

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

## **Small Entity Compliance Guide**

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**U.S. Department of Health and Human Services  
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# Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry<sup>1</sup>

## Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

### 1. Introduction

On December 1, 2014, FDA (we) published a final rule entitled “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines” (“the final rule”) in the *Federal Register* ([79 FR 71259, December 1, 2014](#)). The final rule, which is now codified at Title 21 of the *Code of Federal Regulations* at § 101.8 (21 CFR § 101.8), requires that vending machine operators who own or operate 20 or more vending machines, or who voluntarily elect to be covered, provide calorie declarations 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. Covered vending machine operators must comply with the final rule by December 1, 2016. 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. We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document restates in plain language the legal requirements set forth in the rule and is intended to assist small entities in complying with the final rule (21 CFR 101.8). The final rule is binding and has the full force and effect of law.

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<sup>1</sup> 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.

## *Contains Nonbinding Recommendations*

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.

In the remainder of this guidance, "you" and "I" refer to vending machine operators that are subject to the rule. Many of the answers in this guidance are followed by parenthetical citations that indicate where the information in the answer is codified.

## **2. Who is Subject to the Rule?**

You are subject to the rule if you are a vending machine operator who owns or operates 20 or more vending machines.

If you are a vending machine operator who owns or operates fewer than 20 vending machines, you can voluntarily register to be subject to the rule. (For more information about voluntary registration, see part 2.4 of this guide.) (21 CFR 101.8(c)(1)(ii))

### **2.1. How does the Rule Define "Vending Machine Operator?"**

The rule defines "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. (21 CFR 101.8(a))

### **2.2. How does the Rule Define "Vending Machine?"**

The rule defines "vending machine" as 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))

#### **2.2.1. Does the Rule Apply to "Turret-style"/"Turnstile" Vending Machines?**

Yes, turret-style or turnstile vending machines (as depicted in Figure 1 of this document) are "vending machines" as defined by § 101.8(a). The definition of the term "vending machine" considers whether the machine, as a whole, needs to be restocked after each vending operation and not whether individual spaces for food are replenished.

**Figure 1: Example of a "Turret-style"/"Turnstile" Vending Machine**



**2.2.2. Does the Rule Apply to “Game” Vending Machines that Dispense Food?**

No, 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 Federal Food, Drug, and Cosmetic Act (FD&C Act). Game machines sell the opportunity to play a game or experience entertainment, and not the article of food itself.

**Figure 2: Examples of "Game" Vending Machines**



**2.2.3. Does the Rule Apply to Bulk Vending Machines?**

Yes, the rule applies to vending machines as defined by § 101.8(a), regardless of how many different articles of food or types of food they sell and regardless of whether they have selection buttons.

**Figure 3: Examples of Bulk Vending Machines**



### **2.3. Does the Rule Apply to Food Manufacturers?**

No, section 403(q)(5)(H)(viii) of the FD&C Act and § 101.8 apply to certain vending machine operators rather than food manufacturers.

As food packaging and vending machine technology evolve, food manufacturers, vending machine manufacturers, and vending machine operators may choose to work together to help vending machine operators comply with the rule. For example, food manufacturers may wish to label packaged foods so that they satisfy the requirements of § 101.8, but they are not required to do so. Packaged foods whose labels satisfy the criteria set forth in § 101.8(b) are not covered by the rule and therefore vending machine operators are not required to provide calorie declarations for such foods.

### **2.4. How do I Voluntarily Register to Become Subject to the Rule?**

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 by providing FDA with the following information:

- The contact information (including name, address, phone number, e-mail 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;
- Preferred mailing address (if different from the vending machine operator address), for purposes of receiving correspondence; and



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- 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 the rule.

You must use the form provided on our website at <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm> to ensure that complete information is submitted. (21 CFR 101.8(d)(3)(vi)) You should type complete information into the portable document format (PDF) form, save it on your computer, and send it by e-mail to [menulawregistration@fda.hhs.gov](mailto:menulawregistration@fda.hhs.gov). If e-mail is not available, you 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. (21 CFR 101.8(d))

### **2.4.1. How Long does My Voluntary Registration Last?**

If you voluntarily register to be subject to the requirements of the rule, you must re-register every other year within 60 days before your current registration expires. Registration will automatically expire if you do not renew it. (21 CFR 101.8(d))

## **3. What Foods are Covered by the Rule?**

A covered vending machine food is one that is:

- sold from a vending machine that is operated by a vending machine operator subject to the rule (see part 2 of this guide); and
- sold from a vending machine that does not permit the prospective purchaser to examine the Nutrition Facts label prior to purchase, or does not otherwise provide visible nutrition information at the point of purchase (see part 4 of this guide). (21 CFR 101.8(c)(1))

Foods that are covered by the rule must bear calorie declarations (see part 5 of this guide). (21 CFR 101.8(c)(2))

### **3.1. Are Dietary Supplements Covered by the Rule?**

Yes. 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 (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.

### **3.2. Does the Rule Cover Food Items that Come in Small Packages or Contain Insignificant Nutrient or Caloric Content?**

Yes. The rule makes no exception for 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). The rule provides a number of options for you to post the required calorie information, including the option to post such information on a sign adjacent to a vending machine.

## **4. What Vending Machine Foods are Not Covered by the Rule?**

Articles of food sold from a vending machine that is not subject to the rule (see part 2 of this guide) are not covered by the rule. In addition, articles of food sold from a vending machine that permits the prospective purchaser to examine the Nutrition Facts label before purchase, or otherwise provides visible nutrition information at the point of purchase are not covered by the rule. (21 CFR 101.8(b) and (c)(1))

You do not have to provide calorie declarations (see part 5 of this guide) for foods that are not covered by the rule.

### **4.1. What Permits the Prospective Purchaser to Examine the Nutrition Facts Label?**

The prospective purchaser must be able to view the calories, serving size, and servings per container listed in the Nutrition Facts label on the vending machine food without an obstruction, or the calories, serving size, and servings per container listed in a reproduction of an actual Nutrition Facts label. The Nutrition Facts label, or reproduction of an actual Nutrition Facts label, must be:

- in the format required elsewhere in our regulations, at 21 CFR 101.9(c) and (d);
- presented in a size that permits the prospective purchaser to be able to easily read the nutrition information contained in the Nutrition Facts label; and
- displayed by the vending machine before the prospective purchaser makes his or her purchase.

You do not have to provide calorie declarations for food items whose Nutrition Facts labels can be examined in accordance with the above. (21 CFR 101.8(b)(1))

### **4.2. How Can Visible Nutrition Information Otherwise be Provided?**

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

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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. (21 CFR 101.8(b)(2))

For example: If the word "CHOCOLATE" on the label is in a type size of 60 points and is the largest printed matter on the label, then the nutrition information on the label must be at least a type size of 30 points and must otherwise comply with § 101.8(b)(2).

**Figure 4: Example of Visible Nutrition Information on a Food Label**



Vending machine operators do not have to provide calorie declarations for food items that provide visible nutrition information on their labels in accordance with the above.

#### **4.2.1. Can Visible Nutrition Information be Provided from a Brochure or Booklet?**

No. 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. Nutrition information in brochures or booklets would not be visible at the

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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 Front of Pack (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.

### **4.2.2. Can Visible Nutrition Information be Provided using Front of Package (FOP) Labeling?**

Yes. 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, contrast, and type size are met (§ 101.8(b)(2); (see part 4.2 of this guide), and the total calories contained in the article of food are included.

The criteria in 21 CFR 101.8(b)(2) are important to ensure that prospective purchasers are able to read and use the nutrition information for a vending machine food before purchasing the food.

## **5. How do I Comply with the Calorie Declaration Requirements?**

If you are a vending machine operator subject to the rule, including if you voluntarily register to become subject to the rule (see part 2 of this guide), you must display the number of calories (“calorie declaration”) for a covered vending machine food (see part 3 of this guide) in a clear and conspicuous manner and prominently as detailed in the rule. (21 CFR 101.8(c)(2))

### **5.1. How Must I Declare Calories?**

The calorie declaration for a covered vending machine food must be 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. Additionally, the term “Calories” or “Cal” must appear adjacent to the caloric content value for each food in the vending machine. (21 CFR 101.8(c)(2)(i)(A) and (B))

#### **5.1.1. If the Label on the Food Item is Bilingual or Multilingual, am I Required to Display the Calorie Declarations in Multiple Languages?**

No, the rule does not require you 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.

The calorie declarations must appear in English, unless the foods are distributed solely in Puerto Rico or other territories where the predominant language is not English. (See 21 CFR 101.15(c)(1)) For food items distributed solely in Puerto Rico or other territories where the predominant language is not English, the predominant language may be substituted for English.

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### **5.1.2. If the Food Comes with Condiments, How Must I Declare Calories?**

You must declare the total calories present in the article of food as it is vended. (21 CFR 101.8(c)(2)(i)(C)) For example, we consider a packaged or plastic-wrapped sandwich including, if sold along with the sandwich, any packet(s) of condiments to be the total “article of food” as it is vended for purposes of the rule. As such, you must provide a calorie declaration for the total article of food as it is vended, which includes the total calorie content of each component of the article of food. You may voluntarily declare the calories for each component of the article of food as it is vended (e.g., the calories for the condiments sold with the sandwich; the calories for the sandwich) in addition to the total calories for the article of food.

In contrast, 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 the rule. In such an instance, the vending machine operator should not include such condiment packets in the total calories of the article of food.

### **5.1.3. If the Food Comes with Multiple Servings, How Must I Declare Calories?**

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. (21 CFR 101.8(c)(2)(i)(C))

### **5.1.4. If the Food Comes with Various Customizations (e.g., coffee), How Must I Declare Calories?**

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

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.

## **5.2. Where May I Place the Calorie Declaration?**

Calorie declarations for covered vending machine food must be clear and conspicuous and placed prominently. (21 CFR 101.8(c)(2)(ii))

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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. (21 CFR 101.8(c)(2)(ii)(A))

### **5.2.1. What if My Vending Machine Only Displays a Picture or Other Representation or Name of the Food Item?**

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. (21 CFR 101.8(c)(2)(ii)(D))

### **5.2.2. What Materials Can I Use? Can I Use Stickers?**

You may use any material for posting calorie declarations, including stickers, as long as you meet the applicable calorie declaration requirements. Regardless of the material used for the sign and how it is affixed, 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 sections 403(a)(1),<sup>2</sup> 403(f),<sup>3</sup> and 403(q)(5)(H)(viii) of the FD&C Act, and § 101.8.

### **5.2.3. Must I Provide a Calorie Declaration Next to Each Item or Can I Put Multiple Calorie Declarations on a Sign?**

You may 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 sections 403(a)(1), 403(f), and 403(q)(5)(H)(viii) of the FD&C Act and § 101.8.

## **5.3. Can I Make Calorie Declarations for Foods Other than those Sold in a Vending Machine?**

No. 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.” (21 CFR 101.8(c)(2)(ii)(A))

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<sup>2</sup> Section 403(a)(1) of the FD&C Act requires that a food’s labeling not be “false or misleading in any particular.”

<sup>3</sup> 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 must be placed prominently 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.

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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, you 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 sections 403(a)(1), 403(f), and 403(q)(5)(H)(viii) of the FD&C Act and § 101.8.

### **5.4. Are there Type Size and Color Requirements for the Calorie Declarations?**

Yes. 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 on the packaged food), 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))

The following illustrations provide two examples of how to comply with the type size and color requirements for calorie declarations that are in or on the vending machine. **Figure 5** shows an example of signage (with multiple calorie declarations) placed on the vending machine. **Figure 6** shows an example of calorie declarations made in the vending machine next to each food item.

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**Figure 5: Example of Signage with Multiple Calorie Declarations Placed on the Vending Machine**

The image shows a vending machine with three rows of snacks. The top row has 'Chip', 'Cookies', and 'Popcorn' (A1, A2, A3). The middle row has 'Chocolate', 'Nougat', 'Candy', 'Toffee', 'Caramel', and 'Nuts' (B1-B6). The bottom row has 'Puffy', 'Spirals', and 'Gummies' (C1-C4). A 'PUSH' button is at the bottom. Callout boxes provide font size guidelines for the selection numbers and prices.

**Callout 1:** If the type size here for selection "A3" is 16 points, and for the price "\$1.50" is 20 points,

**Callout 2:** and if the type size here for selection "A3" is 24 points,

**Callout 3:** Then, the type size for the calorie declaration on the signage must be no smaller than the type size of the name of the food on the machine, selection number, or price of the food as displayed on the machine; whichever is smallest. Here, the smallest relevant type size is the selection number below each article of food, at 16 points. Therefore, the type size of the calorie declaration must be no smaller than 16 points. Also, black writing on a white background would likely satisfy the color and contrast requirements.

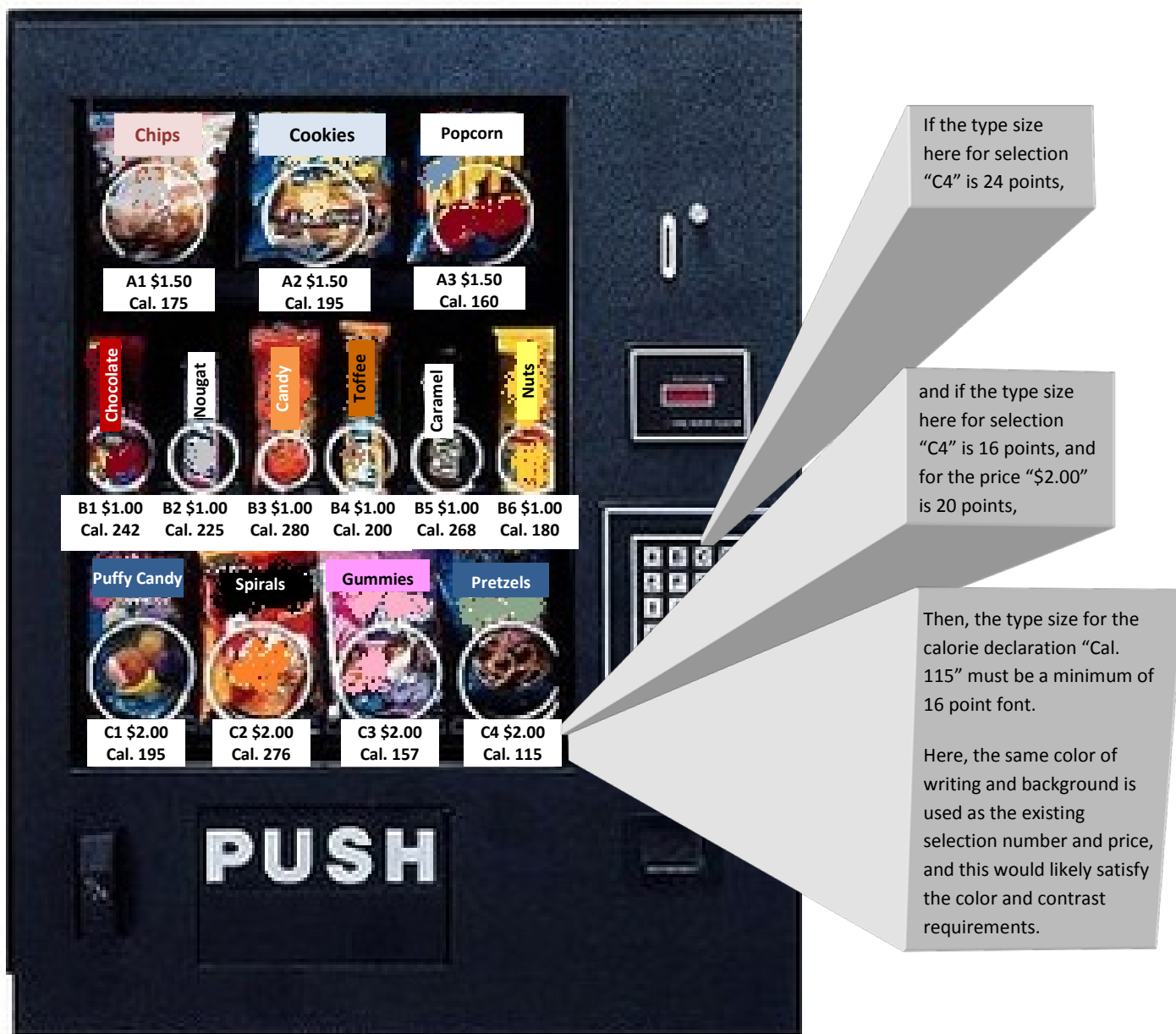
**Calorie Declaration List:**

- A1- Chips, 175 Cal.
- A2- Cookies, 195 Cal.
- A3- Popcorn, 160 Cal.
- B1- Chocolate, 242 Cal.
- B2- Nougat, 225 Cal.
- B3- Candy, 280 Cal.
- B4- Toffee, 200 Cal.
- B5- Caramel, 263 Cal.
- B6- Nuts, 180 Cal.
- C1- Puffy Candy, 195 Cal.



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**Figure 6: Example of Calorie Declarations Made in the Vending Machine Next to Each Food Item**



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. (21 CFR 101.8(c)(2)(ii)(C))

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### **5.4.1. What if My Vending Machine has Few Choices?**

For vending machines with few choices or only one choice, e.g., a vending machine that only dispenses 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. (21 CFR 101.8(c)(2)(ii)(F))

### **5.5. Can I Use an Electronic Vending Machine to Satisfy the Calorie Declaration Requirements?**

Yes, electronic vending machines (e.g., machines with digital or electronic or liquid crystal display (LCD) displays) may be used to provide calorie declarations, provided that the calorie declaration is displayed before the prospective purchaser makes his or her purchase and the calorie declaration is clear and conspicuous and prominently placed. (21 CFR 101.8(c)(2)(ii)(E))

Further, electronic signs otherwise placed in, on, or adjacent to the vending machine can be used to provide calorie declarations, provided that such signs are located in close proximity to the article of food or the selection button, and otherwise comply with sections 403(a)(1), 403(q)(5)(H)(viii), and 403(f) of the FD&C Act and § 101.8.

### **6. What Contact Information Must I Provide and Where Must I Put It?**

If you are a vending machine operator subject to the rule, including if you voluntarily register to be subject to the rule (see part 2 of this guide), you must provide your contact information for vending machines that sell covered vending machine food. The contact information must list your name, telephone number, and mailing address or e-mail address. (21 CFR 101.8(e))

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 § 101.8(c)(2)(ii) (i.e., on the sign in, on, or adjacent to the vending machine).

### **7. How Can I Determine the Calorie Content for Vending Machine Foods?**

You may rely on a number of means to determine the calorie content for foods sold in your vending machine. You may be able to 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 that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and § 101.9, the food package's Nutrition Facts label can provide calorie information for the food.

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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.

You also may be able to 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. Also, FDA provides nutrient values for raw fruits and vegetables in Appendix C of 21 CFR part 101.

Compliance ultimately is based on the accuracy of the declaration rather than just the method used to determine the calorie information. You must ensure that calorie declarations are truthful and not misleading under section 403(a)(1) of the FD&C Act, and otherwise comply with sections 403(q)(5)(H)(viii) and 403(f) of the FD&C Act and § 101.8.

You may be able to generate and maintain a record of the information on which you rely to determine the calorie declaration for the covered vending machine food. We encourage you to be prepared to share the record of information with us upon our request during an inspection if we need to determine whether the calorie declarations are truthful and not misleading.

### **8. When Must I Comply with the Rule?**

If you are a vending machine operator subject to the rule (see part 2 of this guide), you must come into compliance with the rule no later than December 1, 2016. The compliance date also applies to those vending machine operators who voluntarily register to be subject to the rule, although such vending machine operators are only subject to the rule for the duration of their registration (see part 2.4. of this guide). A vending machine operator that becomes subject to the rule after December 1, 2016 must comply when they become subject to the rule (and for the duration that they are subject to the rule).

### **9. What Happens if I Fail to Comply with the Rule?**

Failure to comply with § 101.8 will render the covered vending machine food misbranded under sections 403(a), 403(f), or 403(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.