration requirement. Vending machine operators do not have to declare 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 on the food subject to certain requirements, or if the vending machine operator does not own or operate 20 or more vending machines.

- For those foods subject to the calorie declaration requirement, the final rule specifies how the calories must be declared.
- Calorie declarations must be clear and conspicuous and placed prominently, and may be placed on a sign in, on, or adjacent to the vending machine, so long as the sign is in close proximity to the article of food or selection button.
- The final rule 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 establishes requirements for calorie declarations on electronic vending machines, those vending machines with only pictures or names of the food items, and those vending machines with few choices (e.g., popcorn machines).
- The final rule requires vending machine operator contact information to be displayed for enforcement purposes.
- The final rule makes conforming amendments to FDA’s labeling regulations at § 101.9(j) so that a covered vending machine food that is otherwise exempt from nutrition labeling under § 101.9 would not lose such exemption by complying with the calorie declaration requirements of the final rule.

Costs and Benefits

The Affordable Care Act requires nutrition labeling for standard menu items on menus and menu boards for certain restaurants and similar retail food establishments and calorie labeling for food sold from certain vending machines. FDA is issuing two separate final rules (one for menu labeling and one for vending machine labeling) to implement those labeling requirements. For this rule on vending machines alone, the expected annualized costs are \$37.9 million (over 20 years discounted at 7 percent), while the benefits have not been quantified. Taken together, the mean estimated benefits of the labeling requirements (menu labeling and vending machine labeling rules combined) exceed costs by \$477.9 million on an annualized basis (over 20 years discounted at 7 percent; not including net benefits from this final rule on vending machine labeling, which are not quantified).

SUMMARY OF COSTS AND BENEFITS OF MENU LABELING AND VENDING MACHINE RULES (IN MILLIONS) *

	Rate percent)	Benefits	Costs	Net benefits
Total for Labeling (menu and vending rules) over 20 years	3	\$9,221.3	\$1,697.9	\$7,523.4
	7	6,752.8	1,333.9	5,418.9
Annualized for Labeling (menu and vending rules) over 20 years	3	\$601.9	\$110.8	491.1
	7	595.5	117.6	477.9
Total for Vending Machine Labeling over 20 years	3	Not Quantified ..	531.1
	7	Not Quantified ..	401.1
Annualized for Vending Machine Labeling over 20 years	3	Not Quantified ..	34.7
	7	Not Quantified ..	35.4

* Benefits from this vending machine labeling rule are not quantified and therefore not included.

I. Background

The Nutrition Labeling and Education Act of 1990 (NLEA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require, in part, nutrition information for food labeling (section 403(q) (21 U.S.C. 343(q)). Under the NLEA and its implementing regulations (§ 101.9 (21 CFR 101.9)), when a food is in package form, the required nutrition information generally must appear on the label of the food. The regulations require nutrition information to be provided for a food product intended for human consumption and offered for sale unless an exemption applies (§ 101.9(a)). One of these exemptions applied to food products served in a vending machine, provided that the food bore no nutrition claims or other nutrition information in any context on the label or in the labeling or advertising (§ 101.9(j)(2)).

On March 23, 2010, the President signed the ACA (Public Law 111–148) into law. Section 4205 of the ACA amended section 403(q) of the FD&C Act

and section 403A of the FD&C Act (21 U.S.C. 343–1), which governs Federal preemption of State and local food labeling requirements. Section 4205 of the ACA added section 403(q)(5)(H)(viii) to the FD&C Act to require that if an article of food is sold from a vending machine that (1) “does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase;” and (2) “is operated by a person who is engaged in the business of owning or operating 20 or more vending machines,” then 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.”

Under section 403(q)(5)(H)(ix) of the FD&C Act, vending machine operators who are not subject to the new requirements of section

403(q)(5)(H)(viii) of the FD&C Act can register voluntarily with FDA to become subject to the Federal requirements. In the **Federal Register** of July 23, 2010 (75 FR 43182), we published a notice specifying the terms and conditions for implementation of voluntary registration, pending issuance of regulations.

II. Legal Authority

Section 4205 of the ACA amended section 403(q)(5) of the FD&C Act, in part, by adding a new paragraph (H) to require certain vending machine operators to 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. 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 (21 U.S.C. 321(n)), 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 final 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 (21 U.S.C. 371(a)), which gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

III. Comments on the Proposed Rule, FDA Responses, and Description of the Final Rule

A. Introduction

In the **Federal Register** of April 6, 2011 (76 FR 19238), we published a proposed rule that would establish requirements for calorie declarations for certain articles of food sold from vending machines to implement section 403(q)(5)(H)(viii) and (q)(5)(H)(ix) of the FD&C Act. We proposed definitions, requirements for calorie labeling for certain food sold from vending machines, and requirements for voluntary registration by a vending machine operator that is not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to elect to be subject to such requirements. We provided a 90-day comment period that ended on July 5, 2011.

We received approximately 250 comments on the proposed rule each containing one or more issues. We received comments from consumers; consumer groups; trade organizations; the vending machine industry; public health organizations; Congress; Federal, State, and local government agencies; and other organizations.

We describe and respond to the comments in sections III.B, C, D, and E of this document. To make it easier to identify comments and our responses, the word “Comment,” in parentheses, will appear before the comment’s description, and the word “Response,” in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not

signify the comment’s value, importance, or the order in which it was received.

B. General Comments

Many comments made general remarks supporting or opposing the rule and did not focus on a particular section of the rule. Other comments addressed FDA’s statutory interpretations and general economic issues. We address the general comments including general comments relating to FDA’s statutory interpretations and general economic issues here.

(Comment 1) The majority of comments supported the proposed rule. Some comments stated that the proposed rule strikes the right balance between making important nutrition information available to consumers and avoiding unnecessary financial burdens on small businesses. Other comments said requiring vending machines to display calorie information is an integral part of a comprehensive approach to addressing obesity by providing consumers with more information to make healthier choices. Some comments supported the proposed rule’s flexibility regarding how covered operators are to declare calories on signs.

In contrast, other comments opposed the proposed rule. Some comments stated that people do not need to be told what to eat. One comment stated that labeling responsibilities should be placed on food manufacturers, rather than vending machine operators, because food manufacturers already have the information and can place it on the food label. One comment asserted that calorie declarations on signs in close proximity to articles of food sold in vending machines or selections buttons are unnecessary because packaged foods already have nutrition information on the labels for such foods.

(Response 1) The final rule does not attempt to tell consumers what they should or should not eat. The final rule requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines on signs in close proximity to such articles of food or selection buttons as required by section 403(q)(5)(H)(viii) of the FD&C Act. The purpose of the final rule is to provide accurate and clear calorie information for vending machine foods to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

As for the comment stating that food manufacturers rather than vending machine operators should be responsible for providing calorie

declarations for vending machine foods, section 403(q)(5)(H)(viii) of the FD&C Act expressly applies to certain vending machine operators. Therefore, we decline to revise the rule to apply the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to food manufacturers.

We note that some packaged foods may already list nutrition information (including calories) on their labels. Such articles of food may be exempt from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act if they satisfy the criteria set forth in § 101.8(b).

(Comment 2) Some comments opposed the proposed rule, stating that the costs and work to implement the proposed requirements would be better spent on other programs. Other comments questioned the value of the calorie declaration requirements and asserted that the proposed rule would increase the cost of packaged foods sold in vending machines. Another comment suggested that the Federal Government provide tax incentives to small businesses to offset costs of implementing the rule.

Other comments questioned whether disclosing calorie information would have the intended benefits. The comments questioned whether vending machine calorie labeling would promote healthier choices and the need to educate consumers about the calorie information. The comments also questioned whether consumers would ignore the calorie information, and whether the calorie information would affect consumer behavior.

(Response 2) With respect to those comments suggesting that Federal funds and labor would be better spent on other matters, section 4205 of the ACA requires us to issue regulations to implement the vending machine labeling requirements, as specified in section 403(q)(5)(H)(viii) of the FD&C Act.

The final rule does not require food manufacturers to change the labeling of packaged foods, nor does it require vending machine manufacturers to change the design of vending machines. Nevertheless, it is possible that some costs associated with compliance with this rulemaking might pass through to consumers. However, any changes to the cost of packaged foods sold in vending machines are likely to be very small, because the estimated costs of compliance would be very small relative to overall sales from vending machines. The final rule is directed at certain vending machine operators, and we discuss the final rule’s economic impact and its impact on small businesses in a

full Regulatory Impact Analysis for the final rule (Ref. 1) which is available at <http://www.regulations.gov> (enter Docket No. FDA–2011–F–0171).

As for the comments suggesting tax incentives for small businesses, we recognize that nearly 97 percent of the covered vending machine operators are small businesses, and have provided flexibility in the final rule to reduce the burden on small businesses. Specifically, we have changed the final rule's effective date from 1 year to 2 years, and are allowing covered vending machine operators to choose the method for determining calorie content of the food and the materials through which the calories are declared, including less expensive means such as stickers or signs. We believe this additional flexibility will help minimize burdens on and costs for small businesses in complying with the requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

With respect to the comments questioning the rule's potential benefits, we note that section 4205 of the ACA requires FDA to implement the calorie labeling requirements for vending machines in section 403(q)(5)(H)(viii) of the FD&C Act. Further, the declaration of accurate and clear calorie information for food sold from vending machines will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

(Comment 3) The vending machine labeling requirements in section 403(q)(5)(H)(viii) of the FD&C Act apply to all covered food sold from vending machines operated by a person who is engaged in the business of owning or operating 20 or more vending machines. The preamble to the proposed rule indicates that, as with other vending machine operators, vending machine operators who are blind and operate vending machines through the Vending Facility Program of the Randolph-Sheppard Act of 1936, 20 U.S.C. 107 *et seq.*, would be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act only if they operate 20 or more vending machines that dispense food or if they voluntarily register to be covered (76 FR 19238 at 19240–19241).

Several comments asked that we retain the explanation from the preamble to the proposed rule that section 403(q)(5)(H)(viii) of the FD&C Act does not apply to vending machine operators who are blind and operate vending machines through the Vending Facility Program of the Randolph-Sheppard Act if they operate fewer than 20 machines. The comments expressed

concern that, because State licensing agencies responsible for administering the Randolph-Sheppard Act often own the vending machines, vending machine operators would be subject to the calorie declaration requirements even if they operate fewer than 20 machines.

(Response 3) Section 403(q)(5)(H)(viii) of the FD&C Act applies to all covered food sold from vending machines “operated by a person who is engaged in the business of owning or operating 20 or more vending machines.” Thus, if a vending machine operator under the Vending Facility Program of the Randolph-Sheppard Act does not own or operate 20 or more vending machines, then the food sold from his or her vending machines is outside the scope of the final rule unless the vending machine operator voluntarily registers to be covered by the rule under § 101.8(d).

(Comment 4) One comment asked that we clarify that vending machine operators, rather than food manufacturers, must comply with this final rule.

(Response 4) Section 403(q)(5)(H)(viii) of the FD&C Act makes it clear that the requirements apply to vending machine operators rather than food manufacturers.

Nevertheless, a food manufacturer may provide the number of calories for a vending machine food to a vending machine operator to help the vending machine operator meet the calorie declaration requirements of this rule. In addition, the label for a vending machine food may already include calorie information, which the vending machine operator may use in providing the calorie declarations required by this rule. Further, as food packaging and vending machine technology continue to evolve, food manufacturers, vending machine manufacturers, and vending machine operators may work together to help vending machine operators comply with this rule.

(Comment 5) One comment asked whether dietary supplements and over-the-counter drugs (*e.g.*, cough drops), which are sometimes sold in vending machines, would be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. The comment noted that, in some cases, these products bear calorie information, but the information is within the context of the Drug or Supplement Facts, and not on the front of package (FOP). The comment stated that dietary supplements and over-the-counter drugs should not be considered articles of food and that we should not apply the calorie labeling requirements to these types of items.

(Response 5) Section 201(f) of the FD&C Act defines “food” as: “(1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” Further, section 201(ff) of the FD&C Act explains that dietary supplements are deemed to be foods within the meaning of the FD&C Act except for the purposes of sections 201(g) (definition of “drug”) and 417 (21 U.S.C. 350f) (reportable food registry) of the FD&C Act. The requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply “[i]n the case of an article of food sold from a vending machine” and, therefore, apply to dietary supplements, but do not apply to drugs, including over-the-counter drugs.

(Comment 6) Some comments requested that foods in small packages whose total surface area available to bear labeling is less than 12 square inches, *e.g.*, gum and mints, be exempted from the rule; these comments said such an exemption would be consistent with the existing exemption from nutrition labeling for foods in small packages (§ 101.9(j)(13)). One comment further reasoned that an exemption for foods sold in small packages would be appropriate because such packaged foods lack sufficient label space to provide FOP calorie information that would be easily readable by the consumer through the vending machine window. The comment also speculated that vending machine operators may no longer choose to sell gums and mints in most vending machines. Some comments also noted that these foods in small packages provide an insignificant calorie contribution to the daily diet and requested that such foods be exempted from this rule. These comments argued that the burden of providing calorie information is not justified for such foods.

Some comments stated that foods exempt from nutrition labeling under § 101.9(j) would lose this exemption if they must bear calorie information on the front of the package. Similarly, other comments asked us to exempt bottled water from this rule because bottled water contains insignificant amounts of nutrients and is generally exempt from the nutrition labeling requirements of § 101.9 under the exemption for packaged foods in § 101.9(j)(4). One comment expressed concern that, if bottled water products must comply with this rule, the bottled water would be required to have a Nutrition Facts Panel even though it may be otherwise exempt from the nutrition labeling requirements. The comment expressed concern that vending machine operators

may stock less bottled water because they would stock products only with nutrition information on the label or FOP labeling so that they would not have to post calorie declarations themselves.

(Response 6) The comments referring to the exemptions are describing § 101.9(j)(4) and (j)(13)(i), which FDA issued to implement section 403(q)(5)(B) and (C) of the FD&C Act before the enactment of the ACA. Section 101.9(j)(13)(i) provides that foods in small packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from the nutrition labeling requirements of § 101.9 provided that the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. In addition, § 101.9(j)(4) provides in relevant part that foods containing insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under § 101.9(c) are exempt from the nutrition labeling requirements of § 101.9 provided that these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. However, these exemptions only apply to the requirements of section 403(q)(1) and (2) of the FD&C Act, and not the vending machine labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

Also, section 403(q)(5)(H)(viii) of the FD&C Act does not include an exemption for vending machine foods based on the package size, amount of nutrients, or caloric content of such foods. Instead, it provides that calorie declarations are not required for food sold from a vending machine: (1) That permits a prospective purchaser to examine the Nutrition Facts Panel before purchasing the food; or (2) that otherwise provides visible nutrition information at the point of purchase. If a vending machine food does not fall into either of these two categories, a covered vending machine operator must provide calorie information for the food.

We note that this final rule requires a covered vending machine operator to post calorie information on a sign in close proximity to a vending machine food or its selection button; it does not require that such calorie information be included on the label of a vending machine food. Further, the final rule provides a number of options for covered vending machine operators to post the required calorie information, including posting such information on a sign adjacent to a vending machine (§ 101.8(c)(2)). As a result, the practical

limitations that may apply to including nutrition information on the labels of foods in small packages do not apply to posting calorie information on signs for vending machine food. For these reasons, we are not exempting vending machine foods that come in small packages (e.g., gum, mints) or vending machine foods that contain insignificant nutrient or caloric content (e.g., bottled water) from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

We are also making changes to clarify that a covered vending machine food that is exempt from nutrition labeling under an exemption provided in § 101.9(j) would not lose such exemption by complying with the final rule's calorie labeling requirements. As noted previously, § 101.9(j) provides exemptions from the requirements of § 101.9, including exemptions that apply to vending machine foods. Section 101.9(j)(2)(ii) provides, in relevant part, that food products which are served in establishments other than restaurants in which food is served for immediate human consumption, including vending machines, are exempt from the nutrition labeling requirements of § 101.9 provided that these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Similarly, § 101.9(j)(4) and (j)(13)(i) provide exemptions from the requirements of § 101.9 provided that the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Because of these provisions, a vending machine food that complies with the final rule's calorie labeling requirements would not qualify for the exemptions from nutrition labeling in § 101.9(j)(2)(ii), (j)(4), and (j)(13)(i) because the labeling for such food would bear nutrition information.

To prevent this outcome, we have amended § 101.9(j) so that a covered vending machine food that is otherwise exempt from nutrition labeling under § 101.9(j) would not lose such exemption by complying with the final rule's calorie labeling requirements. We have amended § 101.9(j)(2)(ii), (j)(4), and (j)(13)(i) to clarify that complying with the vending machine food labeling requirements of § 101.8(c) will not cause a food product meeting the exemption to lose the exemption.

However, we note that providing visible nutrition information on the label of a vending machine food through FOP labeling would constitute a nutrient content claim under section 403(r) of the FD&C Act. Section 101.13 (21 CFR 101.13), which provides general principles for nutrient content claims,

states, in relevant part, that information that is required or permitted by § 101.9 or § 101.36 (21 CFR 101.36), as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not considered to be a nutrient content claim and is not subject to the requirements of this section, unless such information is declared elsewhere on the label or in labeling for the food (§ 101.13(c)). If nutrition information that is required or permitted by § 101.9 or § 101.36, including calorie information, appears some place other than the nutrition label for a food, such as on the front of the food's package, it is a nutrient content claim and is subject to the requirements for nutrient content claims (§ 101.13(c); 136 Cong. Rec. 20369, at 20419 (1990) ("Section 403(r)(1) has been amended to make it clear that the information on the nutrition label is not a claim under that provision and therefore is not subject to the disclosure requirements in section 403(r)(2) . . . but the identical information will be subject to section 403(r)(2) if it is included in a statement in another portion of the label.")). Accordingly, visible nutrition information provided through FOP labeling would be considered a nutrient content claim because it is nutrition information that is "declared elsewhere on the label" for a food. As such, a covered vending machine food that provides visible nutrition information at the point of purchase through FOP labeling would not qualify for the exemptions from nutrition labeling in § 101.9(j)(2)(ii), (j)(4), and (j)(13)(i), and therefore would be subject to the nutrition labeling requirements in § 101.9.

(Comment 7) One comment requested that we require vending machine operators to provide calorie declarations in a special format for visually impaired customers. The comment suggested that this format could be large font, Braille, or audio recordings.

(Response 7) We acknowledge the potential difficulty that visually impaired consumers may confront if the calorie declaration exists only in visual form, and we would not object if vending machine operators wish to develop means, such as large font, Braille, or audio, to help provide calorie declarations to visually impaired consumers, so long as the vending machine operators otherwise satisfy the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. We also would not object if vending machine and food manufacturers and designers decide to consider the needs of visually impaired consumers when manufacturing and designing their

products. However, we are not requiring vending machine operators to provide calorie declarations in a special format for visually impaired consumers at this time.

(Comment 8) A few comments supporting the proposed rule noted that requiring calorie labeling for vending machine foods sold in schools would be beneficial. These comments noted that vending machines typically are located in schools. Some of these comments asked that we require covered vending machine operators to provide separate calorie information for children, or list appropriate “daily calorie ranges or percentages” for children.

(Response 8) We agree that calorie labeling for vending machine foods, including vending machine foods sold in schools, would be beneficial.

Nevertheless, at this time, we decline to require covered vending machine operators to provide separate calorie information for children, or list appropriate “daily calorie ranges or percentages” for children as requested by some of the comments. Section 403(q)(5)(H)(viii) of the FD&C Act requires covered vending machine operators to provide a sign “disclosing the number of calories contained in the [covered vending machine food].” The number of calories contained in an article of food does not differ based on the population targeted or served by a vending machine.

Vending machine operators may voluntarily provide additional information that puts the calorie declaration for a covered vending machine food in the context of a total daily diet, provided that such information is truthful and not misleading. However, we decline to require such additional information in the final rule because we are only establishing regulations for the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, and certain related provisions of section 403 of the FD&C Act, as described in section II, at this time.

(Comment 9) Some comments addressed issues unrelated to the proposed rule’s specific calorie labeling requirements for covered vending machine food. These comments addressed color-coded package labeling, labeling genetically engineered foods, and labeling or highlighting other ingredients or nutrients (such as *trans* fat).

(Response 9) This rulemaking is intended to implement the vending machine calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act. Thus, the issues raised by the

comments are beyond the scope of this rulemaking.

(Comment 10) Some comments stated that FDA should not require covered vending machine operators to provide FOP calorie labeling or calorie declarations on signs in languages other than English, even if the label on the article of food is bilingual, but should allow the food manufacturer or distributor to voluntarily provide FOP calorie labeling or calorie declarations in a second language. One comment asked us to confirm that “Cal” is an acceptable abbreviation for “Calories” in both French and Spanish.

(Response 10) We are not requiring covered vending machine operators to provide calorie declarations for covered vending machine food in languages other than English, even if the label on the article of food is bilingual. FDA regulations at § 101.15(c)(1) (21 CFR 101.15(c)(1)) require that all words, statements, and other information required by the FD&C Act to appear on the label or labeling of food must appear in English, except that for foods distributed solely in Puerto Rico or other territories where the predominant language is not English, the predominant language may be substituted for English. Therefore, the calorie declarations provided by the covered vending machine operator, whether through the Nutrition Facts label or other visible nutrition information at the point of purchase (e.g., FOP labeling) in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act or through a sign in close proximity to each article of food or the selection button in accordance with section 403(q)(5)(H)(viii) of the FD&C Act, must appear in English, unless the foods are distributed solely in Puerto Rico or other territories where the predominant language is not English, as provided in § 101.15(c)(1). In that context, we would consider “Cal” to be an acceptable abbreviation for “Calories” in French and Spanish.

C. Comments on Specific Provisions and Description of the Final Rule

Many comments addressed specific provisions in the proposed rule or related topics.

1. Section 11.1(h)—Electronic Signatures

Proposed § 11.1(h) would explain that part 11 (21 CFR part 11) regarding electronic signatures does not apply to electronic signatures obtained under the voluntary registration provision for vending machine operators at proposed § 101.8(d).

We received no comments on this provision and have finalized it without change.

2. Section 101.8(a)—Definitions

a. *Use of statutory definitions.* Proposed § 101.8(a) would define various terms. It also would explain that the definitions of terms in section 201 of the FD&C Act apply to such terms when used in proposed § 101.8. We received no comments regarding the use of statutory definitions in section 201 of the FD&C Act for the purposes of § 101.8, and we have finalized the sentence referring to the use of statutory definitions in § 101.8(a) without change.

b. *“Authorized Official of a Vending Machine Operator”.* Proposed § 101.8(a) would define “authorized official of a vending machine operator” as the owner, operator, or agent in charge or any other person authorized by the vending machine operator to register the vending machine operator, which is not otherwise subject to the requirements of section 403(q)(5)(H) of the FD&C Act with FDA for purposes of proposed § 101.8(d). (Proposed § 101.8(d) would provide for voluntary calorie labeling for foods sold from vending machines.)

We received no comments regarding the proposed definition. However, on our own initiative, we have revised the definition to make non-substantive grammatical and technical changes (such as changing “the vending machine operator” to “a vending machine operator” and replacing “FDA” with “the Food and Drug Administration”). We also have revised the definition to eliminate potential confusion as to who can be the authorized official of a vending machine operator by deleting an unnecessary conjunction (“or”) in the list of persons who may constitute an authorized official, to specify the provision of the FD&C Act covered by the final rule, and to move a descriptive phrase closer to the noun that it modifies. The final rule now defines an “authorized official of a vending machine operator” as an owner, operator, agent in charge, or any other person authorized by a vending machine operator who is not otherwise subject to section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)(viii)), to register the vending machine operator with the Food and Drug Administration (“FDA”) for purposes of paragraph (d) of the section.

c. *“Vending Machine”.* Proposed § 101.8(a) would define “vending machine” as a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses

servings of food in bulk or in packages, or prepared by the machine, without the necessity of replenishing the device between each vending operation.

(Comment 11) One comment argued that “turret-style” (also referred to as “turnstile”) refrigerated vending machines do not meet the proposed definition of vending machine.

According to the comment, once a food item in a turnstile vending machine is sold, the space that was occupied by the food becomes empty and needs to be restocked. The comment stated that a turnstile refrigerated vending machine, therefore, does not meet the part of the vending machine definition that reads: “. . . without the necessity of replenishing the device between each vending operation.” The comment also stated that the legislative intent of Congress may have been to exclude turnstile refrigerated vending machines, which are normally stocked with sandwiches, milk, burritos, or refrigerated foods because they are not the same as snack vending machines that primarily sell “junk food.”

(Response 11) We disagree with the comment’s assertion that “turret-style” or turnstile vending machines are outside the definition of “vending machine.” The definition uses the word “replenished” in relation to the “device” rather than the precise space the food once occupied. Contrary to the comment’s interpretation, the final rule’s definition of “vending machine” considers whether the machine, as a whole, needs to be restocked after each vending operation and not whether individual space(s) for food are “replenished.”

If we were to accept the comment’s interpretation and focus on the need to restock a specific space for a food after a vending operation, then one could argue that every vending machine would be outside the definition because operators do not necessarily restock each space after every purchase. It is true that, in turnstile vending machines, an empty space is created when a consumer buys an item from a particular space. However, the turnstile vending machine has multiple spaces within a level or tray, and the next consumer can rotate the turret to make another selection. Thus, the vending machine operator does not have to replenish the machine after each vending operation.

Furthermore, the type or nutritional quality of a food carried by the vending machine—whether it is a “meal” or a “snack”—makes no difference under section 403(q)(5)(H)(viii) of the FD&C Act, nor did the proposed rule make such a distinction.

For these reasons, turret-style or turnstile vending machines are “vending machines” as defined by § 101.8(a). We note that the proposed definition used both the words “device” and “machine” interchangeably; for consistency, we have revised the definition of “vending machine” by replacing the term “device” with “machine.”

d. “*Vending Machine Operator*”. Proposed § 101.8(a) would define a “vending machine operator” as a person(s) or entity that controls or directs the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, and is compensated for the control or direction of the function of the vending machine.

We received no comments on the proposed definition and have finalized it without change.

3. Section 101.8(b)—Articles of Food Not Covered

a. *Ability to examine the nutrition facts label*. Proposed § 101.8(b) would describe the circumstances under which articles of food dispensed from a vending machine are not “covered vending machine food” such that the requirements of section 403(q)(5)(H)(viii) of the FD&C Act do not apply. Proposed § 101.8(b)(1) would provide that an article of food dispensed from a vending machine is not “covered vending machine food” if the prospective purchaser “can view the entire Nutrition Facts Panel on the label of the vended food without an obstruction,” and the Nutrition Facts are the information, and are in the format, required in § 101.9(c) and (d), and in a size that “permits the prospective purchaser to be able to easily read the nutrition information contained in the Nutrition Facts Panel on the label of the article of food in the vending machine.” Proposed § 101.8(b)(1) also would provide that we would not consider the smaller formats allowed for Nutrition Facts for certain food labeling under § 101.9 to be a size that a prospective purchaser is able to easily read.

(Comment 12) Most comments supported proposed § 101.8(b)(1). One comment suggested that we give additional details as to how the food would need to be positioned in the vending machine in order to ensure the visibility of the Nutrition Facts Panel.

One comment objected to the proposed requirement that a prospective purchaser be able to view the entire Nutrition Facts Panel without an obstruction and said that would be too

restrictive. The comment conceded that the dispensing coils in a vending machine might partially obscure the Nutrition Facts Panel, but said that each coil is only one-eighth of an inch wide, and virtually the entire Nutrition Facts Panel can be visible and readable in the vending machine making additional calorie disclosure unnecessary.

Another comment stated that we should not stipulate that modified or smaller formats of the Nutrition Facts Panel would not satisfy the requirements of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. The comment said that it is possible that a product manufacturer or vending machine operator could design a clearly visible, readable, and conspicuous Nutrition Facts Panel in a modified or smaller format.

(Response 12) We are revising the rule as suggested by one comment. Section 101.8(b) of the final rule provides, in relevant part, that an article of food sold from a vending machine is not covered if the prospective purchaser can view the calories, serving size, and servings per container listed in the Nutrition Facts label (rather than “the entire” Nutrition Facts label) without any obstruction.

Under section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, if the Nutrition Facts label on a vending machine food can be examined by a prospective purchaser before purchasing the article, a vending machine operator is not required to provide the calorie information required by section 403(q)(5)(H)(viii) of the FD&C Act for such food. (Although section 403(q)(5)(H)(viii) of the FD&C Act uses the term “Nutrition Facts Panel” and we used the same term in the proposed rule, for the purposes of this final rule, we use the term “Nutrition Facts label” instead of “Nutrition Facts Panel” to be consistent with how we generally refer to the nutrition information listed under the heading “Nutrition Facts” on the food label.)

In order for a consumer to examine the Nutrition Facts label to determine the amount of calories contained in the article of food, the consumer must be able to see the calories, serving size, and servings per container listed in the Nutrition Facts label. These pieces of information advance the overarching goal of the rule, which is to provide consumers with the necessary calorie information in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. To conclude that the prospective purchaser must be able to see additional nutrition information on the Nutrition Facts label, beyond the number of calories contained in the article of food,

would mean that even if a prospective purchaser could see the relevant calorie information on the Nutrition Facts label, the vending machine operator would still be required to post a calorie declaration for the food under section 403(q)(5)(H)(viii) of the FD&C Act. Such a conclusion seems to provide a redundant or otherwise unnecessary outcome.

Therefore, we have revised § 101.8(b)(1) to indicate that the prospective purchaser must be able to view “the calories, serving size, and servings per container listed in the Nutrition Facts label” rather than “the entire Nutrition Facts label” itself. These three pieces of information must be visible “without any obstruction.” Regarding the comment suggesting that dispensing coils that are one-eighth of an inch thick should not be considered an obstruction, we disagree. Because there are different types of vending machines, different types of food products dispensed from vending machines, as well as different ways in which the Nutrition Facts label may be presented on a food package, any thickness of a coil could potentially obstruct one of the three required pieces of information.

Regarding the use of smaller formats of the Nutrition Facts label, as we noted in the preamble to the proposed rule (76 FR 19238 at 19243), it is unlikely that a prospective purchaser would be able to easily read the nutrition information prior to purchase, as required by section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. We note that certain small format Nutrition Facts labels can display calories in as small as 6 point type size (see § 101.9(j)(13)(i)), and that the information in such formats is compressed (e.g., linear or “string” format; see § 101.9(j)(13)(ii)(A)(2)). Because such formats are more difficult to read on vending machine foods prior to purchase, we, therefore, decline to consider a modified or smaller format size of the Nutrition Facts to be a size that a prospective purchaser could easily read prior to purchase. The comment did not provide any data or information (e.g., label design) that would suggest that such a format would be readable.

On our own initiative, we have further revised § 101.8(b) to make certain non-substantive and editorial changes. We have replaced the term “dispensed” with “sold” in the first sentence in § 101.8(b) to better reflect the language of section 403(q)(5)(H)(viii) of the FD&C Act. We have moved the words “the prospective purchaser” in the first sentence of § 101.8(b)(1) to precede the colon that introduces

§ 101.8(b)(1) and (b)(2), inserted the words “all the information in,” in the first sentence of § 101.8(b)(1), deleted the words “the information” in the second sentence of § 101.8(b)(1), and replaced “Nutrition Facts Panel” with “Nutrition Facts label” in § 101.8(b)(1). We have also capitalized one instance of “nutrition facts” where it was not capitalized in the proposal and added the word “or” between § 101.8(b)(1) and (b)(2).

(Comment 13) Several comments asserted that any display (e.g., a sign or electronic display) of the Nutrition Facts Panel should exempt the vending machine operator from the calorie declaration requirements. The comments added that a display would not have to be on the package of the vending machine food itself, but could be a reproduction of the Nutrition Facts Panel. Another comment stated that some electronic displays allow the consumer to view the full Nutrition Facts Panel and rotate a virtual image of the product, and that FDA should consider such displays sufficient in satisfying section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act.

(Response 13) We agree with the comments that certain reproductions of a Nutrition Facts label would be sufficient to satisfy section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. Specifically, we conclude that a reproduction of a Nutrition Facts label that allows the prospective purchaser to view the calories, serving size, and servings per container would be sufficient to satisfy section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act if the reproduction is a reproduction of an actual Nutrition Facts label that complies with § 101.9 for a vending machine food, is presented in a size that permits the prospective purchaser to be able to easily read the nutrition information, and the calories, serving size, and servings per container are displayed by the vending machine before the prospective purchaser makes his or her purchase. Such reproductions could include electronic reproductions of the Nutrition Facts label displayed by a vending machine. Therefore, we have revised final § 101.8(b)(1) to allow for such reproductions of Nutrition Facts labels.

b. Visible nutrition information at the point of purchase. Proposed § 101.8(b)(2) would provide that an article of food dispensed from a vending machine is not covered vending machine food if the article provides “visible nutrition information at the point of purchase,” including the total number of calories for the article of food as dispensed.

Proposed § 101.8(b)(2) also would require that the visible nutrition information appear on the food label itself, and that it be “clear and conspicuous and easily read on the article of food while in the vending machine, in a type size reasonably related to the largest printed matter on the label and with sufficient color and contrasting background to other print on the label to permit the prospective purchaser to clearly distinguish the information.”

(Comment 14) Because section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and proposed § 101.8(b)(2) did not define the term “visible nutrition information,” the preamble to the proposed rule provided two possible interpretations for the term “visible nutrition information” (76 FR 19238 at 19244). We noted that one approach would be to conclude that “nutrition information” means “total calories in the article of food.” We noted that an alternative approach would be that “nutrition information” means “something more than total calories” and “could include, in addition to total calories in the food, information such as serving size information or information on the nutrients that are required to be disclosed in the Nutrition Facts” (Id.). The preamble to the proposed rule invited comment on “what other nutrition information, if any, should be required if this alternative interpretation were adopted” (Id.).

Many comments agreed that, in the context of the rule, the term “nutrition information” should mean total calories in the article of food. One comment pointed out that “total calories” is the information that section 403(q)(5)(H)(viii) of the FD&C Act otherwise requires covered vending machine operators to provide on a sign for foods sold in vending machines. Another comment would revise proposed § 101.8(b)(2) to read “The visible nutrition information at the point of purchase may include *only* the total number of calories in the article of food, as dispensed, at the point of purchase” (emphasis added).

Other comments supported the alternative approach, which interprets “nutrition information” as something more than total calories. These comments suggested that, for a vending machine food to be exempt from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, “nutrition information” should mean total calories as well as other information such as serving size information, the amount of other nutrients (e.g., sodium, fat), and the presence of allergens. Another comment

stated that “Congress did not depart from its previous definition of ‘nutrition information’ and as such it is logical to conclude that Congress intended the definition in [section] 343(q)(1) [of the FD&C Act] to apply to [section] 343(q)(5)(H)(viii)(I)(aa) [of the FD&C Act]—i.e., the entire Nutrition Facts Panel or its equivalent be visible.”

(Response 14) As described previously, we noted in the proposed rule that there are two possible ways to interpret “nutrition information” within the meaning of section 403(q)(5)(H)(viii) of the FD&C Act. We noted that “nutrition information” could mean “total calories in the article of food” or “something more than total calories” (76 FR 19238 at 19244). As to any comments suggesting that our proposed interpretation that “nutrition information” means “total calories” is not a permissible interpretation, we conclude, as described in more detail to follow, that this interpretation is permissible in light of the language of section 403(q)(5)(H)(viii) of the FD&C Act and other sections of the FD&C Act.

The comments seem to be raising the question of what Congress intended “nutrition information” to mean within the context of section 403(q)(5)(H)(viii) of the FD&C Act. In construing section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented (“Chevron step one”)? *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984). If the “intent of Congress is clear,” an Agency “must give effect to the unambiguously expressed intent of Congress.” (Id. at 843.) However, if “Congress has not directly addressed the precise question at issue,” and the statute is “silent or ambiguous with respect to the specific issue,” then our interpretation of the term “nutrition information” will be upheld as long as it is based on a “permissible construction” of the statute (“Chevron step two”). *Chevron*, 467 U.S. at 842–43; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. See e.g., *Young v. Community Nutrition Institute*, 476 U.S. 974, 980 (1986).

We have determined that, in enacting section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, Congress did not speak directly and precisely to the meaning of “nutrition information.” In conducting the Chevron step one analysis, all the traditional tools of statutory construction are available, e.g., the statute’s text, structure, and legislative history. *Pharmaceutical Research &*

Manufacturers of America v. Thompson, 251 F.3d 219, 224 (D.C. Cir. 2001). Since the term is not defined in section 403(q)(5)(H)(viii) or elsewhere in the FD&C Act, we have examined the language and design of the FD&C Act as a whole to determine that the meaning of “nutrition information” in section 403(q)(5)(H)(viii) of the FD&C Act is ambiguous. See e.g., *Davis v. Michigan Department of Treasury*, 489 U.S. 803, 809 (1989) (“It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.”); *Martini v. Federal National Mortgage Association*, 178 F.3d 1336, 1345 (D.C. Cir. 1999). While the term “nutrition information” is used in other provisions of the FD&C Act, the term is typically accompanied by specific nutrients identified within the particular provision. For example, section 403(q)(1) of the FD&C Act provides that a food is misbranded unless its label or labeling bears certain nutrition information. Specifically, sections 403(q)(1)(C) to (E) of the FD&C Act identify particular nutrients included within the meaning of “nutrition information” under section 403(q)(1) of the FD&C Act (“A food shall be deemed misbranded . . . unless its label or labeling bears nutrition information that provides . . . the total number of calories . . . [t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein . . . any vitamin, mineral or other nutrient required to be placed on the label and labeling of food under this Act [under certain conditions].”).

Similarly, section 403(q)(5)(H)(ii)(III) of the FD&C Act, which was added to the FD&C Act by section 4205 of the ACA, along with the vending machine food labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act, explicitly requires restaurants and similar retail food establishments to provide “the nutrition information required under clauses (C) and (D) of [section 403(q)(1) of the FD&C Act].” Section 403(q)(5)(H)(viii) of the FD&C Act does not expressly identify nutrients other than the number of calories contained in a vending machine food. Further, as one comment noted, the number of calories contained in a vending machine food is the nutrition information that a vending machine operator must provide on a sign under section 403(q)(5)(H)(viii) of the FD&C Act if the provisions in section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act are not met. Having concluded that the meaning of “nutrition information” in

section 403(q)(5)(H)(viii) of the FD&C Act is ambiguous, FDA has considered how to define the term so as to achieve a “permissible construction” (Chevron step two). *Chevron*, 467 U.S. at 842–43. In conducting the Chevron step two analysis, the same tools of statutory construction are available as those for the step one analysis. Because total calories is the nutrition information that a covered vending machine operator would otherwise have to provide on a sign for a covered vending machine food, we believe that “nutrition information” in the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act means, at a minimum, the number of calories contained in the vending machine food. To conclude that “nutrition information” means more than the total number of calories for an article of food would mean that even if a vending machine operator provided such calorie information on the label of the food, the operator would still be required to post a calorie declaration for the food under section 403(q)(5)(H)(viii) of the FD&C Act. Such a reading seems to provide a redundant or otherwise unnecessary outcome. For these reasons, we conclude that a vending machine that otherwise provides visible nutrition information at the point of purchase for an article of food must provide, at a minimum, the total calories in the vending machine food, in order for the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to not apply to such food. As a result, we have revised § 101.8(b)(2) by inserting “at a minimum” before “the total number of calories” to specify that the label for a vending machine food may provide other nutrition information, including serving size information, in addition to the total number of calories.

In addition, we decline to amend § 101.8(b)(2) to include the phrase “may include only” the total number of calories in the vending machine food because it is not necessary to limit the information to calories. We would not object to food manufacturers or vending machine operators voluntarily providing information in addition to total calories to consumers at the point of purchase, provided that such information is truthful and not misleading and otherwise complies with the FD&C Act and FDA regulations.

On our own initiative, we have made non-substantive and editorial changes to § 101.8(b)(2) to complement the changes we made to § 101.8(b)(1), as described in our response to comment 8. We have revised the first sentence in § 101.8(b)(2) to state that 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. We discuss additional considerations and changes to § 101.8(b)(2) in our response to comments 15 and 16 in the paragraphs that follow.

(Comment 15) Because section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act does not specify how a vending machine can provide “visible nutrition information at the point of purchase” for an article of food in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, the preamble to the proposed rule noted that the phrase “at the point of purchase” suggests that “the information, like the Nutrition Facts Panel, should be on the article of food itself” (76 FR 19238 at 19244). We tentatively concluded that such information must be presented on the label of the food itself (76 FR 19238 at 19244). Under proposed § 101.8(b)(2), for nutrition information on the label to be considered “visible,” it would need, in relevant part, to be clear and conspicuous and easily read on the article of food while in the vending machine. Further, under proposed § 101.8(b)(2) a vending machine food would not be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, as long as the food provides visible nutrition information “at the point of purchase,” and that the visible nutrition information “appear[s] on the food label itself.”

The preamble to the proposed rule also stated that the phrase “at the point of purchase” could be read to mean that the visible nutrition information could be provided in places other than on the package of the food in the vending machine, such as on the vending machine itself (Id.). We invited comment on this alternative interpretation and specifically requested comment on whether, under this alternative interpretation, signs (including posters) or booklets would be sufficient in providing “otherwise visible nutrition information at the point of purchase” (Id.). We also requested comment on ways to determine if the nutrition information is “visible” (Id.).

Several comments asserted that any display (including a brochure, sign, or electronic display) of nutrition information at the point of purchase should exempt the vending machine operator from the calorie declaration requirements. The comments added that a display would not have to be on the package of the vending machine food itself, but could be nutrition information through other means, such as booklets.

One comment recommended that we define “point of purchase” as “before and after the consumer inserts the required money, token, card, or key into the machine or manually operates it and before the consumer makes their final item selection.”

(Response 15) We disagree with the comments asserting that any display of nutrition information beyond the package of the food itself “should exempt the vending machine operator from the calorie declarations requirements.” As we noted in the proposed rule, in order for nutrition information to be “visible” at the point of purchase, the information must be clear and conspicuous and able to be easily read by a prospective purchaser (76 FR 19238 at 19244, 19254). Nutrition information in brochures or booklets would not be visible at the point of purchase in the same way that such information would be visible if presented on the label of a vending machine food, such as through FOP labeling. Nutrition information in a brochure or booklet would not be clear and conspicuous such that a prospective purchaser would be able to easily read the information when making a purchase selection as it would if the nutrition information were on the label of the food. In addition, brochures and booklets can be easily detached, lost, or otherwise absent, from a vending machine. For these reasons, we decline to include brochures and booklets within § 101.8(b)(2).

Regarding electronic displays of nutrition information, we note that proposed § 101.8(c)(2)(ii)(E) would provide that electronic vending machines (*i.e.*, machines with digital or electronic or liquid crystal display (LCD) displays) could be used to comply with the calorie declaration requirements in section 403(q)(5)(H)(viii) of the FD&C Act. As discussed further in section III.C.4.b.x of this preamble in connection with § 101.8(c)(2)(ii)(E), we conclude that electronic vending machines can be used to comply with the calorie declaration requirements in section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(c). Further, electronic signs otherwise placed in, on, or adjacent to the vending machine can be used to provide calorie declarations under § 101.8(c), provided that such signs are located in close proximity to the article of food or the selection button, and otherwise comply with section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and the requirements of § 101.8(c). Because electronic vending machines and signs can be used to provide calorie declarations in

accordance with § 101.8(c), it would be difficult and perhaps unnecessary for FDA to determine whether a vending machine operator is using such a method to provide “visible nutrition information at the point of purchase” in accordance with § 101.8(b) or to provide calorie declarations in accordance with § 101.8(c). For these reasons, we believe that it is unnecessary to include such electronic displays within § 101.8(b)(2).

Similarly, regarding non-electronic signs providing nutrition information, we note that § 101.8(c)(2) allows for the use of signs in, on, or adjacent to a vending machine to provide calorie declarations for covered vending machine food. Therefore, to the extent a vending machine operator provides calorie information for a vending machine food on such a sign and otherwise meets the requirements of section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and § 101.8(c), the operator would be in compliance with this rule. Because such signs can be used to provide calorie declarations in accordance with § 101.8(c), it would be difficult and perhaps unnecessary for FDA to determine whether a vending machine operator is using such a method to provide “visible nutrition information at the point of purchase” in accordance with § 101.8(b) or to provide calorie declarations in accordance with § 101.8(c). For these reasons, we believe that it is also unnecessary to include signs within § 101.8(b)(2).

As explained in the previous paragraphs, brochures, booklets, electronic displays, and non-electronic signs would not satisfy § 101.8(b)(2). Therefore we conclude, as we did in the proposal, that “visible nutrition information at the point of purchase” for an article of food sold from a vending machine must be presented on the label of the food itself.

Regarding the comment that would interpret “point of purchase” as a moment in time, we agree that “point of purchase” can be interpreted both with regard to a place (where the prospective purchaser buys the vending machine food item) and a time (when the prospective purchaser makes the selection). Accordingly, to provide visible nutrition information at the point of purchase, such information must be on the label of a food sold in a vending machine before the prospective purchaser makes a purchase. In order for a prospective purchaser to be able to view nutrition information on the label of a vending machine food at the point of purchase, the prospective purchaser must be able to read the nutrition information before purchasing the food, which typically

means that the vending machine would have to have a clear front so that the prospective purchaser would be able to see the information.

(Comment 16) The preamble to the proposed rule stated that FOP labeling could be a way to provide “visible nutrition information” so long as the criteria for color, font, and type size are met, and the total calories contained in the vending machine food are included (76 FR 19238 at 19244). We tentatively concluded that the visible nutrition information must be in a type size reasonably related to the most prominent printed matter on the label and in a color that sufficiently contrasts with the background, such that a prospective purchaser is able to notice and read the information (Id.). The preamble to the proposed rule explained that we consider “reasonably related” to mean a type size that is “at least 50 percent” of the size of the largest print on the label (Id.). We also noted that if a nutrient content claim or health claim is included on the front of the package, the claim must comply with relevant FDA regulations authorizing such claims (Id.).

Many comments supported the idea that FOP labeling could provide visible nutrition information, stating 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 such labeling would exempt the operators from having to provide calorie declarations for such foods on signs under section 403(q)(5)(H)(viii)(I)(bb) of the FD&C Act. These comments added that vending machine operators may pressure food manufacturers to provide FOP labeling in exchange for product distribution in their vending machines.

Several comments argued 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 would revise 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 for inspectors to enforce and, therefore, FDA should require the FOP calorie disclosure to be at least two-thirds the size of the largest font size of any other writing on the package, and a minimum size of 1/2 square inch. Other comments said that the final rule should omit requirements for prominence or type size of the FOP calorie disclosure.

(Response 16) We agree that FOP labeling can be an efficient way to

provide visible nutrition information within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, provided that the criteria for color and type size are met, and the total calories contained in the article of food are included. (We would not consider FOP labeling that provides only the calories per serving to count as “visible nutrition information” within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act). Some manufacturers have already been including calories on their FOP labels. With respect to the comments concerning possible interactions between food manufacturers and vending machine operators, such interactions will depend on, and are best left to, vending machine operators and their suppliers.

In response to the comments regarding type size and prominence of the visible nutrition information on the label of the food, we have revised § 101.8(b)(2)(i) to replace the words “reasonably related” with “at least 50 percent of the size of the largest printed matter on the label.” Specifying the minimum type size for calorie information on vending machine food labels will provide greater clarity for both compliance and enforcement. While we recognize that some comments asserted that 50 percent of the size of the largest print on the label would result in type sizes that are too large, other comments asserted that the resulting type size would be too small, and some comments asked FDA to omit any requirements for prominence or type size.

Further, we clarify that section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act describes foods that are not subject to the vending machine labeling requirements specified in section 403(q)(5)(H)(viii) of the FD&C Act. Therefore, by specifying the type size of the visible nutrition information, we are not imposing any additional requirements on vending machine food. Instead, we are explaining when articles of food sold from vending machines satisfy the language of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act such that such foods are not covered by the labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act. In addition, there are other options that vending machine operators may choose to satisfy 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).

We disagree with comments asking that we omit requirements for

prominence or type size of FOP calorie disclosures for the purposes of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. 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.

Furthermore, § 101.8(b)(2) requires the visible nutrition information to be “clear and conspicuous and able to be easily read on the article of food while in the vending machine.” Type size is one factor in determining whether the nutrition information on a food label is “clear and conspicuous and easily read,” and other considerations, such as color and contrasting background (which § 101.8(b)(2) also addresses), can affect the prospective purchaser’s ability to read the nutrition information. For example, a prospective purchaser might be able to read nutrition information in one vending machine, but not in another vending machine if the first vending machine’s design enabled the prospective purchaser to get close to the food label. In contrast, if a vending machine’s design results in the food label being several inches away from the prospective purchaser, the nutrition information might not be as easy to read. The important consideration is to ensure that prospective purchasers are able to read and use the nutrition information for a vending machine food before purchasing the food.

4. Section 101.8(c)—Requirements for Calorie Labeling for Certain Food Sold From Vending Machines

Proposed § 101.8(c) would establish requirements for calorie declarations for foods sold from vending machines, as required by section 403(q)(5)(H)(viii) of the FD&C Act. In brief, proposed § 101.8(c)(1) would define “covered vending machine food,” and proposed § 101.8(c)(2) would establish requirements for calorie declarations on signs in, on, or adjacent to the vending machine.

a. *Covered vending machine food.* Proposed § 101.8(c)(1) would explain the “applicability” of the calorie labeling requirements to foods sold from vending machines by defining “covered vending machine food” as an article of food that is:

- Sold from a vending machine that:
 - Does not permit the consumer to examine the Nutrition Facts Panel prior to purchase as provided in paragraph (b) of this section, or otherwise provide

visible nutrition information at the point of purchase as provided in paragraph (b);

- Is operated by a person engaged in the business of owning or operating 20 or more vending machines; and
- Is a vending machine with a selection button; or

- Sold from a vending machine that is operated by a vending machine operator that has voluntarily elected to be subject to the requirements of this section by registering with FDA under the provisions of paragraph (d) of this section.

(Comment 17) The preamble to the proposed rule explained that the requirements of section 403(q)(5)(H)(viii) of the FD&C Act do not apply to vending machine operators who own or operate fewer than 20 vending machines that sell articles of food (76 FR 19238 at 19241). Thus, even if a vending machine operator has 50 vending machines, the operator is not subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act if fewer than 20 of those vending machines sell articles of food.

One comment asked us to clarify that a vending machine that dispenses a mix of food and non-food items would be considered a vending machine that sells articles of food when determining whether the vending machine operator is covered. The comment sought to ensure that all vending machines that dispense some articles of food would be covered, if applicable.

(Response 17) In general, § 101.8(a) defines a “vending machine” as a self-service device that dispenses “servings of food in bulk or in packages, or prepared by the machine.” This definition includes vending machines that sell both food and non-food items. However, section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(c) only apply to certain vending machine foods and the operators of vending machines that sell such foods. A vending machine that sells an article of food will be counted towards the “20 or more” threshold for determining whether a vending machine operator is covered, even if the vending machine also sells non-food items, provided that such a vending machine does not dispense those food items as part of a game or other non-food related activity, as discussed further in the paragraphs that follow.

We are aware that “game machines” sometimes dispense candy or other edible items as part of a game or other non-food related activity. However, we conclude that “game machines” are not covered by section 403(q)(5)(H)(viii) of the FD&C Act, and do not count towards the “20 or more” threshold for

determining whether a vending machine operator is covered. As we discussed in the preamble to the proposed rule (76 FR 19238 at 19241) and explain further in our response to comment 18, the primary purpose of a “game machine” is to sell a chance to play a game or to provide entertainment, and not to sell articles of food.

(Comment 18) In the preamble to the proposed rule, we tentatively concluded that vending machines that may dispense food as part of a game or other non-food related activity are not covered by section 403(q)(5)(H)(viii) of the FD&C Act (76 FR 19238 at 19241). For example, as we discussed in the preamble to the proposed rule, if a vending machine contains small toys and individually wrapped candies that can be picked up by maneuvering a large claw arm, we tentatively concluded that the vending machine is selling the opportunity to play the game, and not selling articles of food (76 FR 19238 at 19241).

One comment disagreed with our tentative conclusion in the proposed rule to not cover vending machines that may dispense food as part of a game or other non-food related activity (*e.g.*, claw games with candy prizes amongst other prizes). The comment claimed that a consumer playing a claw game could still maneuver the claw toward a healthier option if the calorie declarations for food prizes were available.

(Response 18) We decline to apply the requirements of section 403(q)(5)(H)(viii) of the FD&C Act to vending machines that may dispense food as part of a game or other non-food related activity. Section 403(q)(5)(H)(viii) of the FD&C Act applies to “an article of food sold from a vending machine.” FDA concludes that an article of food that may be dispensed from a vending machine as part of a game or other non-food related activity does not constitute “an article of food sold from a vending machine” within the context of section 403(q)(5)(H)(viii) of the FD&C Act. Game machines sell the opportunity to play a game or experience entertainment, and not the article of food itself. While the comment disagreeing with our conclusion indicated that calorie information might motivate an individual to “maneuver the game claw towards a healthier option,” the comment provided no basis to support this assumption. For these reasons, we are not amending the final rule to cover game machines, as suggested by the comment.

(Comment 19) The preamble to the proposed rule noted that section

403(q)(5)(H)(viii) of the FD&C Act provides that, for covered vending machine food, the vending machine operator must provide a sign disclosing the number of calories contained in the food “in close proximity to each article of food or the selection button” (76 FR 19238 at 19241). We tentatively concluded that the reference to “selection button” can be read to mean that only vending machines with selection buttons are subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. We indicated that we were not aware of vending machines without selection buttons other than bulk vending machines that dispense, by use of a crank, single types of unpackaged articles of food in preselected amounts (*e.g.*, a single piece of gum or a handful of candy or nuts). We tentatively concluded that vending machines without any type of selection button, including bulk vending machines, were not covered by section 403(q)(5)(H)(viii) of the FD&C Act, and we invited comment on this subject.

Some comments agreed with our interpretation of the reference to “selection button” in section 403(q)(5)(H)(viii) of the FD&C Act. The comments stated that, for bulk vending machines, a consumer only would be choosing whether to buy the bulk product and would not be selecting among food items; therefore, the button on such a vending machine would not constitute a “selection button.” The comments noted that bulk foods tend to be lower in calories because of the vended size (such as a small handful of nuts or candies) compared to other foods (such as candy bars or bags of chips) sold in typical vending machines. One comment asked that we exempt “turret-style” (turnstile) refrigerated food vending machines from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because such machines do not have selection buttons.

Other comments disagreed with our interpretation of the reference to “selection button” in section 403(q)(5)(H)(viii) of the FD&C Act, and argued that the lack of a selection button does not justify an exemption from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. These comments also asserted that there would be no public health rationale for such an exemption. Some comments asserted that the mention of a selection button in section 403(q)(5)(H)(viii) of the FD&C Act was not intended to differentiate between “regular” vending machines (*i.e.*, those that have selection buttons) and machines that use a device

other than a selection button. The comments said that the statute's mention of a selection button was meant to refer to where the nutrition information should be placed. These comments also said that bulk items (usually candy and gumballs) are appealing to children, so calorie information should be made available. They also urged FDA to maintain consistency by requiring calorie labeling for all types of vending machines. In addition, one comment pointed out that excluding vending machines without a selection button would give bulk vending machines an unfair advantage over "traditional" (*i.e.*, non-bulk) vending machines because the operators of bulk vending machines would not have to incur any expenses to implement the calorie declaration requirements.

Other comments noted that complying with the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act would not be burdensome for a bulk machine vending machine operator because such a machine generally only dispenses one product (*e.g.*, nuts, gumballs), and consumers do not select between multiple items. Therefore, several comments asserted that a vending machine operator for a bulk vending machine would only have to affix one sticker or decal displaying the calorie declaration on the bulk machine.

(Response 19) Section 403(q)(5)(H)(viii) of the FD&C Act provides that, for covered vending machine food, the vending machine operator must provide a sign disclosing the number of calories contained in the food "in close proximity to each article of food or the selection button." Although in the proposed rule, we tentatively concluded that vending machines without selection buttons are not covered, upon further consideration and in light of the comments asserting that the presence or absence of a selection button should not determine whether a vending machine is subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, this final rule provides that covered vending machines also include those without selection buttons.

In construing whether vending machines without selection buttons are within the scope of section 403(q)(5)(H)(viii) of the FD&C Act, we are confronted with two questions. First, has Congress directly spoken to the precise question presented ("*Chevron* step one")? *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842 (1984). If Congress has spoken directly and plainly, the Agency must implement

Congress's unambiguously expressed intent. *Chevron*, 467 U.S. at 842–843. If, however, Congress is silent or ambiguous as to the question, our interpretation will be upheld as long as it is based on a "permissible construction" of the statute. ("*Chevron* step two"). *Chevron*, 467 U.S. 843–844; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000).

We have determined that, in enacting section 403(q)(5)(H)(viii), Congress did not speak directly and plainly to the question of whether vending machines without selection buttons are covered. In conducting the *Chevron* step one analysis, all the traditional tools of statutory construction are available, *e.g.*, the statute's text, structure, and legislative history. *Pharmaceutical Research & Manufacturers of America v. Thompson*, 251 F. 3d 219, 224 (D.C. Cir. 2001). The term "vending machine" as used in section 403(q)(5)(H)(viii) is not specific as to whether it must have a selection button. The scant legislative history does not shed any light on whether Congress intended to limit covered vending machines only to those with selection buttons by virtue of the statutory provision regarding the placement of the calorie declaration sign in close proximity to the selection button.

Having determined that Congress's intent regarding whether vending machines without selection buttons are required to have calorie declaration signs is ambiguous, we have determined that the final rule's interpretation of covered vending machine as any machine regardless of whether it has a selection button is a permissible construction of the statute. (*Chevron* step two). In conducting the *Chevron* step two analysis, the same tools of statutory construction are available as those for the step one analysis.

The interpretation in the final rule is consistent with the plain meaning of the statute, which is the starting point of statutory construction. (*See* 2A Sutherland Statutory Construction 137 (7th ed. 2007). Section 403(q)(5)(H)(viii) uses the term "vending machine" in three instances. It refers to "an article of food sold from a vending machine." It refers to "a person who is engaged in the business of owning or operating 20 or more vending machines." Finally, the statute refers to "the vending machine operator." In the two instances in which the statute refers to "vending machines," it does so without qualification or limitation on the type of machine.

Our interpretation is also consistent with the structure of the statute which identifies only two limitations that

apply to the vending machines. Those limitations are set out in section 403(q)(5)(H)(viii)(I)(aa) and (bb) of the FD&C Act. The provisions state that an article of food requires a calorie declaration if it is "from a vending machine that (aa) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and (bb) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines." That is, the vending machines not subject to the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act are those that allow the prospective purchaser to examine the Nutrition Facts label or does not otherwise provide visible nutrition at the point of purchase or those that are operated by a person in the business of owning or operating less than 20 vending machines. Although these provisions address covered vending machines, they do not address a type of vending machine.

Accordingly, we are interpreting section 403(q)(5)(H)(viii) of the FD&C Act to include vending machines with or without selection buttons.

As for the comments asserting that vending machines without selection buttons should not be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because articles of food sold from bulk vending machines tend to contain fewer calories than foods sold in non-bulk vending machines, we clarify that section 403(q)(5)(H)(viii) of the FD&C Act does not exclude articles of food that contain low levels of calories from the calorie labeling requirements. Consistent with section 403(q)(5)(H)(viii) of the FD&C Act's general purpose to provide calorie information for foods sold from certain vending machines, we interpret section 403(q)(5)(H)(viii) of the FD&C Act to apply to vending machines that sell articles of food regardless of the food's caloric content and regardless of whether the vending machine has a selection button.

Further, we agree with the comments asserting that excluding vending machines without selection buttons from the requirements of § 101.8(c) is not supported by a public health rationale. Providing such calorie declarations will make calorie information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. In addition, we agree with the comments stating that

providing calorie information would not be overly burdensome for bulk vending machine operators because such operators can use single stickers or decals to provide the required calorie declarations.

For these reasons, we have revised § 101.8(c)(1) by removing the criterion that a food must be sold from a vending machine with a selection button to be covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. Additionally, because the final rule covers vending machines regardless of whether they have selection buttons, we decline to exempt turret-style or turnstile vending machines.

We also have revised § 101.8(c)(1)(i) and (ii), on our own initiative, to clarify the applicability of the rule. Proposed § 101.8(c)(1)(i) would address vending machines operated by persons who must comply with section 403(q)(5)(H)(viii) of the FD&C Act, and proposed § 101.8(c)(1)(ii) would address vending machines operated by persons who voluntarily register with FDA to become subject to section 403(q)(5)(H)(viii) of the FD&C Act. However, the conditions under which an article of food would not be covered by the rule (if the article of food permits the prospective purchaser to examine the Nutrition Facts label before purchase as provided in proposed § 101.8(b)(1), or otherwise provides visible nutrition information at the point of purchase as provided in proposed § 101.8(b)(2)), were contained in proposed § 101.8(c)(1)(i)(A) and therefore would not have appeared to be applied to persons who voluntarily registered with FDA. As a result, we have reorganized and revised § 101.8(c)(1)(i) to describe the provisions in § 101.8(b) under which an article of food is not covered by the rule. We also have reorganized and revised § 101.8(c)(1)(ii) to refer to the two types of vending machine operators that may be subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act (those required to comply by law and those who may register voluntarily to comply with the requirements). We have connected § 101.8(c)(1)(i) and (ii) with the conjunction “and” to specify that the provisions in § 101.8(b) may apply to both types of covered vending machine operators.

On our own initiative, we also have made an editorial change to replace “the FDA” with “FDA.” Also, we have replaced “consumer” with “prospective purchaser” to be consistent with the rest of the final rule, and have specified paragraphs “(b)(1)” and “(b)(2)” where these provisions are summarized (rather than referring to them both as

“paragraph (b)”), and we have changed “Nutrition Facts Panel” to “Nutrition Facts label” to match terms used in the rest of the final rule.

b. Calorie declaration. Proposed § 101.8(c)(2) would establish requirements for calorie declarations for covered vending machine food.

i. Calorie increments.

Proposed § 101.8(c)(2)(i)(A) would require the calorie declaration to be “clear and conspicuous” and declared to the “nearest 5-calorie increment up to and including 50 calories and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.”

In the preamble to the proposed rule, we tentatively decided against allowing ranges for declaring calories for vending machine food that comes in different varieties and flavors (e.g., coffee or hot chocolate) (76 FR 19238 at 19242). We noted in the preamble of the proposed rule that a “vending machine operator could post a calorie declaration in close proximity to the selection button for a food that comes in different varieties and flavors that is sold in a vending machine that has selection buttons corresponding to the different options” (Id.). Therefore, the vending machine operator could provide calorie declarations for each variety or option adjacent to selection buttons corresponding to each option (Id.). Further, we tentatively concluded that calorie ranges are also not necessary within the context of vending machines because a vending machine operator would be able to disclose calorie information under other options (e.g., use of signs) (Id.).

(Comment 20) Some comments agreed with FDA’s tentative conclusion in the proposed rule and stated that a range or an average would not be necessary. These comments stated that in situations where items are displayed such that multiple flavors or varieties exist in the same space, different selection buttons provide the opportunity for the operator to list separate calorie information for each item, and therefore ranges or averages for these vending machines would not be necessary.

A few comments disagreed with FDA’s tentative conclusion in the proposed rule and recommended that we allow the use of ranges. The comments stated that slight variations will occur such as in fresh coffee vending machines where different types of creamer or flavoring may be used.

Some comments asked that we exempt self-service, custom order vending machines that allow the customer to select size, type of drink,

type of milk, and additional flavors from the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. The comments claimed it would not be feasible for operators of such vending machines to declare calories for all the possible customizations due to lack of space on the vending machine. According to one comment, disclosing calories for customizations can be inaccurate and misleading. For example, the comment asserted that adding syrup to a drink displaces a portion of the beverage that would have otherwise been included in the cup, and as a result some customizations do not add calories to the finished beverage. According to the comment, adding sugar-free syrup actually reduces the beverage’s calories. Because FDA proposed to not apply the nutrition labeling requirements of section 403(q)(5)(H)(i)–(vii) of the FD&C Act (relating to standard menu items offered for sale in restaurants and similar retail food establishments) to custom orders, the comments argued that we should similarly exempt custom beverage vending machines from the vending machine labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act. The comments said that if we do not exempt such vending machines, we should give vending machine operators the flexibility to choose the method of calorie information disclosure for highly customizable self-serve products. For example, vending machine operators should be permitted to simply disclose calorie content for the condiments offered for customization, e.g., calories per ounce of milk or per shot of syrup.

(Response 20) We conclude that calorie ranges are not necessary for vending machine foods that come in different varieties and flavors. Unlike section 403(q)(5)(H)(v) of the FD&C Act—which pertains to nutrition labeling for standard menu items offered for sale in restaurants and similar retail food establishments and allows FDA to establish standards for disclosing the nutrient content for certain standard menu items that come in different flavors, varieties, or combinations, through means determined by FDA, including ranges, averages, or other methods—section 403(q)(5)(H)(viii) of the FD&C Act specifies that, if covered, a vending machine operator must provide a sign disclosing the number of calories contained in an article of food sold from a vending machine.

We also decline to permit calorie ranges because, as noted by the comments, vending machine operators can declare calories for each “option” offered. For a vending machine that has selection buttons corresponding to different options, a vending machine

operator could post a calorie declaration in close proximity to the corresponding selection buttons. In addition, vending machines that dispense various flavors or varieties of beverages do so in measurable quantities; therefore, it is reasonable to require vending machine operators to provide calorie declarations for such options. To give vending machine operators flexibility, the final rule allows vending machine operators to declare calories per option or for the final vended products. For example, if a vending machine dispenses coffee products with options for adding skim milk, whole milk, cream, sugar, or sugar substitute, the vending machine operator could provide calorie declarations for each of those added options individually. If the vending machine operator chose to declare calories for the final vended products sold from the machine, the calorie declarations would be for all final vended coffee products sold from the machine, meaning all dispensed combinations of coffee, skim milk, whole milk, cream, sugar, and sugar substitute. Note that a vending machine operator could post calorie declarations next to each selection button, or on a sign in, on, or adjacent to the vending machine, as provided in § 101.8(c).

We decline to exempt the types of self-service, custom-order vending machines described by the comments from the calorie labeling requirements for vending machine food of section 403(q)(5)(H)(viii) of the FD&C Act. As a preliminary matter, we clarify that while section 403(q)(5)(H)(i)(bb) of the FD&C Act, which pertains to restaurants and similar retail food establishments, provides that the nutrition labeling requirements of sections 403(q)(5)(H)(i) through (vi) of the FD&C Act for standard menu items do not apply to “custom orders”, the vending machine food labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act do not provide for such an exclusion. Furthermore, in the proposed rule for nutrition labeling of standard menu items in restaurants and similar retail food establishments (76 FR 19192, April 6, 2011), we proposed to define “custom order” as a food order that is prepared in a specific manner based on an individual customer’s request, which requires the restaurant or similar retail food establishment to deviate from its usual preparation of a menu item (76 FR 19192 at 19233). The “custom orders” for purposes of nutrition labeling of standard menu items in restaurants and similar retail food establishments are not equivalent to vending machine

foods that come in different varieties or flavors because such vending machine foods are not prepared in a way that deviates from a usual preparation of the item. Instead, vending machines offering articles of food in different varieties or flavors generally are programmed to dispense measurable quantities of beverages, flavors, or other varieties at the customer’s selection. As such, a vending machine operator can declare calories for each variety or flavor on a sign in close proximity to the selection buttons for such varieties and flavors or on a sign adjacent to the vending machine, as provided by § 101.8(c).

In consideration of the comments asking for flexibility for these products, and to provide clarity, we have added a new § 101.8(c)(2)(i)(D). (We have renumbered proposed § 101.8(c)(2)(i)(D) as § 101.8(c)(2)(i)(C) in the final rule, as will be discussed in response 23, and removed proposed § 101.8(c)(2)(i)(E) as will be discussed in response 24). Section 101.8(c)(2)(i)(D), as finalized, provides that if a covered vending machine food is one where the prospective purchaser selects among options to produce a final vended product (e.g., vended coffee, hot chocolate or tea with options for added sugar, sugar substitute, milk, and cream), calories must be declared per option or for the final vended products.

Regarding the comments asserting that it would not be feasible for vending machine operators to declare calories for each variety or flavor due to lack of space on the vending machine, we note that vending machine operators may place a sign declaring calories adjacent to the vending machine, as provided in § 101.8(c). We further discuss the placement of signs disclosing the number of calories in covered vending machine food in our response to comment 28. We also note that vending machine operators have flexibility to declare either the calories from each option or the calories for final vended products.

Consequently, we have finalized § 101.8(c)(2)(i)(A) without change. However, on our own initiative, we have moved the requirement in the introductory sentence of proposed § 101.8(c)(2)(i) that the number of calories “must be clear and conspicuous,” and placed it instead in the introductory sentence of § 101.8(c)(2)(ii) of the final rule. The “clear and conspicuous” standard more appropriately reflects the requirements in § 101.8(c)(2)(ii), which focus on the placement and appearance of the calorie declarations, rather than the requirements of § 101.8(c)(2)(i), which

focus on the content of the calorie declarations.

ii. *Use of the term “Calories” or “Cal”.*

Proposed § 101.8(c)(2)(i)(B) would require that the term “Calories” or “Cal” appear adjacent to the caloric content value for each food in the vending machine.

We received no comments on this provision and have finalized it without change.

iii. *Calorie declaration type size, color, and contrast.*

Proposed § 101.8(c)(2)(i)(C) would specify the calorie declaration’s type size, color, and contrast. For calorie declarations in or on the vending machine, the proposal would require the calorie declaration to be in a type size no smaller than the name of the food on the machine, not the label, selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, i.e., the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, as the item it is in closest proximity to, i.e., name, selection number, or price of the food item as displayed on the machine (76 FR 19238 at 19254).

(Comment 21) Many comments agreed with the proposed requirements for type size, color, and contrast for calorie declarations in or on the vending machine. However, some comments argued that the calorie declaration should be more prominent. Several comments suggested that we revise the rule to state that “calorie labeling be as large as the name of the vended item if it is posted on the machine, selection number, or the price, whichever is largest.” One comment said that the font, size, and color of the calorie declaration should be no less prominent than the price, label (although the comment did not describe what it meant by “label”), or item name. Another comment said that the calorie declaration must be large enough to read from a “normal standing posture.”

Other comments said the proposed rule was too restrictive and wanted greater flexibility for the type size of the calorie declaration—whether on the vending machine or on the food itself. Several comments claimed that the proposed rule would force vending machine operators to make significant changes to the size of product brand names on smaller vending buttons or use “distractingly large” calorie declarations on certain larger vending buttons. (We interpret the comment’s

reference to “vending button” to be the same as a selection button.)

Regarding the proposed requirement for contrasting background, one comment stated that the calorie declaration should have a contrasting background and be in a font color that is at least as visible as, rather than the same as, the background and the color of the selection number or price.

(Response 21) The preamble to the proposed rule explained that for calorie declarations in or on the vending machine, the calorie declaration must be in a type size “no smaller than the name, selection number, or price of the food as displayed on the vending machine, whichever is smallest” (76 FR 19238 at 19243). Proposed § 101.8(c)(2)(i)(C) would state, in relevant part, that the declaration of calories must be in a type size no smaller than the name of the food on the machine, not the label, selection number, or price of the food as displayed on the vending machine, whichever is smallest. To further clarify that the type size of the calorie declarations must be in a type size no smaller than the name of the food on the machine, the selection number, or the price of the food as displayed on the vending machine, whichever is smallest, we have revised the provision that was proposed § 101.8(c)(2)(i)(C) (which is moved and consolidated as § 101.8(c)(2)(ii)(B) in this final rule, as explained later in this response) to place the phrase “not the label” in parentheses. We are connecting the calorie declaration’s type size to the type size of other information on the vending machine that a prospective purchaser uses to make a selection (*i.e.*, the name of the food on the machine, the selection number, the price of the food as displayed), in order to ensure that the calorie declaration is clear and conspicuous and similarly readable.

We decline to make the changes requested by the comments to the requirements for size and color of the calorie declarations in or on the vending machine because the comments did not provide any specific information regarding the size or color of the calorie declarations, particularly information that would give us a basis to revise the rule. For example, the comments asserting that calorie declarations should be larger or more prominent did not provide any information to show that the proposed requirements would not ensure that the calorie declarations are clear and conspicuous and easily readable.

In addition, with respect to the comment asserting that the calorie declaration must be large enough to be

seen from a “normal standing posture,” such a standard would not take into account that there are different types of vending machines and that consumers vary in height and visual acuity. For example, calorie declarations at the top of a vending machine that a tall consumer might see easily could be difficult for a comparatively shorter consumer to see.

As for the comments seeking greater flexibility for vending machine operators, the requirements for the type size, color, and contrast of calorie declarations in or on the vending machine provide vending machine operators with flexibility by linking such requirements to the information that prospective purchasers otherwise use to make selections. Vending machine operators can therefore use the information (*i.e.*, the name of the food, selection number, or price of the food as displayed) that is already on their vending machines as a guide to comply with the type size, color, and contrast requirements for the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act for calorie declarations in or on the vending machine. This flexibility should enable vending machine operators to develop signs declaring calories for calorie declarations in or on the vending machine regardless of the type of vending machine they have. In addition to providing flexibility, the requirements, as finalized, help ensure that calorie declarations are clear and conspicuous, as required by section 403(q)(5)(H)(viii) of the FD&C Act.

In consideration of the comment asking that the contrasting background be “at least as visible as” (rather than “the same as”) the background of the accompanying food item (*i.e.*, its name, selection number, or price), we have revised the provision that was proposed § 101.8(c)(2)(i)(C) (which is moved and consolidated as § 101.8(c)(2)(ii)(B) in this final rule, as explained later in this response) to require that the calorie declaration have the same contrasting background, or a background as least as contrasting as the background used for the item it is in the closest proximity to, *i.e.*, name, selection number, or price of the food item as displayed on the machine. Revising the rule in this manner provides additional flexibility related to the prominence requirements, and parallels the rule’s requirement that the color of the calorie declaration be the same or “at least as conspicuous” as that of the accompanying food item’s name, price, or selection number on the vending machine.

On our own initiative, we are also revising the rule to eliminate a duplicate

requirement. Proposed § 101.8(c)(2)(i)(C) would describe the type size, color and contrast for calorie declarations in or on the vending machine, and proposed § 101.8(c)(2)(ii)(B) would describe the color and contrast requirement for calorie information in or on the vending machine. Organizationally, proposed § 101.8(c)(2)(i) would focus on the content of the calorie declarations, and proposed § 101.8(c)(2)(ii) would focus on the placement and appearance of the calorie declarations. Therefore, for clarity, we are moving and consolidating proposed § 101.8(c)(2)(i)(C) with proposed § 101.8(c)(2)(ii)(B) to eliminate the duplicate requirement, and renumbering subsequent paragraphs that were proposed § 101.8(c)(2)(i)(D) and (E) to be § 101.8(c)(2)(i)(C) and (D) in the final rule.

For these reasons, under § 101.8(c)(2)(ii)(B) of the final rule, when the calorie declaration is in or on the vending machine, the calorie declaration must be in a type size no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, *i.e.*, the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, or a background at least as contrasting as the background used for the item it is in closest proximity to, *i.e.*, name, selection number, or price of the food item as displayed on the machine.

iv. Calorie declarations for single-serving packaged food.

Proposed § 101.8(c)(2)(i)(D) would state that the number of calories for single-serving packaged food declared on the sign must be identical to the number of calories that are declared in the Nutrition Facts, if applicable. Because section 403(q)(5)(H)(viii) of the FD&C Act refers to “an article of food sold from a vending machine,” the preamble to the proposed rule also indicated that calorie information must include the total calories present in the covered vending machine food as it is vended (76 FR 19238 at 19242). For example, for bundled items such as sandwiches that are dispensed with a single serving unit of a condiment (*e.g.*, mayonnaise), the calorie declaration must include the total calories in the sandwich plus any condiment packets bundled with it as a vended article (76 FR 19238 at 19242).

(Comment 22) One comment stated that calorie ranges are necessary with certain foods, such as fresh fruit, cotton

candy, sandwiches, or pastries because such foods can have slight calorie variations. The comment stated that vending machine operators need flexibility to declare calories in ranges and that ranges will make it easier for vending machine operators to implement the calorie labeling requirements.

(Response 22) We recognize that certain vending machine foods, such as fresh fruit, may have naturally occurring variations in calorie content depending on the size of the fruit and other factors. This is different from the situation of a food with various options that a consumer selects (as discussed in comment and response 20), and from the situation of a food that comes bundled with various components (as discussed in comment and response 23). We conclude that a range is not necessary for calorie declarations for vending machine foods that may have naturally occurring variations in calorie content depending on the size of the fruit or other factors. As discussed further in comment and response 34 in section III.D entitled “Determination of Calorie Content,” a vending machine operator may rely on a number of means to determine the calorie content of covered vending machine food. For example, a vending machine operator may obtain calorie information from nutrient databases, such as the “USDA National Nutrient Database for Standard Reference” (<http://ndb.nal.usda.gov/>) and use such information in declaring calories, provided that the calorie declarations are truthful and not misleading and otherwise in compliance with section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and § 101.8.

With respect to a potential variation in prepared food such as cotton candy, sandwiches, and pastries, we also conclude that a range is not necessary for calorie declarations for such foods. As discussed further in comment and response 34 in section III.D entitled “Determination of Calorie Content,” vending machine operators may be able to use various means to determine the calorie content for vending machine foods. For example, if the food is manufactured, the vending machine operator may be able to obtain the necessary calorie information from the food package’s Nutrition Facts label, the manufacturer, or nutrient databases. It is the vending machine operator’s responsibility to ensure that calorie declarations for foods are accurate and otherwise in compliance with section 403(a)(1), (q)(5)(H)(viii), and (f) of the FD&C Act and § 101.8.

(Comment 23) For vending machine foods such as sandwiches that consist of

more than one separately packaged component and are sold as one unit in turnstile vending machines, one comment asked us to allow the vending machine operator to either: (1) Declare the total calories of the food as vended or (2) declare calories for each individual component. The comment said this would, for example, allow mayonnaise already on the sandwich to be included in the calories for the total package and also allow mayonnaise in a separate packet to be excluded from the calorie count of a sandwich that does not already have mayonnaise on it.

The comment further stated that allowing vending machine operators to declare calories for the components of a covered vending machine food separately would give the consumer more information. (The comment referred to its suggestion as “itemized” calorie declaration.) For example, according to the comment, a 428 calorie turkey sandwich with two packets of mayonnaise and two packets of mustard derives 250 calories from the sandwich itself, 86 calories from each packet of mayonnaise, and 3 calories from each packet of mustard. The comment said that it would be simpler for the vending machine operator to declare the calories for the primary item and for each separately packaged item that is provided because the operator would not need multiple versions of posters, labels, etc. depending on the types and quantities of condiments provided. The comment argued that such an approach for articles of food with multiple components, like sandwiches, would be consistent with FDA’s approach to covered vending machine foods that come in different varieties and flavors, such as hot beverages, which FDA concluded, in the preamble to the proposed rule, could be declared per option (e.g., cream for coffee). The comment asked that we revise the rule to give turnstile vending machines flexibility to declare calories separately for condiments sold with a food item.

(Response 23) We disagree with the comment asking us to allow the vending machine operator to either: (1) Declare the total calories of a bundled vending machine food as vended, or (2) declare calories for each individual component of a bundled vending machine food as vended. The requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply, in relevant part, “in the case of an article of food sold from a vending machine.” Regarding a vending machine food that consists of more than one separately packaged component and is sold as one unit (e.g., sandwich dispensed with a single serving packet of condiment), the calorie declaration

for the food must include the total calories present in the food as it is vended, including the calories present in single serving units of condiments. We consider a packaged or plastic-wrapped sandwich including, if sold along with the sandwich, any packet(s) of condiments to be the “article of food” for purposes of applying the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. As such, the vending machine operator must provide a calorie declaration for the “article of food” as it is vended, which includes the calorie content of each component of the “article of food.”

We will not object, however, if the vending machine operator voluntarily declares the calories for a bundled vending machine food that consists of more than one separately packaged component on a per packaged component basis, so long as the vending machine operator also provides the total calorie declaration for “the article of food” as it is vended. We note that condiment packets that are not dispensed with the sandwich (e.g., those condiments that are stocked in a common area near a bank of vending machines) are not part of “the article of food” for purposes of applying the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. In such an instance, the vending machine operator should not include the condiment packets in the total calories of the article of food.

Further, contrary to the comment’s assertion, requiring the calorie declaration for a bundled vending machine food to include the total calories present in the food as it is vended is not inconsistent with the calorie labeling requirements for articles of vending machine food that come in different varieties or flavors (e.g., coffee), which we discussed in our response to comment 20. When the consumer affirmatively can choose the varieties or options dispensed with the food by pressing a selection button corresponding to each variety or option, the vending machine operator may display the calorie declarations for each variety or option in close proximity to the corresponding selection buttons for such varieties or options; however, when the consumer receives a bundled food item (such as a sandwich with a mayonnaise packet accompanying the sandwich), the consumer has selected to receive the food item as dispensed, and therefore, it is appropriate to label the calories for the entire bundled food item.

We also disagree with the comment stating that calorie ranges are necessary for certain foods, such as sandwiches. In

the case of bundled items, the consumer is unable to customize the item that is vended until after it is dispensed, and, therefore, a declaration of total calories is appropriate rather than a range. In the case of bundled items, as we have indicated, we would not object to additional calorie declarations for each component of a bundled item, as long as the vending machine operator also provides the total calorie declaration for the bundled item, as it is vended.

As discussed in response 21, we have moved what had been proposed as § 101.8(c)(2)(i)(C) and therefore we are renumbering proposed § 101.8(c)(2)(i)(D) as § 101.8(c)(2)(i)(C). Also, as discussed further in section III.C.4.b.v, we have made changes to renumbered § 101.8(c)(2)(i)(C) to further clarify that a calorie declaration for a covered vending machine food must include the total number of calories for the food, whether the food is a single-serving or multiple serving food. Section 101.8(c)(2)(i)(C) of this final rule provides that the number of calories for a covered vending machine food must include the total calories present in the food. As discussed in section III.D, a vending machine operator may determine the total calories contained in a covered vending machine food through a variety of methods, including obtaining the calorie information from the food package's Nutrition Facts label, the manufacturer or supplier of the food, nutrient databases, cookbooks or laboratory analyses. Covered vending operators must ensure that the calorie declarations are truthful and not misleading, as required by section 403(a)(1) of the FD&C Act, and otherwise comply with section 403(q)(5)(H)(viii) and (f) of the FD&C Act and § 101.8.

v. Calorie declarations for packaged food having multiple servings.

Proposed § 101.8(c)(2)(i)(E) would require that the calorie declaration for a covered vending machine food that contains multiple servings include the total number of calories present in the vending machine food. Proposed § 101.8(c)(2)(i)(E) would also allow vending machine operators to voluntarily disclose the calories per serving in addition to the total calories for the food.

(Comment 24) Many comments stated that vending machine food, regardless of its serving size, is typically consumed in one occasion. The comments agreed with proposed § 101.8(c)(2)(i)(E) and said that section 403(q)(5)(H)(viii) of the FD&C Act's reference to an "article of food sold from a vending machine" and disclosure of calories contained in the article indicates that a vending machine

operator must declare the total calories contained in a vending machine food as it is packaged for sale, or otherwise sold from a vending machine, even if the food's Nutrition Facts label states that the food contains more than one serving. Similarly, because vending machine food is typically consumed in one occasion, a few comments noted that declaring calories per serving could be potentially confusing to consumers. The comments stated that it would be deceptive, for example, to label a bag of chips as 160 calories (per one-ounce serving) on the vending machine, only to have people discover that the whole bag of chips contained 1.5 servings and 240 calories.

Other comments disagreed with proposed § 101.8(c)(2)(i)(E). The comments would base calorie declarations on the serving size listed on the Nutrition Facts label and said that doing so would be consistent with current nutrition labeling requirements. The comments pointed out that some commonly vended foods contain more than one serving and that, for those foods, the calories as listed per serving in the Nutrition Facts label would not be identical to the calorie declaration disclosing the number of calories contained in the entire article of food.

In contrast to the comments asserting that vending machine foods typically are consumed in their entirety in one occasion, regardless of listed servings on the package, a few comments stated that labeling total calories for foods such as gum would be misleading because typically, people do not chew the entire pack of gum in one occasion and that calories should be allowed to be displayed per serving.

Several comments supporting calorie declarations per serving noted that Congress used the term "item" for the nutrition labeling requirements for standard menu items offered for sale in restaurants and similar retail food establishments of section 4205 of the ACA, but used the term "article" for the vending machine food labeling requirements. One comment stated that because Congress used different words to express the two requirements, the words should have different meanings. The comment contended that "article," which is used in the vending machine labeling requirements of section 4205 of the ACA, suggests that the number of calories per serving, and not the total number of calories contained in the food, must be declared. The comment also noted that the nutrition labeling requirements for packaged foods is per serving. According to the comment, if FDA thinks per serving calorie declarations are not sufficient, we

should address the issue directly through our serving size regulations and not indirectly through the vending machine calorie declaration requirements.

(Response 24) We decline to revise the rule to require the calorie declarations for covered vending machine food to be based on the serving size listed on the Nutrition Facts label. We agree with the comments asserting that many vending machine foods are typically consumed in one occasion. Further, we note that the requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply to an "article of food sold from a vending machine," and section 403(q)(5)(H)(viii) of the FD&C Act requires a vending machine operator to disclose the "number of calories contained in the article [of food]." Thus, we conclude that section 403(q)(5)(H)(viii) of the FD&C Act requires that the calorie declaration for an article of food sold from a vending machine, including foods that contains multiple servings, be equal to the total "number of calories contained in the article [of food]" as dispensed, rather than the number of calories contained in the serving size, if applicable, for the food. The total number of calories can be determined by multiplying the number of calories per serving by the number of servings in the package. For example, if the Nutrition Facts for an article of food states 80 calories per serving and 3 servings per container, the total number of calories in the entire package would be 240 calories.

Further, regarding the comments supporting calorie declarations per serving because Congress used the term "item" for the nutrition labeling requirements for standard menu items offered for sale in restaurants and similar retail food establishments of section 4205 of the ACA, but used the term "article" for the vending machine food labeling requirements, we disagree with the comments. First, the language of section 403(q)(5)(H)(viii) of the FD&C Act generally provides, in relevant part, that "[i]n the case of an article of food sold from a vending machine . . . the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes . . . the number of calories contained in the article [of food]." (Emphasis added.) Therefore, the calorie declaration must include the number of calories contained in the article of food, and not the number of calories per serving of the food.

Second, the fact that Congress used the term "menu item" in section 403(q)(5)(H)(i)-(vii) of the FD&C Act does not indicate that "article of food"

should be interpreted to mean “per serving” within the meaning of section 403(q)(5)(H)(viii) of the FD&C Act. If Congress intended to require calories to be declared in serving size amounts, Congress could have used specific language to indicate this intent, as demonstrated elsewhere in section 403(q) of the FD&C Act (“serving size,” “number of servings,” and “per serving” in section 403(q)(1)(A) and (q)(5)(H)(iii) of the FD&C Act). Such an omission indicates that declaring calories in serving size amounts was not the intent of Congress. E.g., *Russello v. U.S.*, 464 U.S. 16, 23 (1983) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion”) (citation omitted).

We reiterate, however, that proposed § 101.8(c)(2)(i)(E) (which has been consolidated with proposed § 101.8(c)(2)(i)(D) and renumbered as § 101.8(c)(2)(i)(C) in the final rule, as explained further in the paragraphs that follow) would allow for the voluntary declaration of calories per serving for covered vending machine foods. Regarding the comment suggesting that we revise our serving size regulations, we clarify that this rule implements the requirements of section 403(q)(5)(H)(viii) of the FD&C Act for foods sold in vending machines. For the purposes of this rule, calorie declarations for covered vending machine foods must be provided for the total number of calories contained in the article of food.

As discussed in response 21 of this preamble, we have moved proposed § 101.8(c)(2)(i)(C) and therefore have renumbered proposed § 101.8(c)(2)(i)(D) as § 101.8(c)(2)(i)(C). Additionally, for the reasons noted in the previous paragraphs, and as discussed in section III.C.4.b.iv, we have made changes to renumbered § 101.8(c)(2)(i)(C) to further clarify that a calorie declaration for a covered vending machine food must include the total number of calories for the food, whether the food is a single serving or multiple serving food. In addition, we have added a sentence to § 101.8(c)(2)(i)(C) explaining that for a covered vending machine food with multiple servings a vending machine operator may voluntarily disclose calories per serving in addition to the total calories for the covered vending machine food. This sentence was originally included in § 101.8(c)(2)(i)(E). Because we have moved the sentence to § 101.8(c)(2)(i)(C) and § 101.8(c)(2)(i)(C) now applies to both single- and

multiple-serving covered vending machine foods, we have removed proposed § 101.8(c)(2)(i)(E).

vi. *Calorie declarations on signs in close proximity to the article of food or selection button.*

Proposed § 101.8(c)(2)(ii) would establish requirements pertaining to the placement of calorie declarations. Proposed § 101.8(c)(2)(ii)(A) would require the calorie declarations to be placed on a sign in close proximity to the article of food or selection button, i.e., in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine, so long as the sign is visible at the same time as the food, its name, price, or selection button or selection number is visible.

The preamble to the proposed rule explained that “a sign that is a poster may be an appropriate medium to convey the required calorie declarations, so long as the sign is in close proximity to the covered vending machine food or selection button” (76 FR 19238 at 19243). We also tentatively concluded that for certain types of vending machines with a limited number of selections (e.g., popcorn with or without added butter), the sign with the statement of calories may appear anywhere on the front (or face) of the vending machine, and that “a sign may consist of a handwritten sticker in permanent marking that is affixed to the machine” (76 FR 19238 at 19243).

(Comment 25) One comment asked that we permit a “static cling” type label (e.g., a plastic decal that sticks to a surface because of static electricity) to be placed on the outside of “closed-front” vending machines (i.e., vending machines that do not have transparent glass fronts).

(Response 25) Section 403(q)(5)(H)(viii) of the FD&C Act does not specify how a sign declaring calories is to be affixed to a vending machine or what materials are to be used for the sign. To give vending machine operators the greatest flexibility, the final rule also does not specify the type of material to be used as a sign or the manner in which the sign must be affixed to a vending machine. However, regardless of the material used for the sign, compliance with the calorie labeling requirements is contingent on the sign being in close proximity to each article of food or selection button and otherwise satisfying the requirements of section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

(Comment 26) Many comments supported proposed § 101.8(c)(2)(ii)(A), which would allow a vending machine operator to provide a sign in close proximity to each article of food or

selection button that displays calorie declarations for multiple vending machine foods. These comments stated that allowing vending machine operators to provide a sign with calorie declarations in this manner would be the least expensive and least burdensome way for vending machine operators to comply with section 403(q)(5)(H)(viii) of the FD&C Act. Some comments stated that a sign or poster could cost as little as \$5 per vending machine and would be the “least burdensome” on small businesses. Other comments stated that allowing a vending machine operator to provide calorie declarations on a sign adjacent to or on the vending machine would reduce stocking errors by blind vending machine operators.

Conversely, some comments claimed that section 403(q)(5)(H)(viii) of the FD&C Act requires calorie declarations to be on individual “signs” for each article of food and that posting calorie declarations for multiple foods on a single sign that is not adjacent to the corresponding article of food would not meet the statute’s requirements. One comment argued that if FDA permits calorie declarations for multiple vending machine foods on a single sign, we should at least prohibit such single signs from being placed adjacent to the vending machine, and ensure the close proximity of the single sign to each article of food or the selection button by revising the rule to read as follows: “This calorie information must be placed on a sign next to the article of food or its selection button, or on a sign appended to the front of the vending machine at a similar height as the machine’s selection buttons.”

(Response 26) Section 403(q)(5)(H)(viii) of the FD&C Act expressly states, in relevant part, that a vending machine operator must provide “a sign in close proximity to each article of food or the selection button that includes the number of calories contained in the article.” Section 403(q)(5)(H)(viii) of the FD&C Act does not specify whether vending machine operators must use a single sign with calorie declarations for multiple articles of food, or multiple signs corresponding to each article of food or selection button. To give vending machine operators the greatest amount of flexibility and to take into consideration different types of vending machines, we interpret section 403(q)(5)(H)(viii) of the FD&C Act to allow vending machine operators to use one sign with calorie declarations for all of the covered vending machine food sold from the vending machine or a sign for each covered vending machine food sold

from the vending machine, or a combination of the two, as long as the sign or signs are in close proximity to the covered vending machine food or selection button, as provided in § 101.8(c)(2), and otherwise satisfies the requirements of section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

(Comment 27) Some comments asked us to clarify whether the rule would permit a vending machine operator to provide a sign adjacent to the vending machine that lists calorie declarations for all possible products that could be sold from the machine. The comments stated that such signs would be permanent in nature and would reduce the need to print new signs when different products are added to the vending machine.

Other comments suggested that grouping vending machine food items on a sign by category will allow consumers to better compare products.

(Response 27) We decline to revise § 101.8(c)(2)(ii)(A) to allow a vending machine operator to provide a sign adjacent to the vending machine that lists all possible articles of food that could be sold from the machine. However, we would not object to a vending machine operator providing calorie declarations for articles of food that are typically offered for sale in the specific vending machine but may not be offered for sale at all times (for example, in cases where the article sells out, or is temporarily replaced by another item), provided that the calorie declarations are clear and conspicuous and placed prominently. The calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply “[i]n the case of an article of food sold from a vending machine” (emphasis added). Accordingly, whether a vending machine operator provides individual signs for each article of food or selection button, or a sign with calorie declarations for multiple articles of food, section 403(q)(5)(H)(viii) of the FD&C Act requires vending machine operators to provide clear and conspicuous calorie declarations for those articles of food that are sold from the machine. Vending machine operators must also ensure that such calorie declarations are not false or misleading as required by section 403(a)(1) of the FD&C Act and are prominently placed on signs with such conspicuousness and in such terms as to render the calorie declarations likely to be read and understood by the ordinary individual under customary conditions of purchase and use as required by section 403(f) of the FD&C Act. A long listing of food items, some of which are

not available for sale in a vending machine, might make it more difficult for a prospective purchaser to locate the relevant calorie declarations for articles of food actually sold from the vending machine. In other words, depending on the number of foods listed on the sign and other factors, inclusion of calorie declarations for covered vending machine foods that are not sold from the particular vending machine, could result in the calorie declarations for covered vending machine foods actually sold from the vending machine no longer being clear and conspicuous, non-misleading, prominently placed and likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Therefore, we have revised § 101.8(c)(2)(ii)(A) to state that the list of covered vending machine food items on a sign must give calorie declarations for those articles of food that are sold from that particular vending machine.

At the same time, we recognize that calorie declarations could, in some cases, be displayed for vending machine foods that are not available for sale in the machine at a given time. For example, the food may have been offered for sale in the vending machine but the vending machine may have sold out of that item at some point in time. As another example, a food that is typically stocked in a vending machine might be temporarily replaced by another item. Nevertheless, vending machine operators must continue to ensure that calorie declarations on such a sign are tailored to articles of food currently or typically sold from that particular vending machine and otherwise satisfy the requirements of section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

As for the comments suggesting that signs adjacent to the vending machines should group food items together, the final rule does not prescribe the manner in which articles of food and their associated calories are listed on a sign. Therefore, vending machine operators have the flexibility to organize the information on the signs as they wish, provided that the sign and the information on the sign comply with section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and § 101.8.

(Comment 28) Many comments opposed allowing vending machine operators to declare calories on a sign adjacent to the vending machine. Some comments contended that consumers are unlikely to see calorie declarations on a sign adjacent to a vending machine, particularly compared to calorie declarations posted directly next to each

vending machine food, but did not provide any data to support this contention. One comment suggested that we require a statement on the vending machine directing the consumer to the location of the sign adjacent to the machine.

(Response 28) We disagree with those comments stating that we should not allow signs adjacent to the vending machine. Section 403(q)(5)(H)(viii) of the FD&C Act expressly states that “a vending machine operator shall provide a sign in close proximity to each article of food or the selection button” We have determined that a sign that is adjacent to the vending machine is “in close proximity,” to the covered vending machine food or selection button, so long as the calorie declaration on the sign is visible at the same time as the food, its name, or its selection button or selection number is visible.

We also note that § 101.8(c)(2)(ii) requires that the sign be “placed prominently.” To help ensure that calorie declarations on a sign placed adjacent to the vending machine are clear and conspicuous, and placed prominently, § 101.8(c)(2)(ii)(C) requires that the calorie declaration must be in type that is all black or one color printed on a white or other neutral background that contrasts with the type color. Further, § 101.8(c)(2)(ii)(C) also helps to ensure that such calorie declarations are prominently placed on signs with such conspicuousness and in such terms as to render them likely to be read and understood by the prospective purchaser under customary conditions of purchase and use, consistent with section 403(f) of the FD&C Act. Considering our interpretation of “close proximity” and the requirement of § 101.8(c)(2)(ii), we conclude that an additional statement directing the consumer to the sign is not necessary. Therefore, we decline to amend the rule to require a statement on the vending machine that directs the consumer to the location of a sign adjacent to the vending machine. However, to further address the comments’ concern regarding the visibility of the calorie declarations on a sign adjacent to a vending machine, we have modified § 101.8(c)(2)(ii)(A) to specify that the *calorie declaration* must be visible at the same time as the food, its name, price, selection button, or selection number is visible (emphasis added). In addition, on our own initiative, we have replaced the reference to “[t]his calorie information” at the beginning of § 101.8(c)(2)(ii)(A) with “the calorie declarations” to be consistent with the rest of the final rule.

As discussed in response 20, we have also moved the requirement in the introductory sentence of proposed § 101.8(c)(2)(i) that the number of calories “must be clear and conspicuous,” and placed it instead in the introductory sentence of § 101.8(c)(2)(ii) for this final rule. The “clear and conspicuous” standard more appropriately reflects the requirements in § 101.8(c)(2)(ii), which focus on the placement and appearance of the calorie declarations, rather than the requirements of § 101.8(c)(2)(i), which focus on the content of the calorie declarations.

(Comment 29) One comment, opposed to allowing calorie declarations on signs adjacent to vending machines, compared such signs to stanchions at drive-through restaurants. The comment stated that, in the context of drive-through restaurants, FDA has already taken the position in its proposed rule for nutrition labeling of standard menu items in restaurants and similar retail food establishments (76 FR 19192) that requiring consumers to look to one place (*i.e.*, a menu board) for important food-selection information such as price and then to another (*e.g.*, a stanchion) for calories, “is likely to be more difficult for customers attempting to use the declared calorie information at the point of selection” (76 FR 19192 at 19206). The comment contended that it would be similarly difficult for consumers to use calorie information if consumers had to look at the food in the vending machine and at an adjacent sign for calorie declarations.

(Response 29) We disagree with the comment. Section 403(q)(5)(H)(ii)(II)(aa) of the FD&C Act requires, in relevant part, that a covered restaurant or similar retail food establishment disclose the number of calories in a standard menu item “adjacent to the name of the standard menu item . . . on the menu board, including a drive-through menu board . . .” (emphasis added). Section 403(q)(5)(H)(viii) of the FD&C Act, in contrast, requires a covered vending machine operator to “provide a sign in close proximity to each article of food or the selection button . . .” Thus, the placement of calorie declarations for covered vending machine food under section 403(q)(5)(H)(viii) of the FD&C Act is not directly analogous to the placement of calorie information for standard menu items under section 403(q)(5)(H)(ii)(II)(aa) of the FD&C Act.

Further, we do not consider vending machines to present a situation that is analogous to menu boards at drive-through restaurants or similar retail food establishments. A menu board at a drive-through is distinguishable

because, as we discussed in the proposed rule for nutrition labeling of standard menu items in restaurants and similar retail food establishments (76 FR 19192 at 19206), customers have a restricted field of vision from their car windows while in a drive-through, and they may have a relatively short time to consider and review the menu board before ordering (76 FR 19192 at 19206). Vending machine consumers generally are not faced with similar restrictions. Accordingly, we interpret “a sign in close proximity to each article of food or the selection button” within the context of section 403(q)(5)(H)(viii) of the FD&C Act to mean adjacent to the vending machine in addition to in or on the vending machine.

(Comment 30) Another comment noted that some localities prohibit the use of signs without permits and described certain jurisdictions that would levy a \$25 fine for not obtaining a permit. According to the comment, such ordinances could be problematic for vending machine operators who would prefer to use signs adjacent to the vending machine to meet the calorie declaration requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

(Response 30) This final rule gives vending machine operators the flexibility to comply with the calorie labeling requirements for vending machine foods in a way that minimizes burdens and that does not conflict with local requirements described by the comment. For example, where a State or local requirement regulates use of particular types of signs (*e.g.*, large signs, free-standing signs), a vending machine operator could still comply with the requirements of section 403(q)(5)(H)(viii) of the FD&C Act by providing a sign in or on the vending machine (*e.g.*, using small individual signs or stickers). Alternatively, a vending machine operator could stock foods in a vending machine that permits a prospective purchaser to view the calories, serving size, and servings per container listed in the Nutrition Facts label on the foods, or in a reproduction of the Nutrition Facts label; or that otherwise provides visible nutrition information at the point of purchase, as provided in § 101.8(b).

vii. *Color and contrast for calorie declarations in or on the vending machine.*

Proposed § 101.8(c)(2)(ii)(B) would specify that when the calorie information is in or on the vending machine, the calorie declaration must be in the same color or a color at least as conspicuous as the color of the name or the price of the food or selection number.

We received no comments on this provision. However, on our own initiative, as discussed in response 21, we have moved what was proposed as § 101.8(c)(2)(i)(C) to § 101.8(c)(2)(ii)(B) of this final rule to eliminate a duplicate requirement on color and contrast for calorie declarations in or on the vending machine. Section 101.8(c)(2)(ii)(B) now specifies that when the calorie declaration is in or on the vending machine, the calorie declaration must be in a type size no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, *i.e.*, the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, or a background at least as contrasting as the background used for the item it is in closest proximity to, *i.e.*, name, selection number, or price of the food item as displayed on the machine.

viii. *Type size, color, and contrast for calorie declarations adjacent to the vending machine.*

When the calorie declaration is on a sign adjacent to the vending machine, proposed § 101.8(c)(2)(ii)(C) would require the calorie declaration to be in type that is “all black or one color printed on a white or other neutral background that contrasts with the type color” (76 FR 19238 at 19254). The preamble to the proposed rule explained that we were not proposing a minimum type size for the calorie declaration when it is on a sign adjacent to the vending machine (76 FR 19238 at 19243), and we invited comment on this issue.

(Comment 31) One comment asked that we establish additional requirements for size, type face, and color for the calorie declarations on the signs adjacent to the vending machine but the comment did not provide any specific suggestions.

(Response 31) Unlike calorie declarations in or on the vending machine, calorie declarations on signs adjacent to a vending machine are not accompanied, or otherwise surrounded by, pre-existing text or colors to which we could link the requirements. We note however that section 403(q)(5)(H)(viii) of the FD&C Act requires that calorie declarations be clear and conspicuous, and the requirement that the calorie declarations be clear and conspicuous also is codified in § 101.8(c)(2)(i). Further, section 403(f) of the FD&C Act requires, in relevant part, that any word,

statement, or other information required by or under the FD&C Act to appear in the labeling of food be prominently placed thereon with such conspicuousness 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. Thus, we conclude that a calorie declaration on a sign adjacent to a vending machine must be in a type size large enough to render it likely to be read and understood by the prospective purchaser under customary conditions of purchase and use, and we have revised § 101.8(c)(2)(ii)(C) accordingly. In addition, as discussed in response 28, we have modified § 101.8(c)(2)(ii)(A) to specify that calorie declarations on signs adjacent to vending machines must be visible at the same time as the food, its name, price, selection button, or selection number is visible.

On our own initiative, we have revised § 101.8(c)(2)(ii)(C) to replace the reference to calorie “information” with calorie “declaration” to be consistent with the rest of the final rule.

ix. *Vending machines displaying a picture or other representation of food.*

Proposed § 101.8(c)(2)(ii)(D) would require that, where the vending machine only displays a vignette or name of the food item, the calorie information must be in close proximity to the vignette or name or in close proximity to the selection button (76 FR 19238 at 19254).

We received no comments on this provision. However, on our own initiative, we have revised § 101.8(c)(2)(ii)(D) by inserting the words “picture or other representation” in place of “vignette” for plain language purposes, and by replacing the reference to calorie “information” with calorie “declaration” to be consistent with the rest of the final rule.

x. *Electronic vending machines.*

Proposed § 101.8(c)(2)(ii)(E) would require that, for electronic vending machines (e.g., machines with digital or electronic or liquid crystal display (LCD) displays), the calorie information may be displayed when the selection numbers are entered but before the selection is confirmed.

(Comment 32) Some comments supported proposed § 101.8(c)(2)(ii)(E) and stated that such electronic or LCD displays meet the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. One comment stated that some electronic displays allow the consumer to view the full Nutrition Facts Panel and rotate a virtual image of the product, or otherwise allow consumers to compare the Nutrition Facts of two products side by side.

Many comments opposed or would delete proposed § 101.8(c)(2)(ii)(E). Several comments noted that electronic displays would show calorie declarations for just one food item at a time. A few comments said that calorie declarations for all food items must be available to consumers at the same time before selection of an item so that consumers can compare calorie declarations for items simultaneously. Otherwise, the comments argued, consumers would have to keep track of the calorie declarations for each item until they made a final selection.

One comment said that care should be taken in using the term “purchaser,” which the comment considered to be the person paying for the item. The comment said that the purchaser could be at a different location from the “user” of the vending machine. For example, some vending machines allow a “purchaser” to pay for a vended item in one location while a “user” obtains the vended item in another location. This comment also suggested adding a new provision for clarity to read as follows: “For vending machines retrofitted with digital or electronic or liquid crystal display (LCD) displays, the calorie information may be displayed at the user’s request before the purchase is confirmed by entering a selection ID, selecting a product image, searching by name, or filtering product based on specific criteria.” The comment did not explain why the new provision would focus on retrofitted vending machines.

(Response 32) We disagree with the comments asserting that electronic vending machines cannot meet the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because electronic vending machines might be able to display calorie information for only one food item at a time. First, we note that electronic vending machines that provide calorie declarations in close proximity to vending machine foods or their selection buttons would comply with the calorie declaration requirements in section 403(q)(5)(H)(viii) of the FD&C Act, provided that such calorie declarations otherwise comply with section 403(a)(1) and (f) of the FD&C Act and § 101.8. Second, we understand that electronic vending machines have varying capabilities, and so to provide flexibility for vending machine operators to satisfy the requirements of section 403(q)(5)(H)(viii) of the FD&C Act, we are not requiring calorie declarations for electronic vending machines to be rendered simultaneously, although some electronic vending machines may have this capability. An electronic display

that provides calorie declarations for one food at a time, allowing the prospective purchaser to cancel his or her initial selection, and then select other items in order to obtain the calorie declaration for each of them would constitute “a sign in close proximity to each article of food or the selection button . . . disclosing the number of calories contained in the article,” as required by section 403(q)(5)(H)(viii) of the FD&C Act. We therefore conclude that electronic vending machines may satisfy the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

However, to further ensure that the prospective purchaser is able to view the calorie declaration before making a purchase, we have revised § 101.8(c)(2)(ii)(E) on our own initiative to replace the proposed language with language stating that the calorie declaration must be displayed before the prospective purchaser makes his or her purchase.

As discussed in response 13, we also note that an electronic reproduction of the Nutrition Facts label could be one way that a vending machine could permit a prospective purchaser to examine the Nutrition Facts Panel for an article of food to satisfy section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. Therefore, we have revised § 101.8(b)(2) by adding a new paragraph (b)(2)(ii) pertaining to electronic reproductions of the Nutrition Facts label.

We decline to adopt the comment’s suggestion that we revise the final rule to distinguish between a vending machine “user” and “purchaser.” Section 403(q)(5)(H)(viii) of the FD&C Act uses the term “prospective purchaser” and does not make a distinction between a “prospective purchaser” and a vending machine “user.” Accordingly, we decline to make such a distinction in the final rule.

We also decline to adopt the comment’s suggested language regarding “retrofitted” vending machines and the manner in which calorie information may be displayed. Section 403(q)(5)(H)(viii) of the FD&C Act does not address retrofitting of vending machines with digital, electronic, or other displays, and does not distinguish between retrofitted vending machines with such displays and other vending machines. We also note that the comment’s suggested language, “may be displayed at the user’s request,” would make the display of calorie information discretionary, and such a result would be inconsistent with the statutory requirement of section 403(q)(5)(H)(viii) of the FD&C Act that a covered vending machine operator provide a sign

disclosing the number of calories contained in a covered vending machine food.

xi. *Vending machines with limited choices.*

Proposed § 101.8(c)(2)(ii)(F) would provide that for vending machines with limited choices, such as vending machines that dispense only popcorn, the declaration of calories may appear on the face of the machine so long as the declaration is prominent, not crowded by other labeling on the machine, and the type size is reasonably related to the largest print on the vending machine.

We received no comments on this provision. However, as described in response 16 of this preamble, we revised § 101.8(b)(2)(i), in response to comments regarding type size and prominence of the visible nutrition information on the label of the food, to replace the words “reasonably related” with “at least 50 percent of the size of the largest print on the label.” For consistency with our edit to § 101.8(b)(2)(i) and to provide additional clarity, we are revising § 101.8(c)(2)(ii)(F). We considered whether to replace “reasonably related to the largest print on the vending machine” with “at least 50 percent of the size of the largest print on the vending machine.” However, we note that unlike § 101.8(b)(2)(i), where we are establishing a type size requirement based on other printed material on the label of a package of food, here we are establishing a type size requirement based on other printed material on the vending machine itself. Given the comparatively large surface area of vending machines, we are not requiring that the calorie declaration be 50 percent of the size of the largest print on the face of the vending machine, as the largest print could potentially be very large. Instead, § 101.8(c)(2)(ii)(F), as finalized, provides that for vending machines with limited choices, the declaration of calories may appear on the face of the machine so long as the declaration is prominent, not crowded by other labeling on the machine, and the type size is no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest.

5. Voluntary Registration To Provide Calorie Labeling for Foods Sold From Vending Machines

Proposed § 101.8(d) would provide that a vending machine operator that is not subject to section 403(q)(5)(H)(viii) of the FD&C Act may voluntarily register with FDA to be subject to the calorie labeling requirements established in § 101.8(c)(2). Proposed

§ 101.8(d)(1) and (d)(2) would describe the applicability of the voluntary registration provision and who may register. Proposed § 101.8(d)(3)(i) through (d)(3)(iv) would list the information that a vending machine operator would be required to provide to FDA (*i.e.*, contact information for the vending machine operator, address of the location of each vending machine, preferred mailing address, certification of the information submitted) in order to register voluntarily. Proposed § 101.8(d)(3)(v) and (d)(3)(vi) also would describe the mechanism for submission of the information by email, fax, mail, or online form. Finally, proposed § 101.8(d)(3)(vii) would require re-registration every other year within 60 days prior to the expiration of the vending machine operator’s current registration with FDA.

We received comments asking us to expand the voluntary database to require registration of all operators of covered vending machines, and we will address those comments in section III.C.6 of this preamble. We received no other comments on proposed § 101.8(d). However, on our own initiative, we have revised § 101.8(d) to clarify that the vending machine operator, rather than its authorized official, becomes subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act through voluntary registration, even if the authorized official voluntarily registered on the vending machine operator’s behalf. Also, for completeness, we have added “.gov” to the end of the email address provided for voluntary registration under § 101.8(d). The complete email address now reads “*menulawregistration@fda.hhs.gov*.”

6. Vending Machine Operator Contact Information

(Comment 33) Some comments said we should develop a database of covered vending machine operators and those who have elected to comply voluntarily with section 403(q)(5)(H)(viii) of the FD&C Act. The comments stated that the database could enable state and local inspectors to determine which vending machines are subject to the calorie declaration requirements of section 403(q)(5)(H)(viii) of the FD&C Act.

Another comment suggested that, to help with enforcement, we could expand the voluntary registry in § 101.8(d) to require all operators of covered vending machines to provide FDA with their names, contact information, and number and location of vending machines. The comment stated that we could share this

information with States and localities that enforce local calorie labeling laws. As an alternative, the comment suggested that we require vending machine operators to post this information (name, contact information, etc.) on the front of each vending machine.

(Response 33) The final rule, at § 101.8(e)(1) and (e)(2), adds a requirement for vending machine operators to post their contact information for vending machines selling covered vending machine food. (We have renumbered proposed § 101.8(e), which dealt with the topic of signatures, as § 101.8(f) in the final rule). As indicated by a comment, such a requirement is necessary for efficient enforcement of section 403(q)(5)(H)(viii) of the FD&C Act because it enables FDA to contact vending machine operators for enforcement purposes. Without such a requirement, we would not be able to contact vending machine operators subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act because such contact information would not always be readily available to the Agency. Section 101.8(e)(1) specifies that the contact information must list the vending machine operator’s name, telephone number, and mailing address or email address.

Section 101.8(e)(2) specifies that the contact information must be readable and may be placed on the face of the vending machine, or otherwise must be placed with the calorie declarations described in § 101.8(c)(2)(ii) (*i.e.*, on the sign in, on, or adjacent to the vending machine). We are providing flexibility to vending machine operators regarding where they can display the contact information. We note that some States have licensing requirements for vending machine operators, and some of these licensing requirements already require the vending machine operator’s license or contact information to be displayed on the vending machine. If the contact information displayed on a vending machine due to State or local requirements includes some but not all of the contact information required under § 101.8(e)(1), the vending machine operator must display the remaining contact information required under § 101.8(e)(1) in the manner specified under § 101.8(e)(2). In other words, rather than requiring the vending machine operator to display contact information twice, we are providing flexibility by allowing vending machine operators to display the remaining contact information in a manner permitted in § 101.8(e)(2). For example, if a vending machine operator is required to display its name and address

on the face of a vending machine under an applicable State or local requirement and the operator complied with such requirement, the operator could display the remaining contact information required under § 101.8(e)(1) (*i.e.*, its phone number) on the face of the vending machine or on the sign listing calorie declarations in, on, or adjacent to the vending machine in order to comply with § 101.8(e). Regardless of the method that vending machine operators select to satisfy the requirements of § 101.8(e), they should ensure that the information being provided is their contact information.

As for the comments requesting that all vending machine operators (including those who are subject to section 403(q)(5)(H)(viii) of the FD&C Act and those who voluntarily register to be subject to section 403(q)(5)(H)(viii) of the FD&C Act) register with FDA, we decline to establish such a database at this time. We believe it would be more practical to wait until we and vending machine operators have been able to implement the vending machine labeling requirements and see what issues arise as part of that implementation.

7. Signatures

Proposed § 101.8(e) would provide that signatures obtained under the voluntary registration provisions that meet the definition of electronic signatures in § 11.3(b)(7) are exempt from the requirements of part 11.

The preamble to the proposed rule indicated that we expect this exemption for signatures to facilitate the voluntary registration process (76 FR 19238 at 19245).

We received no comments on this provision, however because we have added a new § 101.8(e) (contact information of vending machine operators for vending machines selling covered vending machine food), we have renumbered this provision as § 101.8(f).

D. Determination of Calorie Content

Section 403(q)(5)(H)(viii) of the FD&C Act does not prescribe where or how covered vending machine operators must obtain the necessary calorie information to meet the calorie declaration requirements for covered vending machine foods. If a covered vending machine food does not bear Nutrition Facts, we anticipated in the preamble to the proposed rule, that the vending machine operator could obtain the calorie information from food manufacturers or suppliers (76 FR 19238 at 19242). We invited comment on whether “a vending machine

operator may use nutrient databases, cookbooks, laboratory analyses, and other reasonable means” if calorie information is not available from the food manufacturer or supplier (*Id.*). We also invited comment on “whether vending machine operators should be required to provide FDA the information on which they relied to determine the total calories posted for the vending machine food” (76 FR 19238 at 19242).

(Comment 34) One comment supported allowing covered vending machine operators to use nutrient databases and cookbooks as tools for determining calorie information if calorie information is not available from the food manufacturer or supplier. The comment also suggested allowing menus as a tool for determining calorie information. Further, the comment said that we should not require vending machine operators to give FDA the method or information on which the vending machine operators relied to determine the total calories posted for the vending machine food. The comment said that such a requirement would be an economic burden both for the vending machine operator to provide such information and for FDA to collect, record, and store such information. Another comment suggested that FDA require covered vending machine operators to have a reasonable basis for calorie declarations for vending machine foods, in accordance with the reasonable basis provision for nutrition labeling for standard menu items offered for sale in restaurants and similar retail food establishments in section 403(q)(5)(H)(iv) of the FD&C Act.

(Response 34) We agree with the comments supporting the use of nutrient databases and cookbooks to determine the total calories contained in a covered vending machine food. A vending machine operator may obtain the necessary calorie information from the food package’s Nutrition Facts label, the manufacturer or supplier of the food, nutrient databases, cookbooks, or laboratory analyses. We anticipate that, for most packaged foods, the vending machine operator will use the food package’s Nutrition Facts label to determine calorie information for the food.

Menus likely would not be a reliable means of determining the calorie information for a vending machine food, because the ingredients, portion size, and method of preparing a food listed on a menu may differ from those used for a food sold from a vending machine. Such differences may result in a calorie declaration for a food listed on a menu

that does not accurately reflect the calorie content of the same food sold from a vending machine. We recognize, however, that compliance ultimately is based on the accuracy of the declaration rather than just the method used to determine the calorie information.

We anticipate that vending machine operators are likely to generate and maintain a record of the information on which they relied to determine the total calories posted for the vending machine food. We encourage vending machine operators to be prepared to share it with FDA upon our request during an inspection if we need to determine whether the calories declarations, posted by a vending machine operator under § 101.8(c), are truthful and not misleading.

We disagree with the comment suggesting that we apply the reasonable basis provision in section 403(q)(5)(H)(vi) of the FD&C Act to covered vending machine food. The reasonable basis requirement in section 403(q)(5)(H)(vi) of the FD&C Act applies only to restaurants and similar retail food establishments covered by the requirements of section 403(q)(5)(H) of the FD&C Act, and does not apply to covered vending machine food. We note that covered vending machine operators must ensure that calorie declarations are truthful and not misleading under section 403(a)(1) of the FD&C Act, and otherwise comply with section 403(q)(5)(H)(viii) and (f) of the FD&C Act and § 101.8.

E. Effective Date

The preamble to the proposed rule indicated that a final rule would become effective 1 year from the date of publication of the final rule in the **Federal Register** (76 FR 19238 at 19245).

(Comment 35) Many comments suggested that FDA make the final rule effective 6 months after its publication. Noting that we proposed a 6-month effective date in the proposed rule pertaining to nutrition labeling of standard menu items in restaurants and similar retail food establishments, the comments argued that labeling foods sold in vending machines with calorie information would be even less burdensome than restaurant menu labeling because a vending machine operator could simply post stickers listing calories to meet the requirements. The comments asserted that vending machine operators should be able to comply with the calorie labeling requirements within the same timeframe that we proposed in the proposed rule for nutrition labeling of standard menu items in restaurants and

similar retail food establishments (76 FR 19192).

Other comments—many from vending machine trade associations—requested a minimum of 2 years to come into compliance. The comments claimed that 1 year was not sufficient time to come into compliance because more than 70 percent of vending machine operators have three or fewer employees. Some comments said that because vending machine operators may have few employees, placing calorie declarations for all of their vending machines would be costly and time-consuming.

A few comments asserted that a 2-year effective date is needed due to a lengthy design and test process for new vending machines, and to establish a relationship between vending machine operators and food manufacturers in order to develop “verification procedures” which typically do not exist at the present time. The comments did not explain what they meant by “verification procedures.”

Another comment suggested a phased-in implementation period to give vending machine operators a longer time to meet the calorie declaration requirements. The comment did not state how long the phased-in implementation period should be.

A few comments said we should follow the same approach that we have taken historically for other food labeling changes and cited FDA’s uniform compliance date policy for food labeling regulations. The comments stated that the uniform compliance date for food labeling regulations issued between January 1, 2011, and December 31, 2012, is January 1, 2014 (75 FR 78155 (December 15, 2010)), and we should, therefore, impose an effective date of January 1, 2014, assuming the final rule publishes before December 31, 2012.

(Response 35) We recognize that vending machine operators may have few employees and resources. We also understand that vending machine manufacturers and food manufacturers are continuing to design new products, and that vending machine operators may wish to work with vending machine manufacturers and food manufacturers to develop ways to comply with section 403(q)(5)(H)(viii) of the FD&C Act. We are also taking into consideration FDA’s 2012 final rule (77 FR 70885, November 28, 2012), which establishes January 1, 2016, as the next uniform compliance date for food labeling changes required by food labeling regulations that are issued between January 1, 2013, and December 31, 2014. Because vending machine operators may display the Nutrition Facts label or other visible nutrition

information in order to satisfy § 101.8(b), it would be helpful for vending machine operators to see any changes that manufacturers may make to the labels of packaged foods which may be timed in accordance with the next uniform compliance date. For these reasons, we are revising the effective date of the final rule to 2 years from the date of its publication in the **Federal Register**, which will be after the January 1, 2016 uniform compliance date. All covered vending machine operators must come into compliance with the requirements of this rule no later than 2 years after the date of its publication.

F. Enforcement

(Comment 36) Some comments said we should devise a reporting mechanism for individuals to report possible violations of section 403(q)(5)(H)(viii) of the FD&C Act and a regime of penalties for confirmed violations. These comments also suggested that we develop a protocol for checking the accuracy of the calorie information provided by covered vending machine operators.

(Response 36) We decline to establish a reporting mechanism for individuals to report possible violations of section 403(q)(5)(H)(viii) of the FD&C Act or the final rule. FDA’s regulations already provide individuals with mechanisms to communicate with the Agency. If an individual finds that the calorie declaration for an article of food sold from a vending machine is incorrect, he or she can contact FDA by calling the FDA complaint coordinator for their region (<http://www.fda.gov/Safety/ReportProblem/ConsumerComplaintCoordinators/default.htm>).

As for the comments’ suggestion regarding penalties, penalties are already set forth in the FD&C Act. We are establishing these regulations under sections 201(n), 403(a)(1), (f), (q)(5)(H), and 701(a) of the FD&C Act. Therefore, we note that failure to comply with the regulations will render the covered vending machine food misbranded under section 403(a), (f), or (q) of the FD&C Act. Violations of § 101.8 may result in enforcement action. For example, introducing, delivering for introduction, or receiving a misbranded food in or into interstate commerce, or misbranding a food while it is in interstate commerce or being held for sale after shipment in interstate commerce, are prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331), carrying criminal penalties under section 303 of the FD&C Act (21 U.S.C. 333). In addition, under section 302 of the FD&C Act (21 U.S.C. 332), the

United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 304(a)(1) of the FD&C Act (21 U.S.C. 334(a)(1)), food that is misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce may be seized by order of a Federal court.

With respect to the comments suggesting that we develop a protocol to check the accuracy of calorie information, we intend to develop an enforcement strategy as we gain more experience with the final rule. For example, we could first check to ensure that the calorie declaration provided by a covered vending machine operator matches the calorie information on the article of food from the food manufacturer or supplier, such as on the Nutrition Facts label. We could also use lab analyses to determine whether the calorie declaration for a given vending machine food is accurate.

(Comment 37) Another comment asked us to provide training, guidance, and funding to State and local inspectors to facilitate enforcement.

(Response 37) The final rule does not become effective until December 1, 2016. During that period we will assess resources and consider conducting training or further outreach as necessary.

IV. Analysis of Impacts—Final Regulatory Impact Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a detailed Regulatory Impact Analysis (RIA) that presents the benefits and costs of this final rule (Ref. 1) which is available at <http://www.regulations.gov> (enter Docket No. FDA–2011–F–0171). The full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the **Federal Register** but are submitted to the docket and are available at <http://www.regulations.gov>. We also post the full economic impact analyses of FDA regulations at the following Web site: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

We believe that the 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. According to our analysis, we believe that the final rule will have a significant economic impact on a substantial number of small entities, and we have accordingly analyzed regulatory options that would minimize the economic impact of the rule on small entities consistent with statutory objectives. We have crafted the final rule to provide flexibility for compliance.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 \$141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The analyses that we have performed to examine the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are included in the RIA (Ref. 1).

We had prepared a “Preliminary Regulatory Impact Analysis” (Ref. 2) in connection with the proposed rule. We also included sections titled “Summary Preliminary Regulatory Impact Analysis” and “Initial Regulatory Flexibility Analysis” in the preamble to the proposed rule (76 FR 19238 at 19245–19249). We received comments on our analysis of the impacts presented in those sections, and the RIA (Ref. 1) contains our responses to those comments.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given in this section of the document with estimates of the annual reporting and third-party disclosure burden. Included in each

burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We had included a section entitled “Paperwork Reduction Act” in the preamble to the proposed rule (76 FR 19238 at 19249–19251). We received the following comments on our analysis of the burdens presented in the proposed rule.

(Comment 38) One comment stated that we did not calculate the burdens to the suppliers of vending machine food. The comment stated that these suppliers will bear the larger burden from the requirements of the final rule.

(Response 38) Neither section 403(q)(5)(H)(viii) of the FD&C Act nor the final rule applies to suppliers of vending machine food; instead, section 403(q)(5)(H)(viii) of the FD&C Act and the final rule establish requirements for certain vending machine operators. We recognize that a supplier of covered vending machine food may provide calorie information on front-of-package labeling and such calorie information may constitute visible nutrition information in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act provided that the applicable requirements of § 101.8(b) are satisfied. However, neither section 403(q)(5)(H)(viii) of the FD&C Act nor the final rule requires suppliers to provide such information. As such, the final rule does not impose burdens on suppliers of vending machine food.

(Comment 39) One comment stated that posting calories would not be burdensome, as most foods sold in vending machines already provide calorie information on their Nutrition Facts labels, and for foods that do not already have calorie information, labeling to disclose calories can be accomplished easily by using stickers. Another comment stated that, in light of the major beverage companies’ prior commitment to putting calorie information on selection buttons, we should reduce our burden estimate.

(Response 39) To the extent that foods sold from covered vending machines permit a prospective purchaser to examine the Nutrition Facts label before purchasing the food or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(b), the vending machine operator would not be required to provide calorie declarations for such foods. In addition, we recognize that the “Clear on Calories” commitment by the American Beverage Association, which

includes a pledge that calories will be displayed on selection buttons of “company-controlled vending machines,” may be consistent with the calorie declaration requirements of section 403(q)(5)(H)(viii) of the FD&C Act. Our estimates of the burdens already account for the fact that many vending machine foods will not require additional nutrition analysis under this final rule. For example, we estimate in the RIA that only 723 to 963 covered vending machine operators will need to acquire nutrition information for at least some of their vending machine food (Ref. 1).

Our estimate of the burdens and cost of nutrition analysis also takes into consideration that vending machine operators can comply with the requirements of the final rule by providing calorie declarations through less burdensome and less expensive means (e.g., a poster affixed to the front of the machine could cost, on average, \$20 per machine per year) (Ref. 1). The final rule does not prescribe the types of materials through which calories must be declared, and a sticker, for example, could be an appropriate medium to convey a required calorie declaration.

(Comment 40) One comment stated that our estimate on how frequently labeling would need to change is too low. The comment stated that in almost all cases, machines are restocked and serviced every 5 weeks, with busier locations stocked once or more per week. The comment stated that the restocking will require labeling changes because restocking may result in the substitution of certain products for other products or the addition of new products. The comment stated that relabeling would need to occur between 10 and 17 times per year for each machine, with some machines requiring partial relabeling at least 50 times per year.

(Response 40) In the preliminary RIA, we estimated an average recurring burden of between 5 and 15 minutes per vending machine per year to install or refresh the calorie displays. We said that signs would not always need to be updated every time a machine’s product mix (i.e., the assortment of vending machine foods offered for sale in a vending machine at a particular time) changed.

We recognize that the product mix in a particular vending machine may change with each restocking. For each machine, the rule requires operators to declare the calorie information for those articles of food that are sold from that particular vending machine. However, we would not object to a vending machine operator providing calorie

declarations for articles of food that are typically offered for sale in a vending machine but may not be offered for sale at all times (for example, in cases where the article sells out, or is temporarily replaced by another item), provided that the calorie declarations are clear and conspicuous and placed prominently. Thus, signs would not always need to be updated every time a machine's product mix changed, so long as the sign declares the calories for each article of food sold from the covered vending machine. For example, if a particular article of food is sold out, the vending machine operator would not need to design and print a new sign to remove the calorie declaration for such food. In addition, to the extent that foods sold from covered vending machines permit a prospective purchaser to examine the Nutrition Facts label before purchasing the food or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b), the vending machine operator would not be required to provide calorie declarations for such foods. Therefore, restocking of covered vending machines that sell such foods would not require the vending machine operator to update signs. Furthermore, in order to accommodate the occasional trial or experimental product, the sign template could, for example, be designed with blank space, on which the operator could handwrite the experimental product's name and caloric value, or place a declarative sticker next to the new product within the machine (should it have a glass/plexiglass front). The comment provided an estimate of the number of times a vending machine's sign would likely need to be replaced, or 10 to 17 times. We estimate that in accordance to the factors described in the earlier paragraphs of this response, calorie declaration signs would only need to be replaced between 1 and 4 times per year

(or even zero for some products). This estimate also takes into consideration that vending machine operators have the flexibility to choose a medium (e.g., stickers, posters) and a format (e.g., individual signs per covered vending machine food; sign(s) in, on, or adjacent to the vending machine) for the calorie declaration that will make the most sense for a particular vending machine operator depending on the variability of products that the operator carries and the frequency of restocking.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Information Collection Provisions of the Final Rule on Food Labeling; Calorie Labeling of Articles of Food in Vending Machines

A. Reporting Requirements

Description of Respondents

The likely respondents to this information collection are vending machine operators that voluntarily elect to be subject to the Federal requirements of this rule by registering with FDA.

Description

Vending machine operators not subject to the requirements of the ACA may elect to be subject to the Federal requirements by registering with FDA. Vending machine operators that

voluntarily register must provide FDA with their contact information, the address of the location of each vending machine owned or operated by the vending machine operator that is being registered, the preferred mailing address (if different from the vending machine operator address) for purposes of receiving correspondence, and certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered vending machine will be subject to the requirements of § 101.8. In the proposed rule, the total reporting burden included both the reporting burden for menu labeling and vending machine operator voluntary registration (see 76 FR 19238 and 19251). For the final rule, these burdens are estimated separately for each rule. To keep the establishment's registration active, the authorized official of the vending machine operator must register every other year within 60 days prior to the expiration of the vending machine operator's current registration with FDA. Registration will automatically expire if not renewed.

Vending machine operators that have voluntarily registered to become subject to the Federal requirements must satisfy the calorie labeling requirements of section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8(c). We further note that an article of food sold from a vending machine operator who has voluntarily registered with FDA to be subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act is not required to provide calorie declarations for articles of food sold from a vending machine that permits the prospective purchaser to examine the Nutrition Facts label before purchasing the article as provided in § 101.8(b)(1), or otherwise provides visible nutrition information at the point of purchase as provided in § 101.8(b)(2).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN: VOLUNTARY REGISTRATION ¹

21 CFR part 101	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Initial Burden (annualized over 3 years): § 101.8(d) Initial Registration	13	1	13	2	26
Annual Burden: § 101.8(d) Registration Renewal	19	1	19	² 0.5	9.5
Total Burden Hours	35.5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² 30 minutes.

We lack data on the number of vending machine operators with fewer than 20 machines that might voluntarily register to comply with this final rule. We do not expect the net benefit for voluntary registration by any non-covered vending machine operators to be positive and in the RIA (Ref. 1) we indicate that as of the conducting of this analysis, no vending machine operators have voluntarily registered with FDA. Therefore we did not estimate a significant burden in the RIA (Ref. 1). However, in the event that a few will register anyway, or find some positive incentive to do so, for the purposes of this PRA analysis, we estimate the burden such operators will face. We estimate there are approximately 757 vending machine operators with fewer than 20 machines; this number is based on the mean estimate of the low and high counts of firms with less than \$50,000 in annual revenue from the RIA (Ref. 1). We estimate that 5 percent of vending machine operators with fewer than 20 machines may voluntarily register to become subject to the final requirements, or 38 operators. We estimate a burden of approximately 2 hours per initial registration, which yields a total burden of 76 hours (38 total operators \times 2 hours per response). Annualizing this number over 3 years yields a rounded 13 respondents per year (5 percent \times 757 operators/3 years). With an annualized estimate of 13 vending machine operators and one registration per vending machine operator at 2 hours per registration, we

estimate the initial hourly burden for these operators is 26 hours.

We expect that renewal registrations after the first year will require substantially less time because operators are expected to be able to affirm or update the existing information in an online account in a way similar to other FDA firm registration systems. Therefore, we estimate that re-registration will take 0.5 hours for each registrant. This would indicate that biennial registration would impose a burden of 19 hours (38 operators \times 0.5 hours) every 2 years, or 9.5 hours every year (18 operators every year \times 0.5 hours).

B. Recordkeeping Requirements

The preamble to the proposed rule (76 FR 19238 at 19249–19251) provided an estimate of the recordkeeping burden, which consisted of the burden associated with calorie analysis and the burden associated with generating, providing, or maintaining records. Upon further consideration, we have omitted the burden estimate associated with generating, providing, or maintaining records previously provided in table 3 of the proposed rule because the rule does not require vending machine operators to generate, provide, or maintain records. Further, as discussed in section C of this analysis, we have included a burden estimate for calorie analysis as part of the third party disclosure burden, since the “total time, effort, or financial resources expended by [covered vending machine

operators]” (5 CFR 1320.3(b)) to declare calories for covered vending machine food likely includes time, effort, or financial resources to determine the calorie content of such food.

C. Third-Party Disclosure Requirements

Description of Respondents

The likely respondents to this information collection are vending machine operators that are subject to the ACA’s requirements and those that choose to voluntarily register to comply with the disclosure requirements.

Description

We calculate two types of third party disclosure burdens under the rule. The first burden is the time and effort expended by vending machine operators to determine the calorie content of covered vending machine food for the required calorie declarations, which we refer to as “Calorie Analysis.”

Vending machine operators must also provide calorie declarations for covered vending machine foods on signs in, on, or adjacent to vending machines. The second burden is the cost of materials and the time expended by vending machine operators to physically produce and install the signs for the calorie declarations, which we refer to as “Calorie Declaration Signs.” We estimate the burden of signage for non-bulk and bulk vending machines separately. We provide our estimates of the third party disclosure burdens in table 2.

TABLE 2—THIRD PARTY DISCLOSURE BURDEN

21 CFR part 101	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours	Capital costs
§ 101.8(c)(2)(i), Calorie Analysis	282	11	3,102	1	3,102
§ 101.8(c)(2)(ii), Template Design	3,279	5	16,395	2	32,790
§ 101.8(c)(2)(ii), Sign Creation	3,279	125	409,875	0.475 (28.5 min.) ..	194,710	\$4,671,047
§ 101.8(e)(1), Contact Information	3,279	125	409,875	0.025 (1.5 min.)	10,248
§ 101.8(c)(2)(ii), Sign Installation	1,868,419	1	1,868,419	0.083 (5 min.)	155,079
§ 101.8(c)(2)(ii), Sign Information Update.	511,576	2	1,023,152	0.5 (30 min.)	511,576
§ 101.8(c)(2)(ii), Sign Replacement ..	1,755,986	2	3,511,972	0.17 (10 min.)	597,035
§ 101.8(c)(2)(ii), Bulk Machine Signage.	128,533	1	128,533	0.025 (1.5 min.)	3,213
Total Burden	1,507,753	4,671,047

Third-Party Disclosure Requirements: Calorie Analysis

A calorie analysis entails the burden of determining calorie content for covered vending machine food. Most foods sold from vending machines provide the nutrition labeling required by section 403(q) of the FD&C Act and

§ 101.9, including calorie content information, which means that calorie content for many covered vending machine foods is already available on the Nutrition Facts labels for such foods. In that case, vending machine operators will not need to determine the calorie content of such foods because they can

simply declare the calorie information they find on the Nutrition Facts label. Nevertheless, some operators may need to determine calorie information for those vending machine foods that may not bear Nutrition Facts labels or otherwise provide visible nutrition information at the point of purchase in

accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b). An operator may obtain the necessary calorie information from nutrient databases, cookbooks, or laboratory analyses. Calorie analysis will most likely only be needed for vended food items such as refrigerated, frozen, can/bowl, or other shelf-stable main meal items, hot cup beverages, and cold cup beverages. We anticipate that vending machine operators are likely to generate and maintain a record of the information on which they relied to determine the total calories posted for the vending machine food.

As stated in the RIA (Ref. 1), we estimate the mean number of vending machine operators that need calorie analysis to be 847. Annualizing this estimate over 3 years yields 282 operators. We also estimate the range of products available in a typical machine for each of the three most commonly sold product categories that are likely to require a calorie analysis, or 3 percent of food items, 5 percent of hot beverages, and 1 percent of cold cup beverages. We estimate that food machines typically offer between 10 and 25 different items, and both hot beverage and cold cup beverage machines typically offer between 5 and 10 items. From this, we estimate each vending machine operator will require a calorie analysis for 11 items, on average. These estimates were based upon conversations with vending machine operators (Ref. 3) and our survey of various vending machine models that vend these types of food and beverage (Ref. 4). Based on data from FDA's Recordkeeping Cost Model (Ref. 5), we estimate the time needed to determine the calorie content of each covered vending machine food to be approximately 1 hour. Our estimate for the burden hours that would be required for new calorie analysis is then 9,317 hours (847 operators \times 11 products needing analysis \times 1 hour per analysis). Annualizing this value over 3 years yields 3,102 hours (847 operators/3 years \times 11 products needing analysis \times 4 hours per analysis). (847 operators/3 years = 282 operators per year.) There will not be capital costs associated with a calorie analysis.

Third-Party Disclosure Requirements: Calorie Declaration Signs

Under this rule, covered vending machine operators with 20 or more vending machines and vending machine operators that voluntarily register to become subject to the Federal requirements, must disclose calorie information by providing calorie declaration signs in, on, or adjacent to

their vending machines to a third party who will most often be the prospective purchaser or consumer. Our burden estimate for the calorie declaration signs is based on the total time it takes for vending machine operators to produce and install the calorie declaration signs. We separately estimate the burden for two kinds of vending machines, non-bulk and bulk machines. For non-bulk vending machines, we estimate the burden to operators as the initial time it takes them to develop the calorie disclosure signage, which includes the time for the sign template design (*i.e.* the creation of generalized sign templates), sign creation (*i.e.* using templates to design machine-specific signs), and installation; and then the time for the recurring burden, which includes the time to update or change calorie information and the physical replacement of the disclosure signage when the product mix of the machine changes. For bulk machines, we estimate the burden to operators for the cost of individual calorie labels. (We assume that individual calorie declaration stickers will be placed on the face of each individual bulk vending machine, since each machine only vends a single product.) Recurring updates to signage will only likely be required for non-bulk, non-beverage machines since the product mixes of these machines are changed regularly, while the product mix for bulk machines is unlikely to change.

We estimate there is an average of 9,838 (9,800 covered non-bulk + 38 voluntary) vending machine operators subject to the rule. (9,838/3 = 3,279 annualized). Our estimate for the average number of non-bulk vending machines that will require declaration signage is based upon data obtained from the Vending Times Survey and National Automatic Merchandising Association (NAMA) and the Economic Census, and as summarized in table 8 of the final RIA (Refs. 1, 6 to 8). We estimate there is an average of 5.61 million non-bulk vending machines. Digital signage is an emerging technology, and according to NAMA approximately 0.1 percent of all vending machines in operation currently have electronic video displays capable of providing calorie information, or approximately 4,014 to 5,670 vending machines (Ref. 3). Subtracting the number of vending machines with the electronic video from the total machine count yields an average of 5.611 million vending machines that will need signage. We expect the number of vending machines that will require signage to decline over time as

manufacturers continue to add the required calorie information to the principal display panel of the package as part of "front of package labeling," and because we anticipate greater use of electronic video displays on vending machines. In addition, to the extent that covered vending machines sell foods that permit prospective purchasers to examine the Nutrition Facts label before purchase or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b), this analysis may overestimate the burden estimate for calorie declaration signs.

We estimate the time it takes for the one-time design of a calorie disclosure sign template to be 2 hours. The number of templates a given firm would need to design to produce signs that comply with the rule may vary based upon the number of different types of products the firm purveys. We estimate a range of one to ten templates would be necessary. We base this range on the eight general food and beverage vending categories monitored by the Vending Times Census, plus two additional templates to account for the existence of combination machines, which vend more than one general product type (*e.g.* snacks and cold canned beverages)—see table 4 of the final RIA (Refs. 1, 6). Since not all firms will sell items from each of the general food categories, we estimate that on average, firms will sell items from approximately four general food categories and operate one set of combination machines, requiring the need to develop (on average) five templates. At 2 hours per template, the total initial burden for designing templates comes to an estimated 98,380 hours (9,838 operators \times 5 templates \times 2 hours per template). Annualizing this value over 3 years yields a burden of 32,790 hours (9,838 operators/3 years \times 5 templates \times 2 hours per template). There are no capital costs associated with template design.

We estimate the time it takes to enter calorie information into a single sign template and prepare it for printing to be 0.475 hours. Again, we estimate the number of machine configurations to be 125. The count of machine configurations is a general estimate of the number of different types of machines an operator uses to sell its products, and takes into account that fact that a machine's specific product mix will depend on locational characteristics (*e.g.* office vs. hotel) and the type of machine (*e.g.* beverage vs. snack). We estimate the total initial burden for sign creation using the predesigned templates to be 584,131

hours (9,838 operators \times 125 sign formats \times 0.475 hours per sign). Annualized over 3 years, this burden becomes 194,710 hours (9,838 operators/3 years \times 125 signs \times 0.475 hours per sign). Capital costs associated with sign creation correspond to the cost of paper and ink for printing the signs. As estimated in the RIA (Ref. 1), the capital costs are \$2.50 per sign, which results in a total capital cost of \$14,013,143 [(5,604,914 covered non-bulk machines + 343 voluntarily registered machines) \times \$2.50 per machine]. Annualized over 3 years, this value becomes \$4,671,048 (5,605,257 machines/3 years \times \$2.50 per machine).

Vending machine operators must also provide their contact information on each vending machine selling covered vending machine food as required under § 101.8(e)(1). We assume that vendors that do not already have a sign or label with their contact information will add their contact information into the initial sign design. We estimate the time it takes to include contact information is 1.5 minutes (0.025 hours) for each sign. We estimate the total initial burden for including contact information on the predesigned templates to be 30,744 hours (9,838 operators \times 125 sign formats \times 0.025 hours per sign). Annualized over 3 years, this burden becomes 10,248 hours (9,838 operators/3 years \times 125 signs \times 0.025 hours per sign). There are no capital costs associated with adding contact information. (Some States have licensing requirements for vending machine operators, and some of these licensing requirements already require the vending machine operator's license or contact information to be displayed on the vending machine. If the contact information displayed on a vending machine due to State or local requirements includes some but not all of the contact information required under § 101.8(e)(1), the vending machine operator is required to display the remaining contact information required under § 101.8(e)(1) in a manner specified under § 101.8(e)(1). We do not have an estimate of the number of machines already in compliance; to the extent that some operators are already in compliance, we overestimate the burden of third-party disclosure.)

We estimate the time it takes to install a sign onto a single machine to be 5 minutes (0.083 hours) for each sign. With 5,605,257 machines (5,604,914 covered machines + 343 voluntarily registered machines), we estimate the annual burden for initial sign installation to be 465,236 hours (5,605,257 machines \times 1 sign per machine \times 0.083 hours installation).

Annualized over 3 years, this burden becomes 155,079 hours (5,605,257 machines/3 years \times 1 sign per machine \times 0.083 hours installation). (5,605,257 machines/3 years = 1,868,419 machines per year.) There are no capital costs associated with sign installation.

We divide the estimates for the recurring burden of non-bulk third-party disclosure into two parts: Updating calorie sign information for changes in the product mix (which involves updating the digital format) and physical sign replacement (which involves printing and installation). We estimate the average number of product configurations for machines that will experience regular changes to their product mix to be 52. This value is lower than the overall average of 125 since some machines (such as beverage machines) do not experience regular changes to the product mix. We estimate the average number of times that calorie signs will need to be updated to be twice per year. Finally, we estimate the time it takes to update a single sign using the predesigned template to be 0.5 hours. Thus, the total burden for updating sign information is 511,576 hours [511,576 records (made up of 9,838 operators \times 52 product configurations) \times 2 updates per year \times 0.5 hours per update].

We estimate the annual number of covered machines that will need regular sign replacement to be 1,755,986 machines (1,755,879 covered machines + 107 voluntarily registered machines). We estimate the time it takes to remove and replace old signs with new signs to be 0.17 hours (10 minutes). Thus, the total annual burden for replacing signs is 597,035 hours (1,755,986 machines \times 2 replacements per year \times 0.17 hours per replacement). There are no capital costs associated with updating sign information or physical sign replacement.

We estimate there is an average of 385,600 covered bulk vending machines, based on data obtained from the Vending Times Census and NAMA (Refs. 6, 8). We assume each bulk machine vends a single bulk product, and we further assume they will choose the most economical signage, which means they are likely to use a small sticker on the face of each machine. We estimate the time to print and apply each sticker is 1.5 minutes (0.025 hours). Thus, the total burden for bulk machine signage is 9,640 hours (385,600 bulk machines \times 0.025 hours per machine). Annualized over 3 years, this value becomes 3,213 hours (385,600/3 years \times 0.025 hours per machine). (385,600/3 years) = 128,533 machines per year.)

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the title "Information Collection Provisions of the Final Rule on Food Labeling; Calorie Labeling of Articles of Food in Vending Machines."

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have resubmitted the information collection provisions of this final rule to OMB for review, because the final rule provides an additional modification to § 101.8. These requirements will not be effective until we obtain OMB approval. Interested persons are requested to submit comments regarding information collection to OMB (see **DATES and ADDRESSES**).

Prior to the effective and compliance date of this final rule, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Federalism

We have analyzed this final 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 requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) [of the FD&C Act [21 U.S.C. 343(q)]]", 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 (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the

voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix) [of the FD&C Act]" (21 U.S.C. 343(q)(5)(H)(ix)). The final rule creates 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 ACA also included a Rule of Construction providing that nothing in the amendments made by [section 4205] 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 Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)] (as added by subsection(b)) 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 Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)(ix)] (as added by subsection (b)), 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 such Act [21 U.S.C. 343(q)(5)(H)(i)]. (See Public Law 111–148, Sec. 4205(d), 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 the Rule of Construction in 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 which 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.

The preamble to the proposed rule (76 FR 19238 at 19252) described an alternative interpretation of section 4205 of the ACA that could leave less room for States and localities to require nutrition labeling for food sold from vending machines. Under this alternative interpretation, State or local nutrition labeling requirements for food sold from vending machines would be preempted because such nutrition labeling requirements would be “nutrient content disclosures of the type required under section 403(q)(5)(H) [of the FD&C Act]” and would not fall within the exception to preemption in section 403A(a)(4) of the FD&C Act (“except that this paragraph 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 . . .”).

Under this alternative interpretation, States and localities could not have nutrition labeling requirements for food sold in vending machines that were not identical to the Federal requirements, unless they successfully petitioned FDA. The position that no State or locality may have a vending machine food nutrition labeling requirement not identical to the Federal requirements, regardless of how many vending machines the operator owns or operates, was the position in the guidance we issued (entitled “Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws” (75

FR 52427, August 25, 2010)). Federal law provides that, upon petition, we may exempt State or local requirements from the express preemption provisions of section 403A(a) of the FD&C Act under certain conditions (21 U.S.C. 343–1(b)). We have issued regulations at § 100.1 (21 CFR 100.1) describing the petition process that is available to State and local governments to request such exemptions from preemption. Under our proposed interpretation, for food sold from vending machines that is not subject to the nutrition labeling requirements of section 403(q)(5)(H) of the FD&C Act, States and localities may establish or continue to impose nutrition labeling requirements. Under the alternative interpretation, there would be food sold in vending machines for which the Federal Government has not required nutrition labeling and for which States and localities would be precluded from establishing such labeling requirements unless they successfully petitioned FDA and a rulemaking was completed. This approach would risk creating a regulatory gap that would be inconsistent with the purposes of section 4205 of the ACA. It would also impose a restriction and burden on the States and localities that is inconsistent with the Federalism principles expressed in Executive Order 13132, as well as a substantial administrative burden on FDA if States petition for exemption.

We invited comments on our interpretation of section 4205 of the ACA related to preemption, as well as on the alternative interpretation described in the Federalism section. We also requested comments on the use of the petition process in this context and on other potential interpretations that interested persons identify as appropriate given both the preemption-related language of section 4205 of the ACA and the statutory goals.

(Comment 41) Several comments supported the preemptive scope being limited to State and local requirements imposing additional or different nutritional labeling requirements for food sold from covered vending machines, including food sold from machines operated by a person who has elected to be subject to the requirements of section 403(q)(5)(H) of the FD&C Act (76 FR 19238 at 19251–19252). Some comments stated that the alternative interpretation, that no State or locality may have a vending machine food nutrition labeling requirement that is not identical to the Federal requirements regardless of how many vending machines the operator owns or operates, would restrict State and local

authorities and create a “regulatory vacuum” because the Federal system exempts vending machine operators with fewer than 20 machines. A few comments stated that the alternative interpretation, which would create a gap in coverage of vending machines, would be inconsistent with the purposes and language of section 4205 of the ACA. These comments also stated that imposing a restriction on States and localities is inconsistent with Federalism principles expressed in Executive Order 13132. Another comment stated that section 4205 of the ACA intends that States and localities have authority to regulate nutritional information for machines that do not come under the purview of the Federal law.

Several comments would have us revise the rule to clarify that “identical” does not mean verbatim in wording rather in effect. One comment suggested the following language: “The specific words of the State or local requirements need not be the same. State or local requirements that are worded differently from the Federal requirements and/or provide for different enforcement schemes may still be ‘identical’ under [section 4205 of the ACA].”

Other comments noted that the savings clause for warnings about the safety of food is included in the Rule of Construction in section 4205(d) of the ACA. A few comments suggested that we codify the Rule of Construction because its omission from the rule may lead to confusion over how the statute should be interpreted. The comments noted that the lack of a codified statement for a similar rule of construction in the NLEA has led to confusion and to court decisions that did not take that rule of construction into account. One comment stated that we should include a savings clause that expressly identifies that nutrition labeling for less than 20 machines is not preempted in the absence of voluntary compliance by non-covered vending machine operators.

(Response 41) We agree with the comments asserting that the preemptive effect of the Federal nutrition labeling requirements of section 4205 of the ACA for food sold from vending machines is limited to State and local requirements that impose additional or different nutrition labeling requirements for food sold from vending machines that are covered by the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.8. We also agree that the alternative interpretation described in the proposed rule (76 FR 19238 at 19251 through 19252), that no State or locality may have a nutrition labeling

requirement for food sold from vending machines that is not identical to the Federal requirements regardless of how many vending machines the operator owns or operates, would restrict State and local authorities and create a regulatory gap that would be inconsistent with the purposes and language of section 4205 of the ACA and the Federalism principles expressed in Executive Order 13132. In addition, as we noted in the preamble to the proposed rule (76 FR 19238 at 19251 through 19252), there would be no reason for Congress to include vending machine operators in the voluntary registration provision of section 403(q)(5)(H)(ix) of the FD&C Act, which allows vending machine operators not subject to the requirements of section 403(q)(5)(H) of the FD&C Act to opt into the Federal requirements if State and local governments could not otherwise require non-identical nutrition labeling for food sold from any vending machines.

For these reasons, we interpret the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not establish or continue into effect nutrition labeling requirements for food sold from vending machines covered by the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.8, unless the State or local requirements are identical to the Federal requirements of section 403(q)(5)(H) of the FD&C Act and § 101.8. In other words, States and localities cannot have additional or different nutrition labeling requirements for food sold either from: (1) 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 and § 101.8; or (2) vending machines operated by a person not otherwise subject to the requirements of section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8 who voluntarily elects to be subject to those requirements by registering biannually with FDA in accordance with section 403(q)(5)(H)(ix) of the FD&C Act and § 101.8(d). 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.

In response to the comments asserting that we revise the rule to clarify the meaning of “identical” within the context of section 403A(a)(4) of the FD&C Act, we note that we have already issued a regulation at § 100.1 that explains the meaning of “not identical to” in the context of section 403A of the

FD&C Act in describing the petition process available to State and local governments to request an exemption from the express preemption provisions of section 403A of the FD&C Act under section 403A(b) of the FD&C Act. FDA regulations, at § 100.1(c)(4), provide, in relevant part, that, within the context of section 403A of FD&C Act, “not identical to” does not refer to the specific words in the State or local requirement but instead means that the State or local requirement directly or indirectly imposes obligations or contains provisions concerning the labeling of food that: (1) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 403 of the FD&C Act or (2) differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 403 of the FD&C Act. Accordingly, a State or local nutrition labeling requirement for food sold from vending machines covered by the requirements of section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8 that directly or indirectly imposes obligations or contains labeling provisions that: (1) Are not imposed by or contained in section 403(q) of the FD&C Act and § 101.8; or (2) differ from those specifically imposed by or contained in section 403(q) of the FD&C Act and § 101.8 would be “not identical to” the Federal requirements and therefore would be preempted under section 403A(a)(4) of the FD&C Act. Because the meaning of the phrase “not identical to,” within the context of section 403A of the FD&C Act, is already described in § 100.1 and is further clarified here in the context of vending machines, we decline to revise the rule to clarify the meaning of “identical” as suggested by the comments.

We decline to amend § 101.8 to restate the Rule of Construction at section 4205(d) of the ACA or to add a savings clause that expressly provides that nutrition labeling for fewer than 20 vending machines is not preempted in the absence of voluntary compliance. As discussed in section III.C.4.a of this preamble, and specified in § 101.8(c)(1), § 101.8 only applies to food sold from a vending machine that: (1) Is operated by a person engaged in the business of owning or operating 20 or more machines; or (2) is operated by a vending machine operator that has voluntarily elected to be subject to § 101.8 by registering with FDA in accordance with § 101.8(d). In addition, we explain our interpretation of the provisions of section 4205 of the ACA

related to preemption mentioned previously, including our interpretation that State and local governments may impose nutrition labeling requirements for food sold from vending machines not subject to the requirements of section 403(q)(5)(H) of the FD&C Act, which would include vending machines operated by a person engaged in the business of owning or operating fewer than 20 vending machines. Because § 101.8(c)(1) specifies what foods and vending machines are covered by the requirements of section 403(q)(5)(H) and § 101.8, and we have described the Rule of Construction at section 4205(d) of the ACA and explained our interpretation of the provisions of section 4205 of the ACA related to preemption mentioned previously, we decline to revise § 101.8 as suggested by the comments.

VII. 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. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. FDA/CFSAN, "Food Labeling: Calorie Labeling of Articles of Food in Vending Machines, Regulatory Impact Analysis," 2014.
2. FDA/CFSAN, "Food Labeling: Calorie Labeling of Articles of Food in Vending Machines NPRM, Preliminary Regulatory Impact Analysis," 2011.
3. Memo to File. Correspondence with Eric Dell of the National Automatic Merchandising Association. April 10, 2013.
4. Memo to File. Correspondence with Eric Dell of the National Automatic Merchandising Association. April 13, 2013.
5. Eastern Research Group I. "Evaluation of Recordkeeping Costs for Food Manufacturers, Final Report," A. Sertkaya, A. Berlind, and S. Erdem, Eds. Contract No. 223-01-2461, Task Order Number 5. 2007.
6. "2012 Census of the Industry," *Vending Times*, 2012; 52(12).
7. 2012 State of the Vending Industry Report, 2013," *Automatic Merchandiser*.
8. National Automatic Merchandising Association. Comments of: The National

Automatic Merchandising Association.
Docket No. FDA-2010-N-0298. 2010.

List of Subjects

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

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, 21 CFR parts 11 and 101 are amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

- 1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

- 2. Section 11.1 is amended by adding paragraph (h) to read as follows:

§ 11.1 Scope.

* * * * *

(h) This part does not apply to electronic signatures obtained under § 101.8(d) of this chapter.

PART 101—FOOD LABELING

- 3. The authority citation for 21 CFR 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.

- 4. Section 101.8 is added to subpart A to read as follows:

§ 101.8 Vending machines.

(a) **Definitions.** The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this section. In addition, for the purposes of this section:

Authorized official of a vending machine operator means an owner, operator, agent in charge, or any other person authorized by a vending machine operator who is not otherwise subject to section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)(viii)), to register the vending machine operator with the Food and Drug Administration ("FDA") for purposes of paragraph (d) of this section.

Vending machine means a self-service machine that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses

servings of food in bulk or in packages, or prepared by the machine, without the necessity of replenishing the machine between each vending operation.

Vending machine operator means a person(s) or entity that controls or directs the function of the vending machine, including deciding which articles of food are sold from the machine or the placement of the articles of food within the vending machine, and is compensated for the control or direction of the function of the vending machine.

(b) Articles of food not covered.

Articles of food sold from a vending machine are not covered vending machine food if:

(1) The prospective purchaser can view:

(i) The calories, serving size, and servings per container listed in the Nutrition Facts label on the vending machine food without any obstruction. The Nutrition Facts label must be in the format required in § 101.9(c) and (d). The Nutrition Facts label must be in a size that permits the prospective purchaser to be able to easily read the nutrition information contained in the Nutrition Facts label on the article of food in the vending machine. Smaller formats allowed for Nutrition Facts for certain food labeling under FDA regulation at § 101.9 are not considered to be a size that a prospective purchaser is able to easily read; or

(ii) The calories, serving size, and servings per container listed in a reproduction of the Nutrition Facts label on the vending machine food, provided that the reproduction is a reproduction of an actual Nutrition Facts label that complies with § 101.9 for a vending machine food, is presented in a size that permits the prospective purchaser to be able to easily read the nutrition information, and the calories, serving size, and servings per container are displayed by the vending machine before the prospective purchaser makes his or her purchase; or

(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 50 percent of the size of the largest printed matter on the label and with sufficient color and contrasting background to other print on the label

to permit the prospective purchaser to clearly distinguish the information.

(c) *Requirements for calorie labeling for certain food sold from vending machines*—(1) *Applicability; covered vending machine food*. For the purposes of this section, the term “covered vending machine food” means an article of food that is:

(i) Sold from a vending machine that does not permit the prospective purchaser to examine the Nutrition Facts label prior to purchase as provided in paragraph (b)(1) of this section or otherwise provide visible nutrition information at the point of purchase as provided in paragraph (b)(2) of this section; and

(ii) Sold from a vending machine that:

(A) Is operated by a person engaged in the business of owning or operating 20 or more vending machines; or

(B) Is operated by a vending machine operator that has voluntarily elected to be subject to the requirements of this section by registering with FDA under paragraph (d) of this section.

(2) *Calorie declaration*. (i) The number of calories for a covered vending machine food must be declared in the following manner:

(A) To the nearest 5-calorie increment up to and including 50 calories and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.

(B) The term “Calories” or “Cal” must appear adjacent to the caloric content value for each food in the vending machine.

(C) The calorie declaration for a packaged food must include the total calories present in the packaged food, regardless of whether the packaged food contains a single serving or multiple servings. The vending machine operator may voluntarily disclose calories per serving in addition to the total calories for the food.

(D) If a covered vending machine food is one where the prospective purchaser selects among options to produce a final vended product (e.g., vended coffee, hot chocolate or tea with options for added sugar, sugar substitute, milk, and cream), calories must be declared per option or for the final vended products.

(ii) Calorie declarations for covered vending machine food must be clear and conspicuous and placed prominently in the following manner:

(A) The calorie declarations may be placed on a sign in close proximity to the article of food or selection button, i.e., in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine, so long as the calorie declaration is visible at the same time as the food, its name, price,

selection button, or selection number is visible. The sign must give calorie declarations for those articles of food that are sold from that particular vending machine.

(B) When the calorie declaration is in or on the vending machine, the calorie declaration must be in a type size no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest, with the same prominence, i.e., the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, or a background at least as contrasting as the background used for the item it is in closest proximity to, i.e., name, selection number, or price of the food item as displayed on the machine.

(C) When the calorie declaration is on a sign adjacent to the vending machine, the calorie declaration must be in a type size large enough to render it likely to be read and understood by the prospective purchaser under customary conditions of purchase and use, and in a type that is all black or one color on a white or other neutral background that contrasts with the type color.

(D) Where the vending machine only displays a picture or other representation or name of the food item, the calorie declaration must be in close proximity to the picture or other representation or name, or in close proximity to the selection button.

(E) For electronic vending machines (e.g., machines with digital or electronic or liquid crystal display (LCD) displays), the calorie declaration must be displayed before the prospective purchaser makes his or her purchase.

(F) For vending machines with few choices, e.g., popcorn, the calorie declaration may appear on the face of the machine so long as the declaration is prominent, not crowded by other labeling on the machine, and the type size is no smaller than the name of the food on the machine (not the label), selection number, or price of the food as displayed on the vending machine, whichever is smallest.

(d) *Voluntary provision of calorie labeling for foods sold from vending machines*—(1) *Applicability*. A vending machine operator that is not subject to the requirements of section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act may, through its authorized official, voluntarily register with FDA to be subject to the requirements established in paragraph (c)(2) of this section. An authorized official of a vending machine operator

that voluntarily registers cannot be subject to any State or local nutrition labeling requirements that are not identical to the requirements in 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act.

(2) *Who may register?* A vending machine operator that is not otherwise subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act may register with FDA.

(3) *What information is required?* The vending machine operator must provide FDA with the following information:

(i) The contact information (including name, address, phone number, email address), for the vending machine operator;

(ii) The address of the location of each vending machine owned or operated by the vending machine operator that is being registered;

(iii) Preferred mailing address (if different from the vending machine operator address), for purposes of receiving correspondence; and

(iv) Certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered vending machine will be subject to the requirements of this section.

(v) Information should be submitted by email by typing complete information into the portable document format (PDF) form, saving it on the registrant's computer, and sending it by email to menulawregistration@fda.hhs.gov. If email is not available, the registrant can either fill in the PDF form and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301-436-2804 or mail it to FDA, CFSAN Menu and Vending Machine Labeling Registration, White Oak Building 22, rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(vi) Authorized officials of a vending machine operator who elect to be subject to the Federal requirements can register by visiting <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm>. FDA has created a form that contains fields requesting the information in paragraph (d) of this section and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

(vii) To keep the establishment's registration active, the authorized official of the vending machine operator must register every other year within 60 days prior to the expiration of the vending machine operator's current

registration with FDA. Registration will automatically expire if not renewed.

(e) *Vending machine operator contact information.* (1) A vending machine operator that is subject to section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act or a vending machine operator that voluntarily registers to be subject to the requirements under paragraph (d) of this section must provide its contact information for vending machines selling covered vending machine food. The contact information must list the vending machine operator's name, telephone number, and mailing address or email address.

(2) The contact information must be readable and may be placed on the face of the vending machine, or otherwise must be placed with the calorie declarations as described in paragraph (c)(2)(ii) of this section (*i.e.*, on the sign in, on, or adjacent to the vending machine).

(f) *Signatures.* Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

■ 5. In § 101.9, revise paragraphs (j)(2)(ii) and (j)(4) and the introductory text of paragraph (j)(13)(i) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(j) * * *

(2) * * *

(ii) Served in other establishments in which food is served for immediate human consumption (*e.g.*, institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate consumption on the premises; food service vendors, such as lunch wagons, ice cream shops, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices), *Provided*, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), subject the food to the provisions of this section;

* * * * *

(4) Foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section, *Provided*, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as

provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), subject the food to the provisions of this section. An insignificant amount of a nutrient or food component shall be that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram." Examples of foods that are exempt under this paragraph include coffee beans (whole or ground), tea leaves, plain unsweetened instant coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors.

* * * * *

(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided*, That the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), subject the food to the provisions of this section.

* * * * *

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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