

Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371 or CalorieLabelingVend@fda.hhs.gov.

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Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry¹

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I. Introduction

In the *Federal Register* of December 1, 2014 (79 FR 71259), the Food and Drug Administration (FDA or we) issued a final rule entitled “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines” (“the rule”). The rule is codified at 21 CFR 101.8. The rule implements section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and amends FDA’s food labeling regulations in title 21 of the *Code of Federal Regulations* (21 CFR) by adding § 101.8. The rule requires vending machine operators who own or operate 20 or more vending machines, or who voluntarily register with FDA to be covered, to declare calories for those vending machine foods for which the Nutrition Facts label cannot be examined before purchase or for which visible nutrition information is not otherwise provided at the point of purchase (see section 403(q)(5)(H)(viii) of the FD&C Act).

We have prepared this guidance to help vending machine operators and industry to better understand and comply with the rule. In the remainder of this guidance, “you” refers to persons or entities that are subject to the rule. In addition, we cite the applicable regulations in many places throughout this document.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Definitions

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. (21 CFR 101.8(a))

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. (21 CFR 101.8(a))

III. Questions and Answers

A. Covered Operators

1. Who is a covered operator?

The rule applies to you as a “covered operator” if you are a vending machine operator who:

- owns or operates 20 or more vending machines; or
- owns or operates fewer than 20 vending machines and voluntarily registers to follow the rule

(Section 403(q)(5)(H)(viii) of the FD&C Act and 21 CFR 101.8)

2. Are food manufacturers required to place calorie information on the product label of foods sold from vending machines?

No. Section 403(q)(5)(H)(viii) of the FD&C Act and 21 CFR 101.8 apply to certain vending machine operators rather than food manufacturers. Food manufacturers may elect to provide the information you will need to make your own calorie declarations for their products, but they are not required to do so. See question B.2 for other suggestions on determining the calorie information of a food item.

3. Am I required to register with the FDA to be subject to the rule?

No. If you are a vending machine operator who owns or operates fewer than 20 vending machines, you may voluntarily register to be subject to the rule. If you wish to voluntarily register, we refer you to 21 CFR 101.8(d). Once you register, you must follow the regulations and are considered a covered operator for the duration of your registration (see 21 CFR 101.8(d)). If you own or operate 20 or more vending machines, you are automatically covered under this rule and do not need to register.

4. Why would a vending machine operator voluntarily register to be covered by the rule?

By voluntarily registering, you would be subject to the calorie disclosure requirements, and consumers would be able to examine calorie information before purchase. Additionally, you would not be subject to State or local nutrition labeling requirements for foods sold in vending machines that are not identical to the requirements of section 403(q)(5)(H) of the FD&C Act. (21 CFR 101.8(d)(1)).

5. What registration information am I required to submit in order to register?

A vending machine operator (or its authorized official) must provide us the following information using Form FDA 3757, Menu/Vending Labeling Registration Form, at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm239947.pdf> (21 CFR 101.8(d)(3)):

- Contact information (including name, address, phone number, and email address) for the vending machine operator;
- 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 the information is authorized to do so, and that each registered vending machine will be subject to the requirements of section 403(q)(5)(H) of the FD&C Act and 21 CFR 101.8.

6. Must I use Form FDA 3757 to voluntarily register my vending machines?

Yes. There is a fillable Form FDA 3757 at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm239947.pdf>. You must use this form to ensure that complete information is submitted.

7. How do I submit the completed form?

After saving your completed form, you should email the form to menulawregistration@fda.hhs.gov. If email is not available, you can either complete the fillable form and print it, or print a blank form and fill in the information by hand or typewriter; then fax the completed Form FDA 3757 to 301-436-2804 or mail it to: FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, room 0209, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

8. Do I have to renew this registration and if so, when?

The registration period covers two years and becomes active from the date of submission. To keep the registration active, the vending machine operator (or its authorized official) must submit a new registration within 60 days before the expiration of the vending machine operator's current registration. (21 CFR 101.8(d)(3)(vii)). If we do not receive this re-registration, the original registration will automatically expire.

9. Will FDA send reminders that it is time to re-register?

No. We will not send reminders.

10. Does a covered operator have to register with State or local authorities for licensing purposes?

Yes, if State or local agencies require you to register for licensing purposes, you should still register with those agencies for that purpose. The rule has no impact on State licensing requirements.

11. I own several vending machines at my business location (more than 20 machines) but I do not control the operation of them. I contract the operation of the vending machines to someone else. Who is responsible for posting calorie information? What if I lease the machines?

Vending machine operators, as that term is defined in the vending machine labeling final rule, are responsible for posting calorie information for vending machine foods and otherwise complying with the final rule. Whether you own or lease your vending machines, if you are not a vending machine operator (i.e., you do not control or direct 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 you are not compensated for the control or direction of the function of the vending machine), then you would not be responsible for posting the calorie information for the foods sold from your vending machines. The person or entity you contract with, to control or direct the function of your vending machines would be responsible for posting the calorie information. (21 CFR 101.8(c)(1))

12. If I own 15 machines that dispense food and 10 machines that dispense nonfood items, am I a covered vending machine operator?

No. The rule defines “vending machine,” in part, as a machine that “...dispenses servings of food in bulk or in packages...” (See 21 CFR 101.8(a) or section II of this guidance for the full definition.) The rule does not apply to machines that dispense nonfood items. However, if you voluntarily register, you would be a covered operator and would be required to provide calorie information for products vended in the 15 machines that dispense food.

13. I have a total of 20 vending machines in three States. Does the rule apply to me?

Yes, if your machines meet the definition of “vending machine” in the rule, the rule applies to you, regardless of the location of the vending machines within the United States and U.S. territories.

14. Do small businesses have to comply with this rule?

Yes. If you are a covered operator, you must comply with the rule. Neither section 403(q)(5)(H)(viii) of the FD&C Act nor 21 CFR 101.8 exempts “small businesses” from the requirements.

B. Calorie Declaration

1. Am I required to declare calorie information for food sold in vending machines in schools?

Yes. If you are a covered operator, you must declare calorie information for certain foods sold in vending machines in schools. Neither section 403(q)(5)(H)(viii) of the FD&C Act nor 21 CFR 101.8 exempts the calorie requirements for machines located in schools.

2. How do I find the calories for a food item?

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. We anticipate that, for most packaged foods, the food package’s Nutrition Facts label will provide the information that you can use for your calorie declarations. (Please note however, that not all packaged foods are required to bear a Nutrition Facts label.) The manufacturer or supplier of the food may be able to supply calorie information for foods such as those that do not have Nutrition Facts labels. If the manufacturer does not provide the calories for the food, consider finding the calories using one of the following resources:

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- The U.S. Department of Agriculture’s National Nutrient Database for Standard Reference” (<http://ndb.nal.usda.gov/>).
- Appendix C of 21 CFR part 101 for raw fruits and vegetables.
- Another public or private database. When deciding which database to use, you should look for:
 - One that has a name and version number. The most recent version can help ensure you have current information. In some cases, the version number might be a date.
 - One that is transparent and provides more information. A transparent database provides information on its calculations or operations (for example, worksheets or computer printouts) and includes the analytical method. Databases that compute the total calories in a finished food article are more informative than those that only give calories for individual ingredients.

3. Am I required to label the calories of fresh food (such as a sandwich or apple) sold in the vending machine? Does the source of the fresh food (commissary, restaurant, or wholesaler) matter?

You must include calories for fresh food (such as a sandwich or apple) that you sell in vending machines regardless of the source of the fresh food. The requirements of section 403(q)(5)(H)(viii) of the FD&C Act apply to articles of food sold from a vending machine and, therefore, apply to packaged and fresh food.

4. How can I determine the calories for vending machine foods that can vary in calorie content (such as fruit)?

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. You 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 the information is truthful and not misleading, and otherwise in compliance with applicable requirements of the FD&C Act and 21 CFR 101.8. Where a natural variation based on size or other factors for vending machine foods is significant, you should ensure that the calorie declarations for such foods are accurate. You could do this by offering for sale vending machine foods of approximate standard size and calorie content or by modifying calorie declarations as appropriate. As another option you could provide calorie declarations for vending machine foods as two or more different types of items, e.g., “Apple: small; 77 calories,” “Apple: medium; 95 calories;” “Apple: large; 116 calories.”

5. If a sandwich in a vending machine includes a single serving unit of a packaged condiment, such as a mayonnaise packet, must the calorie declaration include the calories contained in the condiment packet?

Yes. A condiment packet sold with the sandwich is part of the “article of food” for purposes of applying the requirements of section 403(q)(5)(H)(viii) of the FD&C Act. You must declare the total calories for the article of food as it is vended, which includes the calories for each component. (21 CFR 101.8(c)) You may voluntarily declare the calories for packaged components (e.g., the calories for the sandwich only) *in addition to* the total calories for the complete article of food.

6. If a machine offers options for beverages, such as coffee with sugar and cream or hot chocolate with whipped cream, how do I list the calories?

If a vending machine offers the customer options to customize the base product (for example, coffee, hot chocolate, or tea with options for sugar, sugar substitute, milk, and cream), you must declare the calories in one of two ways:

- Declare the calories for the base product and each option individually (e.g., black coffee; added calories from sugar; added calories from cream; etc.); or
- Declare the calories for every possible final product (e.g., black coffee; coffee with sugar; coffee with cream; coffee with sugar and cream; etc.).

(See 21 CFR 101.8(c)(2)(i)(D).)

7. If a vended food item has multiple servings (such as a package of mini donuts) and lists calorie information for a single serving, must I provide additional calorie information for the entire package?

Yes. 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. You may voluntarily disclose calories per serving *in addition to* the total calories for the food. (See 21 CFR 101.8(c)(2)(i)(C).)

C. Calorie Display

1. What method must I use to display the calories?

You have flexibility in determining how to display the calories because the rule provides for a range of methods. Regardless of the method—many of which we discuss below—you must ensure that the calorie declarations are clear and conspicuous and placed prominently (21 CFR 101.8(c)(2)(ii)) so that customers can read the calories before purchasing the product.

2. Does a vending machine with an electronic display that can show a virtual image of a Nutrition Facts label or digital display of the calories meet the requirements of the rule?

Yes. You may use electronic vending machines (e.g., machines with digital or electronic or LCD (liquid crystal) displays) to present calorie declarations, provided that the calorie

declaration is displayed before the customer buys the product (21 CFR 101.8(c)(2)(ii)(E)). These electronic displays, like all calorie declarations, must be clear and conspicuous and placed prominently (near the article of food or the selection button) (see 21 CFR 101.8(c)(2)(ii)).

3. May I use a sign or stickers to display the calories?

Yes. The rule permits you to use signs in, on, or adjacent to the vending machine, provided that applicable requirements of 21 CFR 101.8(c) are met (see 21 CFR 101.8(c)(2)(ii)). You may use one sign with calorie declarations for all of the food sold from the machine, or individual signs for each food item. Alternatively, you may affix stickers with the calorie information to the vending machine. You must place the sign or sticker near each article of food or selection button (see 21 CFR 101.8(c)(2)(ii)).

4. Does the sign have to use letters in a particular font size? Can a sign be handwritten?

Calorie declarations on a sign *next* to the machine “must be in a type size large enough to render it likely to be read and understood by the prospective purchaser” (21 CFR 101.8(c)(2)(ii)(C)). We are not prescribing a minimum font size for the sign, but the customer must be able to read it under “customary conditions of purchase and use” (21 CFR 101.8(c)(2)(ii)(C)). Additionally, the type must be all black or one color on a white or other neutral background that contrasts with the type color (21 CFR 101.8(c)(2)(ii)(C)). You can use a handwritten sign if it meets these readability criteria.

If 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 of the food product), 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 (21 CFR 101.8(c)(2)(ii)(B)). You can use a handwritten sign if it meets the criteria specified in 21 CFR 101.8(c)(2)(ii)(B).

5. How often do I have to update calorie information on a sign? Can a sign include calorie information for food items that may not always be stocked in the machine?

The calorie declarations for the foods sold in the vending machine must be accurate and up to date. Section 101.8(c)(2)(ii)(A) specifies, in relevant part, that the sign “must give calorie declarations for those articles of food that are sold from that particular vending machine.”

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 vending machine may have sold out of a particular item and it has not yet been restocked. As another example, you may have temporarily replaced a food in a vending machine that is typically stocked with another item. You must display the calorie declarations for articles of food currently or typically sold from that vending machine (see 21 CFR 101.8(c)(2)(ii)(A)) and otherwise satisfy the requirements of section 403(a)(1), (f), and (q)(5)(H)(viii) of the FD&C Act and 21 CFR 101.8.

6. If I am vending a new item and have not listed it yet on the sign, how long do I have to comply?

To comply with the rule, you must declare the calories for all covered vended food items sold from your vending machine (see 21 CFR 101.8(c)(2)(ii)(A)). If you are using a sign adjacent to the vending machine to declare calories for multiple covered vending machine foods, you may wish to consider leaving empty spaces on such sign and then, when you add new products, list the new product and its calories to your existing sign, rather than preparing a new sign every time you add a product to the vending machine. Alternatively, you could use individual signs for each item and switch them in or out as you introduce or retire various items.

7. Can a sign with the calorie information be attached to the side of the machine?

No. The customer must be able to see the sign when selecting the food. Attaching the sign to the side of the machine, such that the customer *cannot* see it at the same time as selecting the food, would not meet the criteria in 21 CFR 101.8(c)(2)(ii)(A). Specifically, the sign must be near the article of food or selection button (that is, in, on, or adjacent to the vending machine, but not necessarily attached to the vending machine), and the customer must be able to see the calorie declaration, the food, its name, price, and selection button or number at the same time. However, a sign on a wall next to the vending machine could be permissible if it meets these criteria.

8. Does a sign declaring calorie information have to include food items in the vending machine that have front of pack (FOP) labeling?

You do not have to include calorie labeling for products that have FOP calorie declarations if the declaration meets the criteria described in 21 CFR 101.8(b)(2) for visible nutrition information within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. However, if you are using a sign adjacent to the vending machine to declare calories for multiple covered vending machine foods, we encourage you to include on such sign *all* the food products that are being sold in that vending machine, even those that already have FOP calorie labeling. Packaging for food items could change, and so a revised package may not always include FOP labels declaring calories.

9. If the food item has an FOP calorie declaration, is the food subject to the labeling requirements of the rule?

If the FOP calorie declaration for a vending machine food meets the criteria described in 21 CFR 101.8(b)(2), such food would not be subject to the calorie declaration requirements of the rule, and a covered vending machine operator would not have to provide calories for such food. The FOP declaration must be clear and conspicuous, and the customer must be able to easily read the calorie declaration while the food is in the vending machine. (21 CFR 101.8(b)(2)). Therefore, you must ensure that the machine does not block the FOP declaration (for example, machine coils must not cover the declaration). Furthermore, the font color must be sufficient with contrasting background as compared to other print on the label to distinguish the information. (21 CFR 101.8(b)(2)).

If there are products in the vending machine with FOP calorie information that do not comply with the criteria described in 21 CFR 101.8(b)(2), it does not necessarily mean that those products are misbranded. It just means that vending machine operators cannot rely on the FOP calorie information on those products to provide visible nutrition information within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act. You would need to prepare your own calorie declarations for those products, consistent with the requirements for calorie declarations in 21 CFR 101.8(c).

10. If the FOP declaration is declared as “x calories per serving and y servings per package,” would the FOP declaration be a way to provide visible nutrition information within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act?

Yes, provided other criteria described in 21 CFR 101.8(b)(2) are met. This is the same information that would be conveyed by the Nutrition Facts label if the operator relied on the Nutrition Facts label to convey the calorie information. Having the FOP declaration include both information on calories per serving *and* servings per package allows the consumer to determine the total calories in the article of food as vended.

11. What if parts of the vending machine (such as the coil in the vending machine) block some of the FOP calorie information?

There are various ways you can comply with the rule. If you are trying to use the FOP calorie information to provide visible nutrition information within the context of section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act, but the machine coil blocks the FOP calorie information and you cannot change the position or otherwise ensure that the information will be visible, then you must post the calorie declarations for the food items in one of the ways described in 21 CFR 101.8(c)(2)(ii). Another possibility would be to display the Nutrition Facts label for the food if available as provided for in 21 CFR 101.8(b)(1).

12. Can I just turn the package in the machine so the Nutrition Facts label is visible through the glass front of the machine?

Yes, if this would allow the customer to easily read the nutrition information on the Nutrition Facts label before purchasing the product and the other criteria described in 21 CFR 101.8(b)(1) are satisfied. However, we do not consider smaller Nutrition Facts formats (such as those on gum or mints) to be of a size that customers can easily read through the glass front of the machine. (See 21 CFR 101.8(b)(1).)

13. Does the calorie information have to be available in Braille?

No. The rule does not require you to declare calorie information in an alternative format for people who are visually impaired. However, if you wish, you may provide calorie information in an additional form, such as large font, Braille, or audio, as long as you continue to comply with section 403(q)(5)(H)(viii) of the FD&C Act.

D. Compliance

1. How long do I have to comply with the rule?

If you are a covered vending machine operator (i.e., you own or operate 20 or more machines or you voluntarily register with FDA to be covered), you have until December 1, 2016, to comply with the rule, which is 2 years after the date of the final rule’s publication in the *Federal Register*. However, in the *Federal Register* of August 1, 2016 (81 FR 50303), we issued a final rule entitled “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date.” This rule provides that the compliance date for type size front-of-pack labeling requirements (§ 101.8(b)(2) (21 CFR 101.8(b)(2))) and calorie disclosure requirements (§ 101.8(c)(2)) for certain gums, mints, and roll candy products in glass-front machines in the final rule published December 1, 2014 (79 FR 71259) is extended to July 26, 2018. The compliance date for all other requirements in the final rule (79 FR 71259) remains December 1, 2016. If you become subject to the rule after this date, you must comply immediately. Vending machine operators who may be adding machines to their operation (and thus become covered under the rule) should have calorie information available for all of their machines at the time that their machines are added.

2. Must I provide my contact information on the vending machine?

Yes. The rule requires covered vending machine operators and vending machine operators that voluntarily register with FDA to be covered by the rule to list the operator’s name, telephone number, and mailing address or email address. (21 CFR 101.8(e)). This information must be readable and placed on the face of the vending machine, or otherwise must be placed with the calorie declarations (i.e., on the sign that is in, on, or adjacent to the vending machine).

3. What are the penalties for not providing accurate calorie information?

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If the calorie information is not accurate, the foods would be considered misbranded and subject to the same penalties that misbranded packaged foods are subject to under the FD&C Act.