

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: Proposed rule.

SUMMARY: To implement the vending machine labeling provisions of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), the Food and Drug Administration (FDA) is proposing requirements for providing calorie information for certain articles of food sold from vending machines. The Affordable Care Act, in part, amended the Federal Food, Drug and Cosmetic Act (FD&C Act) to, among other things, require that for an article of 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, and is operated by a person engaged in the business of owning or operating 20 or more vending machines, the vending machine operator must disclose the number of calories for the article of food. Vending machine operators not subject to the requirements of the Affordable Care Act may elect to be subject to the Federal requirements by registering with FDA. Providing calorie disclosures for food sold from vending machines would assist consumers in making healthier dietary choices.

DATES: Submit either written or electronic comments on the proposed rule by [insert date 90 days after date of publication in the FEDERAL REGISTER]. Submit comments on the information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-F-0171 and/or RIN 0910-AG56, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

FAX: 301-827-6870.

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal

information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Nutrition Labeling Requirements That Currently Apply to Packaged Foods

The Nutrition Labeling and Education Act of 1990 (NLEA) amended the FD&C Act, in part, by adding section 403(q) (21 U.S.C. 343(q)), which specifies, in pertinent part and with certain exceptions, that a food is considered to be misbranded unless its label or labeling bears nutrition information. See 21 U.S.C. 343(q)(1). When a food is in package form, the required nutrition information generally must appear on the label of the food. FDA's final regulations establishing nutrition labeling requirements were published in 1993 (58 FR 2079, January 6,

1993) and are found at Title 21 of the Code of Federal Regulations (21 CFR) section 101.9. Regulations implementing the NLEA require nutrition information for a food product intended for human consumption and offered for sale unless an exemption is provided for the product (§ 101.9(a)). The declaration of nutrition information on the label and labeling of food generally must include information about the following nutrients: Total calories, calories from fat (unless the product contains less than 0.5 g of fat), total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, and certain vitamins and minerals (§ 101.9).

The NLEA amendments to the FD&C Act included an exemption from nutrition labeling for food that is served in restaurants or other establishments in which food is served for immediate human consumption or sold for sale or use in such establishments (21 U.S.C. 343(q)(5)(A)(i)). The NLEA amendments to the FD&C Act also included an exemption from nutrition labeling for food that is processed and prepared primarily in a retail establishment, ready for human consumption, of the type of food described in section 403(q)(5)(A)(i) of the FD&C Act, offered for sale to consumers but not for immediate human consumption in such establishment, and not offered for sale outside such establishment (21 U.S.C. 343(q)(5)(A)(ii)). However, these exemptions were contingent on there being no nutrient content claims or health claims made on the label or labeling, or in the advertising, for the food. In our regulations implementing these exemptions, we included vending machines among the examples of establishments in which food is served for immediate human consumption that generally are exempt from nutrition labeling requirements because like the other examples, vending machines offer food products that are generally consumed immediately where purchased or while the consumer is walking away. See § 101.9(j)(2).

B. Requirements of Section 4205 of the Affordable Care Act

On March 23, 2010, the Affordable Care Act (Public Law 111-148) was signed into law. Section 4205 of the Affordable Care Act (section 4205), amends section 403(q) of the FD&C Act, which governs nutrition labeling requirements, 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. The Affordable Care Act requires FDA to issue proposed regulations to carry out section 403(q)(5)(H) of the FD&C Act no later than one year from the date of enactment. As amended, section 403(q)(5)(H)(viii) of the FD&C Act requires that if an article of food is sold from a vending machine that does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the food or does not otherwise provide visible nutrition information at the point of purchase and the vending machine is operated by a person who is engaged in the business of owning or operating 20 or more vending machines, the vending machine operator must provide calorie information for the food. Specifically, 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.”

Section 403(q)(5)(H)(ix) of the FD&C Act allows vending machine operators not subject to the requirements of section 4205 of the Affordable Care Act to voluntarily register with FDA to become subject to the Federal requirements. In the Federal Register of July 23, 2010, (75 FR 43182), FDA published a notice in the Federal Register specifying the terms and conditions for implementation of voluntary registration, pending promulgation of final regulations. See 75 FR 43182.

C. FDA Activities Related to Implementation of Section 4205 of the Affordable Care Act

Section 4205 of the Affordable Care Act also requires certain restaurants and similar retail food establishments to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Elsewhere in this issue of the Federal Register, FDA is proposing requirements to implement the menu labeling provisions of section 4205. As discussed in that proposal, FDA has published in the Federal Register a number of documents concerning section 4205. On July 7, 2010, FDA published a notice entitled “Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold from Vending Machines” (“docket notice”) (75 FR 39026, July 7, 2010) to solicit comments and suggestions on the new law. In response to this notice, FDA received approximately 875 letters and emails. Of those, approximately 60 contained one or more comments pertaining to vending machine calorie labeling. Many of these comments were general comments on the law itself and either supported or opposed the requirement in section 403(q)(5)(H)(viii) of the FD&C Act that calorie information be provided for foods sold from vending machines. Comments in opposition stated that providing calorie information for foods sold from vending machines would be overly burdensome to the industry. FDA describes these comments in more detail and responds to those comments in this proposal.

On July 23, 2010, FDA published the Federal Register notice entitled “Voluntary Registration by Authorized Officials of Non-Covered Retail Food Establishments and Vending Machine Operators Electing to be Subject to the Menu and Vending Machine Labeling Requirements Established by Section 4205 of the Patient Protection and Affordable Care Act of 2010” (“registration notice”) (75 FR 43182). FDA issued this registration notice to provide

assistance for voluntary registration for restaurants, similar retail establishments, and vending machine operators that are not subject to the nutrition labeling requirements of section 4205 (e.g., restaurants and similar retail food establishments with fewer than 20 locations, and vending machine operators with fewer than 20 machines). In the registration notice, FDA specified the terms and conditions for implementation of voluntary registration, pending promulgation of regulations. In response to the notice, FDA received 7 comments, none of which addressed registration.

On August 25, 2010, FDA published a "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" ("preemption guidance") (75 FR 52427, August 25, 2010). The preemption guidance discusses the preemptive effect of section 4205 and identifies the provisions of amended section 403(q) of the FD&C Act that became requirements upon enactment. Our current thinking on the preemptive effect of section 4205 is set out in section VII of this document.

Also on August 25, 2010, FDA published a "Draft Guidance for Industry: Questions and Answers Regarding the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Availability" ("draft implementation guidance") (75 FR 52426, August 25, 2010). This draft guidance addressed only the menu labeling provisions of section 4205. It did not address the calorie labeling requirements for vending machine operators in section 4205. FDA subsequently withdrew the draft implementation guidance (76 FR 4360, January 25, 2011).

II. Legal Authority

As stated in section I.C. of this document, on March 23, 2010, the Affordable Care Act was signed into law. Section 4205 of the Affordable Care Act amended 403(q)(5) of the FD&C Act (21 U.S.C. 343(q)(5)) by amending section 403(q)(5)(A) and by creating new clause (H) to require, in relevant part, that vending machine operators provide calorie information for certain articles of food sold from vending machines. Under section 403(a)(1), such information must be truthful and nonmisleading. 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 actually made in the labeling. Section 403(q)(5)(H)(x) requires the Secretary of Health and Human Services (Secretary) to issue proposed regulations no later than 1 year after enactment. Thus, FDA has the authority to issue this proposed rule under sections 201(n), 403(a)(1), and 403(q)(5)(H), as well as under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which vests the Secretary with the authority to issue regulations for the efficient enforcement of the FD&C Act.

FDA is proposing requirements that vending machine operators provide calorie information for certain articles of food sold from vending machines. FDA is also proposing the terms and conditions for voluntary registration by vending machine operators not subject to the requirements of section 4205 of the Affordable Care Act that elect to become subject the requirements. FDA is proposing to set out these provisions in new § 101.8.

III. The Proposal

A. Definitions

We are proposing in the introductory paragraph of § 101.8(a) that the terms defined in section 201 of the FD&C Act are applicable when these terms are used. Additional terms are defined alphabetically in the proposed codified and are discussed in alphabetical order in this section. "Act" is defined as the Federal Food, Drug, and Cosmetic Act.

1. Authorized Official of a Vending Machine Operator

We are proposing in § 101.8(a) that the term “authorized official of a vending machine operator” means the owner, operator, or agent in charge of a vending machine, or any other person authorized by a vending machine operator not subject to the requirements of section 4205 of the Affordable Care Act to voluntarily register the vending machine operator with FDA to become subject to the requirements. For the purposes of this definition, the agent in charge would not be the person who is only in charge or in control of the location where the vending machine is located.

2. Vending Machine Operator

We are proposing in § 101.8(a) that the term “vending machine operator” means a person that controls or directs the function of the vending machine, including deciding which articles of food are sold from the vending 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. Section 201(e) of the FD&C Act defines “person” to include an individual, partnership, corporation, and association. For example, a vending machine operator could be a corporation that manufactures beverages and sells these products in its machines. A vending machine operator also could be an individual or a business that only operates and stocks vending machines, such as a private company with onsite vending machines.

3. Vending Machine

Section 403(q)(5)(H)(viii) of the FD&C Act sets forth labeling requirements for certain vending machine food but does not define the term “vending machine.” We are proposing in § 101.8(a) that the term “vending machine” means 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, in packages, or prepared by the machine, without the necessity of replenishing the device between each vending operation. This definition is almost identical to the definition of “vending machine” in the FDA Food Code 2009.¹ Examples of food dispensed from vending machines may include prepackaged foods (e.g., candy, snacks, gum, bottled or canned soft drinks), unpackaged bulk foods (e.g., handful of gum, candy, or mixed nuts), prepared foods (e.g., sandwiches or fresh fruit), multi-serving foods (e.g., gallon of milk), or foods prepared in the machine and dispensed in bulk (e.g., coffee, soup, or popcorn).

B. Who Must Comply with this Rule

Section 4205 of the Affordable Care Act provides that “in the case of an article of 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, and is operated by a person engaged in the business of owning or operating 20 or more vending machines, the vending machine operator

¹ FDA regularly publishes the Food Code, which provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted by State and local governments for the retail segment of the food industry. The Food Code provisions are not Federal requirements; however, they are designed to be consistent with Federal food laws and regulations. The 2009 Food Code defined the term “vending machine” to mean a “self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.” (U.S. Public Health Service, FDA, 2009 Food Code, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, College Park, MD 20740, chapter 1, section 1-201.) <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm186464.htm>

shall 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 of food.” Consistent with the requirements of section 4205, all vending machine operators with 20 or more vending machines, as defined in section III.A.3. of this document, will be subject to these requirements. Therefore, FDA is proposing in § 101.8(c)(1)(i)(A) and (B) that the labeling requirements of this proposed rule apply to vending machine operators that own or operate 20 or more vending machines that do not allow a prospective purchaser to examine the Nutrition Facts Panel prior to purchase or do not otherwise provide visible nutrition information at the point of purchase. As discussed in below in section III.D. of this document, vending machine operators that are not subject to the requirements of the law may elect to be subject to the Federal requirements by voluntarily registering with FDA.

Several comments requested that FDA apply the small business nutrition labeling exemption (§ 101.9(j)(1)) to vending machine operators. The comments said that: (1) 90-95 percent of vending machine operators have 20 or more machines, and therefore, would be covered by section 403(q)(5)(H) of the FD&C Act and (2) 70 percent of vending machine operators have three or fewer employees, and would likely be generating sales less than \$500,000.

FDA is not proposing an exemption from the vending machine nutrition labeling requirements for small businesses. FDA notes that section 403(q)(5)(H) of the FD&C Act does not include an exemption from the vending machine nutrition labeling requirements for small businesses. Section 403(q)(5)(D) includes an exemption from the nutrition labeling requirements in sections 403(q)(1) through (q)(4) for small businesses. The requirement that vending machine operators disclose calories for covered vending machine food is not found in sections 403(q)(1)

through (q)(4); instead, it is found in section 403(q)(5)(H)(viii). Therefore, the small business exemption in 403(q)(5)(D) does not apply. We believe that the proposed rule provides adequate flexibility to allow these small businesses to comply with the proposed requirements in a cost-effective and equitable way. For example, the proposed requirements allow vending machine operators to choose from various approaches for compliance, including adopting less expensive measures as discussed below in section III.E. and section IV. of this document. We request comment on additional ways that FDA can make the requirements of this rule less burdensome on small businesses, while still meeting the requirements of section 403(q)(5)(H).

The Agency also received comments regarding operators of vending machines who are blind and operate vending machines through the Vending Facility Program operated by the U.S. Department of Education under the Randolph-Sheppard Act of 1936, 20 U.S.C. 107 et seq. These comments suggested that regardless of the number of machines that were operated by an operator, all operators of vending machines under the Randolph-Sheppard Act would be covered.

The Agency wishes to clarify its interpretation of the applicability of section 4205 of the Affordable Care Act to vending machine operators who fall under the Randolph-Sheppard Act. Section 403(q)(5)(H)(viii) of the FD&C Act sets forth requirements for vending machine operators based on the number of machines that they operate. Thus, as with other operators, Randolph-Sheppard Act operators would only be covered by the disclosure requirements if they operate 20 or more vending machines that dispense food or if they voluntarily register to be covered.

These comments also stated that operators of vending machines who are blind “may place different products in the same row due to limited visual recognition and the similarity of product packaging.” These comments requested flexibility for posting calorie information. Specifically,

the comments requested that the calorie disclosure requirements permit the “stacking of multiple products in the same coil.”

FDA is proposing requirements that provide flexibility for vending machine operators to comply with the labeling requirements for covered vending machine food. As discussed later in this document, the required calorie information may be posted on a sign adjacent to the vending machine, so long as the sign is visible to the prospective purchaser at the same time as the food, its description, or its selection button is visible.

C. Who is Not Required to Comply with this Rule

FDA is aware that many vending machine operators operate machines that dispense a variety of articles other than articles of food. For example, some vending machines may dispense detergent, compact discs, gift cards or toiletries. If a vending machine operator operated a total of 50 vending machines, only 15 of which sell articles of food, the vending machine operator would not be subject to the requirements of 403(q)(5)(H)(viii) of the FD&C Act because the vending machine operator operates fewer than 20 vending machines that sell articles of food.

Further, FDA tentatively concludes that vending machines that may dispense food as part of a game or other non-food related activity are not covered by 403(q)(5)(H) of the FD&C Act. For example, a vending machine may contain a variety of items ranging from small toys, coins, or individually wrapped candies that can be picked up by maneuvering a large claw arm. In this instance, the vending machine does not sell articles of food, even though in the course of

maneuvering the arm, candies could be dispensed. The vending machine is selling the opportunity to play the game. FDA seeks comment on this tentative conclusion.

Bulk vending machines dispense unpackaged articles of food in preselected amounts (e.g. gumball machines, mixed nut machines). FDA received a few comments suggesting that bulk vending machines are different from “more modern types of vending machines,” and therefore should be exempt from these disclosure requirements. The comments argued that bulk vending machines should be distinguished from other vending machines for three reasons. First, they noted that these machines do not have selection buttons, and as a result a vending machine operator could not place a sign “in close proximity to * * * the selection button” that includes the calorie information required by section 403(a)(5)(H)(viii)(I) of the FD&C Act. Second, they argued that food sold from bulk vending machines represents only a small fraction of overall market sales of the vending machine industry. Finally, the comments stated that there is no reported association between foods sold from bulk vending machines and obesity.

FDA notes that section 403(q)(5)(H)(viii) of the FD&C Act does not limit its applicability to vending machines for which there has been a reported association between the food vended by the machine and obesity. However, section 403(q)(5)(H)(viii) 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.” FDA tentatively concludes that the reference to “selection button” in the statute can be read to mean that the types of vending machines subject to requirements in section 403(q)(5)(H)(viii) are those with selection buttons. FDA is 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). FDA tentatively concludes that vending machines, including bulk vending machines, without any type of selection button are not covered by section 403(q)(5)(H)(viii). However, FDA tentatively concludes that a bulk vending machine that has a selection button, regardless of the type of food it dispenses, e.g., unpackaged articles of food such as soup, popcorn, or hot or cold beverages, is covered under section 403(q)(5)(H)(viii), if it meets the other statutory criteria. FDA is proposing in § 101.8(c)(1)(i)(C) that the nutrition labeling requirements of § 101.8 apply to an article of food sold from a vending machine that, among other things, has a selection button. FDA seeks comment on these tentative conclusions. FDA is also interested in comments demonstrating any unintended adverse effect resulting from the exclusion of vending machines without selection buttons from the calorie labeling requirements.

D. Voluntary Registration by a Vending Machine Operator That is Not Subject to the Requirements of Section 4205 of the Affordable Care Act That Elects to Be Subject to the Requirements

Section 4205 of the Affordable Care Act provides that vending machine operators not subject to the requirements of section 403(q)(5)(H)(viii)² of the FD&C Act may elect to become subject to the requirements by registering “biannually” with FDA (21 U.S.C. 343(q)(5)(H)(ix)). As discussed below, operators that choose to be subject to the Federal requirements would not be subject to non-identical state or local nutrition labeling laws for food sold from vending machines. In the proposed rule entitled: Food Labeling; Nutrition Labeling of Standard Menu

² As discussed in section I.B. of this document, vending machine operators that own or operate fewer than 20 vending machines could elect to be subject to the requirements of 403(q)(5)(H)(viii) of the FD&C Act by voluntarily registering with FDA.

Items in Restaurants and Similar Retail Food Establishments, published elsewhere in this issue of the Federal Register, FDA explains that “biannual” can be defined as occurring twice every year or as occurring every other year. (Ref. 1). FDA tentatively concludes that registration every other year is a more reasonable interpretation, because it does not seem warranted or necessary for a vending machine operator to tell FDA every 6 months that the operator wants to be subject to Federal requirements. FDA began accepting registrations on July 21, 2010, and will continue to accept them on a continuous basis. FDA is proposing in § 101.8(d) that an authorized official for a vending machine operator that is not subject to the Federal requirements may register with FDA every other year by providing FDA 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
- 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.

An authorized official of a vending machine operator who elects to be subject to the Federal requirements can register by visiting <http://www.fda.gov/menulabeling>. FDA has created a form that contains fields requesting the information in § 101.8(d) and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

E. Requirements for Vending Machine Operators Subject to this Rule and Operators that Elect to be Subject to the Rule When Calorie Declarations are Required

Calorie Declaration for a Covered Vending Machine Food

a. Calorie declaration. Section 403(q)(5)(H)(viii) of the FD&C Act provides that, for a covered vending machine food, the vending machine operator must “provide a sign in close proximity to the article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.” FDA is proposing in § 101.8(c)(2)(i)(A) to require that for a covered vending machine food, the statement of the number of calories in the food must be expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories. For a covered vending machine food that has fewer than 5 calories, the calorie declaration may be expressed as zero. These rounding rules are consistent with the declaration of calories for packaged foods as provided in § 101.9(c)(1).

In addition, FDA tentatively concludes that the number of calories must be accompanied by a term, e.g., “calories,” to make clear what that number refers to. Consequently, FDA is proposing in § 101.8(c)(2)(i)(B) that the term “Calories” or “Cal” must appear adjacent to the number of calories for the covered vending machine food. This is the “calorie declaration.” We tentatively conclude that permitting the use of the abbreviation “Cal” will provide flexibility for vending machine operators, especially those that have limited space on their machines, in meeting the proposed requirements.

Because section 403(q)(5)(H)(viii) of the FD&C Act refers to "an article of food sold from a vending machine," FDA tentatively concludes that calorie information must include the total calories present in the covered vending machine food as it is vended. For example, if a covered vending machine food, such as a sandwich, is dispensed with a single serving unit of a condiment, such as mayonnaise, the calorie declaration must include the number of calories contained in the sandwich and the package of mayonnaise. FDA also tentatively concludes that the number of calories declared for the article of food must be identical to the number of calories that are declared in the Nutrition Facts, if present. If the food contains multiple servings and bears a Nutrition Facts Panel, FDA tentatively concludes that the number of calories declared must be equal to the total number of calories contained in the food item as dispensed. 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 states 80 calories per serving and 3 servings per container, the total number of calories in the entire package would be 240 calories. FDA tentatively concludes that for a covered vending machine food that contains multiple servings, a vending machine operator may voluntarily disclose calories per serving in addition to total calories for the food.

Several comments requested that FDA permit the use of calorie ranges, similar to those provided for restaurants and similar retail food establishments under section 403(q)(5)(H)(v) of the FD&C Act, in declaring calorie information for covered vending machine foods that come in different flavors and varieties, e.g., coffee which comes in different flavors, brew strength, serving size, sweeteners or different types of sandwiches or fruit. The comments discussed the need for flexibility to provide calorie ranges for such items.

FDA acknowledges that some articles of food sold from vending machines come in varieties, such as different flavors and types of hot beverages (e.g., coffee or hot chocolate). For some of these varieties, there could be a large range for calories. For example, calories for coffee could range from zero calories for a plain brewed coffee to over 400 calories for a large mocha coffee with whole milk and whipped cream. We point out, however, 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. For example, if there is a button to select cream for a coffee, a vending machine operator would be able to post a calorie declaration for that cream item in close proximity to the selection button. FDA has considered vending machines that typically dispense fresh sandwiches and fruit (often these machines are turnstile type). FDA believes that such machines do not present a unique situation where the proposed options for declaring calorie information would not be appropriate. FDA tentatively concludes, therefore, that calorie ranges are not necessary within the context of vending machines because a vending machine operator would be able to disclose calorie information under other options, as explained below (e.g., use of signs including posters).

b. Determination of calorie content. If a covered vending machine food does not bear Nutrition Facts, FDA anticipates that the manufacturer or supplier of the food may provide the number of total calories for the food to the vending machine operator so that the operator has the necessary calorie information to meet the calorie disclosure requirements of section 403(q)(5)(H)(viii) of the FD&C Act. FDA notes that covered vending machine operators must ensure that the calorie declaration is truthful and not misleading in accordance with section 403(a)(1) of the FD&C Act. In the event the calorie information is not available from the

manufacturer of the food, FDA seeks comments on whether a vending machine operator may use nutrient databases, cookbooks, laboratory analyses, and other reasonable means. FDA notes that such flexibility is provided in § 101.10 and section 403(q)(5)(H)(iv). Further, FDA seeks 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.

c. Placement and prominence of calorie declarations. Section 403(q)(5)(H)(viii) of the FD&C Act provides that for a covered vending machine food, the vending machine operator must provide a sign in close proximity to the article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the food. FDA is interpreting the requirement that a sign be placed in close proximity to the article to mean that the sign is placed either in or on the vending machine itself or adjacent to the vending machine and near the food, its price, its selection number, or its selection button.

Section 403(q)(5)(H)(viii) also requires that the calorie declaration be clear and conspicuous. FDA notes that to be clear and conspicuous the calorie declaration must be in a font size large enough to be seen and easily readable. However, FDA recognizes that vending machines come in a variety of sizes, shapes, and styles. We also understand that vending machines will often have limited space. We think that it is important to provide businesses with flexibility while, at the same time, fulfilling the requirements of the statute. Therefore, we think it would not be appropriate to require one specific type size and font for calorie declarations for all covered vending machine food. Generally, if a calorie declaration is in a similar color as and

a type size no smaller than the name³ of the food, price of the food, or the selection number (e.g., A9 or E4), consumers should be able to read the calories in the same manner as they read the name and price of the food item. Therefore, FDA is proposing in § 101.8(c)(2)(i)(C) that if the calorie declaration is in or on the vending machine itself, the calorie declaration for a covered vending machine food 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. In addition, to help ensure that the calorie declaration is clear and conspicuous, FDA is proposing in § 101.8(c)(2)(i)(B) and § 101.8(c)(2)(i)(C) that the calorie declaration be made in the same color, or in a color at least as conspicuous, as the color of the name, price, or selection number of the food. Further, FDA proposes that the calorie declaration on the machine must have the same contrasting background as the name or price or selection number it is in closest proximity to. FDA notes that if a calorie declaration is presented in a color that is not sufficiently contrasted with its background or the declaration is in a type size that is too small to be read by a prospective purchaser, FDA tentatively concludes that the calorie declaration for a covered vending machine food is not disclosed in a clear and conspicuous manner, and the declaration would not be in compliance with the requirements of section 403(q)(5)(H)(viii)(I). FDA requests comment on whether these requirements meet the conditions for “clear and conspicuous” or whether the requirements should be more or less prescriptive.

A number of comments suggested that calorie information be provided on a poster or sign near the machine, such as for a bank of several vending machines that may use a common singular payment acceptor. However, several comments noted a concern that calorie information would not be read by the consumer unless the calorie information were posted immediately next

³ Here the discussion of “name” refers to the name of the food on or in the vending machine and not the name of the food on the label of the food package.

to each food item. The comments stated that “vending menus” (such as a menu poster for a bank of vending machines) would not provide the buyer with easy access to the calorie information.

FDA agrees with the comments 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. The Agency tentatively concludes that “close proximity” could mean adjacent to the vending machine, but not necessarily attached, so long as the sign adjacent to the machine is clear and conspicuous at the same time as the food, its name, or its selection button or selection number is visible. The Agency requests comments on this tentative conclusion. FDA is also proposing in § 101.8(c)(2)(ii)(B) that if the sign required by section 403(q)(5)(H)(viii) of the FD&C Act is placed adjacent to the vending machine, 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. The Agency is not proposing a minimum type size for the calorie declaration, but we request comment on this tentative decision. Comments should provide a rationale supporting their position and any supporting data, including consumer research. Where the vending machine only displays a vignette (i.e., picture of the food) or name of the food item, FDA is proposing in § 101.8(c)(2)(ii)(D) that the calorie disclosure sign must be in close proximity to the vignette or name or in close proximity to the selection button.

For electronic vending machines (e.g., machines with digital or electronic or liquid crystal display (LCD) displays), FDA tentatively concludes that the calorie disclosure sign required by the statute may be displayed when the selection numbers are entered but before the selection is confirmed, as proposed in § 101.8(c)(2)(ii)(E).

FDA tentatively concludes, 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. A sign may consist of a handwritten sticker in permanent marking that is affixed to the machine, provided that the statement is prominent, not crowded by other labeling on the machine and in a type size reasonably related to the largest print on the vending machine.

F. When Calorie Declaration is Not Required

1. Examination of the Nutrition Facts Panel

If the Nutrition Facts Panel of an article of food sold from a vending machine may be examined by a prospective purchaser before purchasing the article, the vending machine operator is not required to provide the calorie information. FDA is interpreting the term “Nutrition Facts Panel” to mean the nutrition information in the format required in § 101.9(c) and (d) on the label of the food. FDA tentatively concludes in order for the Nutrition Facts Panel to be examined, it must be visible in full, without obstruction, before purchase. For example, a vending machine’s automatic dispensing coil that holds the food in place or the placement of the package in the machine must not obscure, cover, or cause to be covered any portion of the Nutrition Facts Panel. To enable the prospective buyer to obtain the total number of calories of the article of food, the information that would be required to be made available on a sign by the vending machine operator if the provisions of section 403(q)(5)(H)(viii)(I)(aa) are not met, the agency notes that, in most cases, the prospective purchaser must use several parts of the panel to

determine the total number of calories for the article of food. This is one reason that it is critical that no portion of the Nutrition Facts Panel be obscured.

In addition, the Nutrition Facts Panel must be in a size that permits the prospective purchaser to easily read the nutrition information while the food is in the vending machine. FDA regulations allow certain foods to bear Nutrition Facts in a modified or smaller format based on the composition of the food, the size of the food package or other factors (see § 101.9(d), (e), (f), (h) and (j)). Where the Nutrition Facts Panel is in a smaller format consistent with the regulations, a prospective purchaser is unlikely to be able to easily read it on the label of the article of food in the vending machine prior to purchase. In such cases, the Agency tentatively concludes that the prospective purchaser is not able to examine the Nutrition Facts Panel prior to purchase. FDA requests comment on these tentative conclusions.

FDA recognizes that ordinarily the vending machine operator is not responsible for the printing of the Nutrition Facts Panel. Nor is the vending machine operator required by section 403(q)(5)(H)(viii)(I) to make examination of the Nutrition Facts possible by the prospective purchaser prior to purchase. However, food manufacturers may have an incentive to work with vending machine operators to find ways to have their packaged food displayed with the Nutrition Facts easily readable in the vending machine. In this way, potential purchasers would have more information about the manufacturers' food than just calories.

2. Visible Nutrition Information at the Point of Purchase

The second prong of section 403(q)(5)(H)(viii)(I)(aa) specifies that if a vending machine “otherwise provide[s] visible nutrition information at the point of purchase” for an article of food sold from the machine, the vending machine operator is not required to provide the calorie

information. As with the Nutrition Facts Panel this alternative means of satisfying the requirement of section 403(q)(5)(H)(viii) is optional for vending machine operators..

The terms “visible nutrition information” and “point of purchase” in section 403(q)(5)(H)(viii)(I)(aa) are not defined in the statute. FDA sees two possible ways to understand and apply the terms. One approach is to conclude that (1) "nutrition information" in this context means total calories in the article of food, because this is the information that the vending machine operator must provide by sign if the provisions in section 403(q)(5)(H)(viii)(I)(aa) are not met; and (2) “otherwise provide[d] * * * at the point of purchase” suggests, in the context of the provision as a whole, that the information, like the Nutrition Facts Panel, should be on the article of food itself. FDA proposes this approach in proposed § 101.8(b).

FDA received several comments supporting the use of “front of package” nutrition information contained on the food label as a means of “providing visible nutrition information at the point of purchase.” For example, some packaged food manufacturers voluntarily place certain nutrition information on the principal display panel that includes calorie and other nutrition information about the product. This type of nutrition information is sometimes referred to as “front of package” by industry, whereas Nutrition Facts typically appear on the information panel of a food label. FDA tentatively concludes that “front of package” nutrition information could be a way to provide visible nutrition information, so long as the criteria for color, font and type size are met and total calories in the article of food are included. If a nutrient content claim or a health claim for the article of food also is included on the front of the package, the claim must comply with relevant FDA regulations authorizing nutrient content claims (a claim on food labeling regarding the level of a nutrient, e.g., low fat) or health claims (a claim on food labeling

regarding the relationship between a substance and a disease, e.g., calcium and osteoporosis), as applicable.

FDA also received a few comments stating that the Nutrition Facts Panel and any “front of package” nutrition information may be small and difficult to read in a vending machine. FDA recognizes that a consumer may not be able to easily read some nutrition information in a vending machine and therefore this information may not inform the consumer about the number of total calories in the article of food. Section 101.8(b) of this proposed rule sets out the provisions regarding "visible nutrition information at the point of purchase" discussed above.

Under proposed § 101.8(b), for the nutrition information on the label to be considered “visible,” it must be clear and conspicuous. To ensure that it is clear and conspicuous, it must be both (1) in a type size easily readable from the distance between the prospective purchaser and the label and (2) in print with sufficient color and contrasting background to be readily distinguishable from other types of information on the label. FDA tentatively concludes that the visible nutrition information presented on the label of the food at the point of purchase 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. Generally, FDA has considered “reasonably related” to mean a type size that is at least 50 percent of the size of the largest print on the label. (Ref. 2).

The alternative approach is to interpret the words “otherwise provide visible nutrition information at the point of purchase” by concluding that (1) “nutrition information” means something more than total calories, and (2) “point of purchase” means something more than on the package of the food itself. Under this interpretation, the non-Nutrition Facts Panel option in the statute would include information in addition to total calories because the broader term

“nutrition information” was used instead of “calories.” Just as the Nutrition Facts Panel contains more than calorie information, so too, would “visible nutrition information at the point of purchase.” This 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 as described in § 101.9 or 21 U.S.C. 343(q)(1)(D) and (E). FDA seeks comment on what other nutrition information, if any, should be required if this alternative interpretation were adopted. FDA also notes that under this alternative interpretation, the vending machine operator could rely on any “visible nutrition information at the point of purchase” that included total calories in addition to other nutrition information regardless of what entity supplied the information.

Likewise, under the alternative approach, “point of purchase” would 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.

In the case of the alternative interpretation, in which the “visible nutrition information at the point of purchase” appears other than on the label of the article of food, there are also the questions of where and through what means the information may be provided. The agency specifically requests 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” and we especially request any consumer studies or social scientific data on this issue.

Regardless of the precise location or means of providing the nutrition information, under the alternative interpretation there would also be a question of ensuring that the information is adequately “visible.” At a minimum, the nutrition information should be clear and conspicuous

and noticeable at the point of purchase, in the context of the surroundings. One way to ensure this visibility if the nutrition information is not on the label of the article of food would be to provide the information in type that is all black or one color, printed on a white or other neutral background that contrasts with the type color. Another way would be to also provide the information using a minimum type size. The agency requests comments on these and other ways to determine if the information is "visible."

Another aspect of whether information that is not on the food itself is visible to the consumer is where the information is placed relative to the "point of purchase." FDA requests comment on the meaning of "the point of purchase" in this context and on all aspects of the alternative interpretation of "visible nutrition information at the point of purchase."

FDA seeks comment on the alternative approaches to interpreting and applying "otherwise provide visible nutrition information at the point of purchase."

G. Conforming Amendment

FDA is proposing to exempt electronic signatures submitted to satisfy the requirements of this proposed section from the requirement to comply with Part 11--Electronic Records; Electronic Signatures (21 CFR part 11) and proposing to amend part 11 to reflect this exemption. We expect this exemption to facilitate the registration process for those vending machine operators who voluntarily choose to register under section 403(q)(5)(H)(ix) of the FD&C Act.

H. Effective Date

FDA received a few comments regarding the effective date of the final rule that would issue based on this proposal. These comments suggested that vending machine operators would need 2 years to implement the requirements for calorie labeling for vending machines due to the costs of producing posters and driving to each site to post the information.

FDA is proposing that the final rule become effective one year from the date of its publication. Because FDA is proposing flexibility for compliance, *i.e.*, the use of signs in, on, or adjacent to vending machines, vending machine operators would be able to choose among a wide variety of less expensive avenues to achieve compliance, depending on their situation. Many foods sold from vending machines are packaged and have Nutrition Facts. Therefore, vending machine operators have the opportunity of orienting the food in the vending machine such that the prospective customer may examine the Nutrition Facts Panel. In this case, the operators would not need to provide calorie information required by 403(q)(5)(H)(viii)(I) of the FD&C Act. If the operator chooses not to orient the food such that the prospective customer may examine the Nutrition Facts Panel, or if it is not practicable to do so because the vending machine is not of the type where the food is visible, the operator may obtain the calorie information from the Nutrition Facts to place on the signs. Further, the proposed rule, if finalized, does not require any particular manner of obtaining calorie information. As discussed above in this document, FDA anticipates that, if a covered vending machine food does not bear Nutrition Facts because it falls under an exemption, the manufacturer or supplier of the food may provide the number of total calories for the food to the vending machine operator so that the operator has the necessary calorie information to meet the calorie disclosure requirements of section 403(q)(5)(H)(viii)(I). Because of the flexibility provided in this proposed rule, the Agency finds that it is reasonable to make the requirements effective in 1 year. Based on

the comments and on what vending machine operators will need to do to come into compliance, the Agency tentatively finds that making the final rule effective 1 year after publication is practicable. The Agency seeks comment on the appropriateness of this timeframe.

IV. Summary Preliminary Regulatory Impact Analysis

The summary analysis of benefits and costs included in this document is drawn from the detailed Preliminary Regulatory Impact Analysis which is available at <http://www.regulations.gov>, Docket No. FDA-2011-F-0171, and is also available on FDA's website at <http://www.fda.gov/Food/LabelingNutrition/ucm217762.htm>.

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Orders 13563 and 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated an "economically" significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the proposed rule has been reviewed by the Office of Management and Budget (OMB).

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Using the Small Business Administration (SBA) definition of small vending machine operators as classified by the North

American Industry Classification System (NAICS 45421), FDA estimates that a significant number of operators impacted by this proposed rule are small businesses. As directed by statute, the requirements of the proposed rule only apply to vending machine operators that own or operate 20 or more vending machines. However, according to data from the Vending Times Census and from the National Automatic Merchandising Association (NAMA), the average annual revenue per machine is less than \$7,000 (Refs. 3 and 4). An operator with only 20 machines may have vending machine revenue of less than \$140,000. In order to exceed the SBA's definition of a small vending machine operator, a firm would need at least \$10 million in annual revenue (Ref. 5). This suggests that a firm with revenue exclusively from vending machine sales would need more than 1,400 machines to exceed the definition of small business. Based on the latest available U.S. Economic Census data that breaks down establishments by revenue, we project that 97 percent of firms selling covered vending machine food, as that term is used in this document, that identify primarily as vending machine operators that are engaged in the business of owning or operating 20 or more vending machines would be small businesses as defined by SBA. Therefore, the Agency believes that the proposed rule would have a significant economic impact on a substantial number of small entities. This impact is discussed further in section V of this document.

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 \$135 million, using the most current (2009) Implicit Price

Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Need for This Regulation

This proposed rule is necessary to implement section 4205 of the Affordable Care Act, which principally amends sections 403 and 403A of the FD&C Act, and requires operators of 20 or more vending machines to disclose calorie information for covered vending machine food. The provision of calorie information for covered vending machine food may help consumers make better informed dietary choices.

Economic justifications for regulatory interventions in private markets rely on the presence of some market failure. In the case of food sold from a vending machine, the private market is particularly robust and competitive. Thousands of individual firms vie for consumer dollars in millions of vending machines across the United States (Ref. 3). Low entry costs for firms and low switching costs for customers suggest that if a sizable fraction of consumers were willing to pay for--and discriminate based on--the visible calorie information at the point of purchase then the industry would provide it to them. In fact, some vending machine operators are voluntarily providing more healthful choices and additional information on machines (Refs. 4 and 6).

Although many of the usual market failures that justify regulatory action, such as the existence of market power or of ill-defined property rights, do not apply here (Refs. 7 and 8), the primary support for regulatory intervention is that there are systematic biases in how consumers process information and weigh current benefits (from consuming higher calorie foods) against future costs (higher probability of obesity and its comorbidities).

The bias is more directly related to the requirements of this proposed rule: Consumer demand for calorie information does not create incentives for the provision of calorie information at the vending machine. This market failure occurs because at the time of purchase, consumers do not value calorie information as much as they do later, when the effects of excess calorie consumption are evident. Studies have shown that consumers have present-based preferences, meaning that they are continually optimistic about the healthfulness of their future choices (Ref. 9, 10 and 11).

These studies suggest that calorie information often lacks salience, or relevance, for consumers at the time of purchase and consumption, even though they may experience regret about their decisions at a later date. This tendency may explain why consumers have not generally demanded calorie and other nutrition information for food sold from vending machines before, or at, the point of purchase, even if they may, at a later point in time, value that information. Because of competition for consumer time and attention vending machine operators have limited time and space in which to convey information to consumers. These limits mean that there is a substantial opportunity cost to the operator of providing calorie information. That is, just as an operator may have to decide which possible foods to leave out of a vending machine with limited space (thus giving up the opportunity to sell those items), it must choose which pieces of information about its foods it wants to convey. Adding an additional piece of information means that an operator may need to downplay or remove some other piece of information. This opportunity cost of information holds true whether the calorie information is displayed on the machine or, as with an increasing number of packaged foods, on the principal display panel of the package.

The proposed requirements mitigate the apparent market failure in information provision stemming from present-biased preferences, although not necessarily the tendency of consumers to underutilize that information. Specifically, for a covered vending machine food, this proposed rule requires that the vending machine operator provide a sign in close proximity to the food or the 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 number. This information must be presented in a color that is sufficiently contrasted with the background, must be in close proximity to the vignette or name or in close proximity to the selection button when a name or vignette is displayed, and, for electronic vending machines, the calorie information may be displayed when the selection numbers are entered but before the selection is confirmed. These requirements are designed so that the calorie information is made available to consumers before they purchase such food. Providing the information will likely increase consumer awareness regarding the calorie content in covered vending machine food and increase the perceived relevance of that information to their decision making. Providing the information may serve to highlight the potential future costs of additional calorie consumption. This increased attention to the caloric content of covered vending machine food may then result in an increased availability of lower calorie options, and an increased demand for these options.

C. Summary of Costs and Benefits of the Proposed Requirements and Regulatory Options

In this section FDA describes the bases of benefits and costs of the proposed requirements and summarizes the results of the detailed Preliminary Regulatory Impact Analysis (PRIA).

Benefits in response to the proposed requirements Obesity is a major public health concern in the United States and one of the top leading health indicators addressed by the United States Healthy People 2020 goals. Nationally representative data indicate an increase in the prevalence of obesity over the past three decades (Ref. 12). The 2007-2008 National Health and Nutrition Examination Survey (NHANES) data showed that 34 percent of the adult U.S. population is obese and 34 percent are overweight (Ref. 13).

Excess body weight has many health (Ref. 14), social (Refs. 15 and 16), psychological (Refs. 17 and 18), and economic consequences (Ref. 19) for the affected individuals. Lower life expectancy, elevated risk of diabetes, hypertension, stroke and other cardiovascular diseases have been documented to rise simultaneously with the increased prevalence of obesity (Ref. 14). The economic impact is especially evident in health-care costs in terms of greater health-care utilization and higher medical expenditures (Ref. 20). More specifically, medical expenditures attributable to overweight and obesity accounted for more than 9 percent of the total U.S. medical expenditures in 1998, or between \$85.7 billion and \$147 billion (Ref. 20). Researchers have proposed various factors to explain this dramatic rise in obesity including declining food prices and physical requirements of labor (Refs. 21 and 22), declining time costs of food preparation (Ref. 23), fast-food restaurant density (Ref. 24) and social interactions (Refs. 25).

Although the relationship between obesity and poor dietary choices is multi-faceted, there is a general agreement in the literature that reduction in excess calories is helpful in preventing or delaying the onset of excess weight gain (Ref. 26). Vending machines are a likely source of high-calorie snack or discretionary foods, as well as some high-calorie meal items. Industry data indicate that there is approximately one vending machine for every 40 adults in the United States, and that up to 5 percent of the money consumers spend on food away from home is spent

on vending machine food (Ref. 27). This suggests that providing calorie information for covered vending machine food to consumers may have a significant effect on calorie intake, the prevalence of obesity, and thus the cost of health care and lost productivity.

To the extent that the proposed requirements mitigate the increase in the prevalence of obesity and the prevalence of these costly co-morbidities such as hypertension and diabetes, society gains the opportunity cost of the averted medical expenditures and an increase in productivity from averted debilitation and death. In addition to educating consumers about calorie content, major predicted elements of the consumer and industry response to this proposed rule are:

1. Increased awareness regarding the caloric content in covered vending machine foods, and the perceived relevance of that information to decision making, which may help reduce the present-bias in preferences, and thus encourage the consumption of lower calorie options.

2. Increased consumer interest in lower calorie options, and greater transparency in the caloric content of foods sold in vending machines, which may give manufacturers an incentive to:

- a. Reduce the calorie content of foods sold in vending machines through reformulation or by decreasing portion size.

- b. Provide additional items with lower calorie formulations.

These changes may reduce consumers' caloric intake from food sold in vending machines. Note that any reduction in calorie intake in these settings may be at least partially offset by increases in calorie intake during other meals or snacks. Because FDA lacks data on how consumers will substitute among caloric sources, the benefit estimations given here may be higher or lower than those that will be realized if the rule is finalized as proposed.

Coverage of the proposed rule and industry overview. The proposed rule covers certain vending machine operators that are engaged in the business of owning or operating 20 or more vending machines and those vending machine operators that voluntarily register with FDA to become subject to the Federal requirements. The proposed rule does not cover vending machines without a selection button, including bulk vending machines that dispense gum, candy and nuts. Vending machines are operated both by food service firms and by firms in other businesses that operate machines for the benefit of their customers or employees and do not identify as vending machine operators. Because this latter group cannot be accurately counted, published estimates of the number of vending machine operators will generally undercount the number of covered operators under the proposed rule. For the purposes of this preliminary regulatory impact analysis, we will use the term “covered operators” or “covered vending machines” to refer to operators or machines that sell covered vending machine foods. According to the NAMA, there are approximately 13,500 companies that operate vending machines in the United States (Ref. 4). Other estimates put the total closer to 10,000 (Ref. 3). This total includes 5,000 firms whose primary business identification is as vending machine operators (NAICS 4542), plus a variety of other firms that operate vending machines, but do not primarily identify as such. These other companies include, for example, beverage manufacturers and food service contractors. Because of the difficulty in determining which firms are covered, and because FDA has no data on the potentially significant number of covered vending machine operators that self-identify as businesses outside the food industry, we take NAMA’s higher estimate of 13,500 firms as the number of covered firms.

FDA estimates that 97 percent of firms selling covered vending machine food that identify primarily as vending machine operators that are engaged in the business of owning or

operating 20 or more vending machines are small businesses as defined by the SBA. Other estimates indicate that more than 90 percent of the firms covered by the proposed rule are defined as small businesses (Ref. 3). This percentage may be lower for firms that have primary business identification other than as vending machine operators, but the majority of covered businesses will likely still be defined as small businesses. Because very small, informal businesses that are not captured by economic census data might operate 20 or more machines, these figures may underestimate the number of affected small businesses. Conversely, approximately 72 percent of industry revenue--and thus a comparably large fraction of consumption--comes from firms with more than \$10 million in annual sales, and 85 percent comes from firms with more than \$5 million in revenue (Ref. 3).

Vending machine operators together operate an estimated 5 to 7 million machines (Refs. 3 and 4) in at least 1.5 million locations (Ref. 3). Approximately 70 percent of these machines sell packaged food, including beverages, that are required to bear nutrition labeling under section 403(q)(1) of the FD&C Act and FDA regulations at § 101.9, and thus have Nutrition Facts. This 70 percent is comprised mostly of packaged beverage machines, which account for more than 50 percent of all vending machines, with the remainder--approximately 20 percent of all machines--selling packaged confections or snacks. Ten percent sell a variety of hot and cold cup beverages, frozen or fresh food products and miscellaneous other food products. The final 20 percent of machines are bulk candy, nut or gum machines that are not covered by section 403(q)(5)(H)(viii) and the proposed requirements because they lack selection buttons. While these bulk machines form a large percentage of vending machines, they account for less than 0.5 percent of vending machine sales (Ref. 4).

Summary of costs and benefits of the proposed rule and regulatory options In this section we briefly summarize the costs and benefits of the proposed rule that are analyzed in the detailed PRIA. These estimates are collected in table 1. Costs of complying with the proposed requirements have been estimated for three major areas: Cost of nutrition analysis, cost of new signs, including posters, and labor costs. In the case of the proposed rule, FDA estimates that there would be approximately 10,800 operators under the proposed requirements, controlling between 4 million and 5.6 million machines that sell covered vending machine foods. The initial mean estimated cost of complying with the proposed requirements is \$25.8 million, with an estimated mean ongoing cost of \$24.0 million. Mean annualized costs are \$24.5 million at a 7 percent discount rate, and \$24.2 million at 3 percent discount rate. Per operator costs are estimated to be \$2,400. FDA estimates that average per machine costs are less than \$10 annually.

FDA has not estimated the actual benefits associated with proposed requirements. Food choice and consumption decisions are complex and FDA is unaware of any comprehensive data allowing accurate predictions of the effect of the proposed requirements on consumer choice and vended foods. Therefore, FDA has constructed a plausible individual effect of the proposed rule, and has conducted a break-even analysis in order to determine the proportion of the U.S. obese adult population that would need to attain this minimal response in order for the proposed requirement to yield a positive net benefit. Using a 100 calorie per week reduction in intake as the benchmark effect, FDA estimates that at least 0.02 percent of the adult obese population would need to reach this benchmark in order for the rule to break even on the initial total cost. On an ongoing basis, again, at least 0.02 percent of the adult obese population would need to reach this benchmark in order for the rule to break even on the recurring annual costs. These effects are summarized in table 1 of this document.

Finally, although registration by firms wishing to register with FDA in order to come under the proposed requirements and the associated preemption from State or local regulations is voluntary, and will only occur to the extent that the costs of registration and compliance with Federal regulation is lower than that of State or local laws, this registration constitutes a collection of information under the Paperwork Reduction Act of 1995. Therefore, FDA has also estimated the burden associated with this collection of information in the detailed analysis.

Table 1 -- Accounting Statement: Annualized Cost and Break-Even Benefit Point for the Proposed Requirements

	Primary Estimate	Low Estimate	High Estimate	Year Dollar	Discount Rate	Period Covered
Benefits						
Annualized Monetized (\$millions/year)	Not Quantified					
Annualized Quantified:						
Qualitative: FDA estimates that at least 0.02 percent of the adult obese population would need to reduce caloric intake by at least 100 calories per week in order for benefits from the proposed requirements to reach a break even point on annualized costs (at either 3% or 7%)						
Costs						
Annualized Monetized (\$millions/year)	\$24.5	\$12.5	\$39.8	2009	7%	10
	\$24.2	\$12.1	\$39.6	2009	3%	10

Regulatory Options In addition to a baseline, FDA has identified four regulatory options for this proposed rule. The costs and benefits of these options are summarized in table 2 of this document.

(0) Baseline for the purpose of analysis--No new Federal regulatory action.

(1) Option 1, the proposed rule, allowing 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 number, and with an effective date of 1 year after publication of the final rule.

(2) Option 2, similar to the proposed rule, but requiring that calorie declarations be immediately adjacent to the article of food or selection button for all calorie disclosures. For this option, FDA estimates the cost of individual signs for each article of food or selection button.

(3) Option 3, Similar to the proposed rule, but with an additional year in compliance period for vendors with less than \$500,000 in annual revenue from vending machines.

(4) Option 4, similar to the proposed rule, but with coverage extended to bulk vending machines without selection buttons.

Table 2-- Summary of Estimated Annualized Compliance Costs for Each Option

Summary Of Options	Primary Estimate (in millions)	Low Estimate (in millions)	High Estimate (in millions)	Percent Discount Rate (10 year horizon)	Proportional Cost Relative to Primary Estimate of the Proposed Requirements	Proportional Dollar Sales of Restaurant Food Relative to Primary Estimate of the Proposed Requirements
(Baseline)	N/A	N/A	N/A	N/A	N/A	
Option 1: the Proposed Rule	\$24.2	\$12.1	\$39.6	3%	0.0%	0.0%
	\$24.5	\$12.5	\$39.8	7%		
Option 2: Individual Signs	\$81.8	\$36.1	\$140.4	3%	+229.2%	0.0%
	\$82.5	\$36.6	\$141.1	7%		
Option 3: Longer Compliance Time for Small Businesses	\$24.2	\$12.1	\$39.6	3%	0.0%	0.0%
				7%		
Option 4:	\$24.5	\$12.5	\$39.8	3%	+25.6%	+0.5%
	\$30.2	\$15.1	\$49.4			

Extended Scope to Include Bulk Machines	\$31.0	\$15.8	\$50.3	7%		
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FDA estimates that Option 2, which would require individual signs or labels for each covered vended food, has a ten-year annualized costs of between \$36.1 million per year and \$140.4 million per year at a 3 percent discount rate, with a primary estimate of \$81.8 million. Averaged over primary, low and high estimates, the costs of Option 2 are 229.2 percent higher than those of the proposed requirements. These changes are discussed more fully in the detailed analysis.

Option 3 which considers a longer compliance time for small businesses represents only a delay in the costs. This delay has a small positive impact on the annualized cost, but one that does not change the (rounded) estimate of costs for Option 3 from the estimate, of costs for Option 1. Option 4, expands the scope of the requirements to include foods in bulk vending machines without selection buttons, has costs that are 25.6 percent higher than the proposed option, and covers an additional 0.5 percent of sales of vended foods.

For full documentation and discussion of these estimated costs and benefits see the detailed Preliminary Regulatory Impact Analysis, available at <http://www.regulations.gov>, Docket No. FDA-2011-F-0171, and is also available on FDA's website at <http://www.fda.gov/Food/LabelingNutrition/ucm217762.htm>.

V. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze

regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA tentatively concludes that this proposed rule will have a significant economic impact on a substantial number of small entities.

However, FDA has built flexibility into the proposed rule. The proposed rule does not mandate a particular method for determining calorie disclosure; instead, the proposed rule provides options for how vending machine operators can determine calorie information for covered vending machine food. Further, the proposed rule does not prescribe the materials that may be used by vending machine operators in disclosing calorie information; instead, the proposed rule provides options for how vending machine operators can disclose calorie information for covered vending machine food. Therefore, vending machine operators may choose among a wide variety of less, or more, expensive avenues to achieve compliance, depending on their situation. Because no particular method for compliance is mandated, the proposed rule gives small businesses the leeway to use cheaper solutions that meet the requirements of the proposed rule (e.g., stickers).

A general way to add flexibility for small firms during a rulemaking is to lengthen the time for these firms to comply with the rule. An example of a delayed compliance time for small businesses applied to this proposed rule is the option for vendors with less than \$500,000 in annual revenue from vending machine food sales to have an additional year to comply. Generally, FDA uses the SBA's definition of "small business" as it applies to the relevant economic sector, in this case, NAICS 4542. However, as noted in the detailed Preliminary Regulatory Impact Analysis, available at <http://www.regulations.gov>, Docket No. FDA-2011-F-0171, and is also available on FDA's website at <http://www.fda.gov/Food/LabelingNutrition/ucm217762.htm>, SBA defines a small vending

machine operator as one with annual revenue less than \$10 million, and this definition would cover at least 97 percent of the industry. Adding flexibility --such as a longer time to come into compliance--specifically for small firms would mean that most vending machine operators would be given that added flexibility. Therefore FDA has taken the approach of building substantial flexibility into the proposed rule for most vending machine operators in order to give the entire industry the opportunity to comply in the most cost-effective way.

VI. Paperwork Reduction Act

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the 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.

The information collection provisions for all provisions of this proposed rule have been submitted to OMB for review as revisions of collections approved under OMB control numbers 0910-0664 and 0910-0665. Interested persons are requested to fax comments regarding information collection by [insert date 30 days after date of publication in the FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB. 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: 202-395-5806.

FDA invites comments on: (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.

Vending Machine Labeling: Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act of 2010--(OMB Control Number 0910-0665)--Revision

Section 4205 of the Affordable Care Act, which amends sections 403(q)(5) and 403A of the FD&C Act, requires disclosure of calorie and other nutrition information by restaurants and vending machine operators. Section 4205 became effective on the date the law was signed, March 23, 2010. Restaurants and vending machine operators not subject to the requirements of section 403(q)(5)(H) may elect to become subject to the requirements of section 403(q)(5)(H) by registering biannually with FDA. Section 4205 required FDA to publish a notice in the Federal Register within 120 days of the date of enactment of section 4205, providing information on the terms and conditions for persons who voluntarily elect to be subject to nutrition disclosure requirements specified in the law.

A. Statutory Compliance

To comply with the PRA and with the statutory deadline under the provisions of section 4205 for publication of registration information, FDA initially obtained a 6-month OMB approval of the collection of information requirements under the emergency processing provisions of the PRA. With OMB approval of the collection of information requirements of section 4205, FDA took several actions: (1) Developed an electronic form, "Menu And Vending Machine Labeling Voluntary Registration," Form FDA 3757, (2) as required by section 4205, published a notice in the Federal Register of July 23, 2010 (75 FR 43182) (the July 23, 2010, notice) to explain how retail food establishments and vending machine operators not otherwise subject to the provisions of section 4205 may voluntarily elect to become subject to them, and (3) developed and implemented the guidance 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." This guidance among other things clarified section 4205's effect on State and local menu and vending machine labeling laws, to ensure that industry and State and local government understood the immediate effects of the law. FDA's current thinking on the preemptive effects of section 4205 is set out in the Federalism sections of the preamble to the proposed rule implementing menu labeling and this proposed rule.

FDA has requested a 3-year approval of the information collection requirements under the same assigned OMB Control Nos. 0910-0664 and 0910-0665. In the Federal Register of January 31, 2011, FDA published two notices announcing the submission to OMB of the information collection requests for No. 0910-0664 (76 FR 5384) and No. 0910-0665 (76 FR 5380). Elsewhere in this Federal Register, FDA published a proposed rule entitled "Food Labeling; Nutrition labeling of standard menu items in restaurants and similar retail food

establishments” (the Menu Labeling proposed rule). As noted, the information collection requests previously submitted sought OMB approval of the reporting, recordkeeping, and third party disclosure burdens of section 4205, not the provisions of the Menu Labeling proposed rule. With that proposed rule, FDA submitted a revised information collection request seeking OMB approval of the changes caused by the Menu Labeling proposed rule to the collections approved under OMB Control Nos. 0910-0664 and 0910-0665. This proposed rule seeks further revision of those information collections with regard to the recordkeeping and third party disclosure burdens for vending machine operators caused by this proposed rule.

B. Revision of OMB Control No. 0910-0665 by the Proposed Rule

These estimated annual recordkeeping burdens have changed from the burdens estimated for the OMB control number 0910-0665 30 day notice (76 FR 5380, January 31, 2011). Total initial hours have risen by 1,920 due to an increase in the estimated number of recordkeepers from 600 to 915 and an increase in the number of hours per record from 2 hours to 4 hours. The estimated burden of recurring hours increased by 8 hours to 128 hours. This estimate of third party disclosure hours has decreased by approximately 13.2 million hours, from the 14 million hours estimate given in the 30-day notice.

C. Consolidation of OMB Control No. 0910-0664 Under 0910-0665

The Menu Labeling proposed rule contains a revision request in which the burden hours for the information collection request under OMB control number 0910-0664, “Restaurant Menu and Vending Machine Labeling: Registration for Small Chains Under Section 4205 of the Patient Protection and Affordable Care Act of 2010” are being consolidated under the information collection request assigned OMB control number 0910-0665, “Restaurant Menu and Vending

Machine Labeling: Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act of 2010.” In addition, this proposed rule is a revision request in which these two information collection requests will be further revised with regard to the estimated burden of the proposed rule on vending machine operators. The revised information collection request for 0910-0665 will be renamed “Restaurant Menu and Vending Machine Labeling: Registration, Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act of 2010.” Upon approval of this revision request, the information collection request for OMB control number 0910-0664 will be discontinued.

D. Analysis of Changes in Burden Estimates Caused by the Proposed Rule

Description of Respondents: The likely respondents to this information collection are operators of 20 or more vending machines. The following analysis provides FDA’s estimate of the changes caused by this proposed rule to the previously approved recordkeeping and third party disclosure burdens for vending machine operators. The analysis of burden included in this document is drawn from the detailed Preliminary Regulatory Impact Analysis which is available at <http://www.regulations.gov>, Docket No. FDA-2011-F-0171, and is also available on FDA’s website at <http://www.fda.gov/Food/LabelingNutrition/ucm217762.htm>.

Most food sold from vending machines is subject to nutrition labeling requirements under section 403(q) of the FD&C Act and §101.9, which means that calorie content is already collected. A likely scenario in response to vending machine labeling is that food manufacturers will include a set of calorie label stickers in each case of product. This would be efficient both because most manufacturers will already have the calorie information available, and because

economies of scale exist for the manufacturer. In this case, vending machine operators will not need to keep a record of calorie content. Instead, the burden for most operators will be limited to that of creating records and passing the existing information on to consumers.

FDA estimates that there is an average of 600,000 machines that sell unpackaged products. FDA tentatively estimates that between 5 and 10 percent of all operators of vending machines with covered vending machine food, or an average of 810 operators, will need to acquire nutrition information for at least some covered vending machine food. FDA tentatively estimates that there are between 5 to 10 covered vending machine foods that do not include nutrition information per operator, so that the average number of possible new calorie analyses would be 6,480 (8 items/firm x 810 firms). FDA requests comment on these estimates. Based on data from FDA's Recordkeeping Cost Model (Ref. 28), we estimate approximately 4 hours as the time per covered vending machine food for creating the record of nutritional information. Although the proposed rule does not mandate recordkeeping, vending machine operators will likely need to be able to ensure that calorie disclosures for covered vending machine foods are accurate and consistent without needing to re-analyze these foods. The estimated number of hours required for new calorie analysis in the first year is then 25,920 hours. This number is displayed in the first row of table 3 of this document.

FDA believes that the subgroup of covered vending machine foods sold in these vending machines is approximately constant. If there is 0.5 percent growth or turnover in the number of firms providing these unpackaged foods, then approximately four new firms will become subject to section 4205 of the Affordable Care Act and the proposed requirements in a given year. The burden associated with these firms would be 128 hours (4 firms x 8 items/firm x 4 hours/item). This amount is given in second row of table 7 of this document.

These estimated annual recordkeeping burdens have changed from the burdens estimated for the OMB control number 0910-0665 30 day notice (76 FR 5380, January 31, 2011). Total initial hours have risen by 1,920 due to an increase in the estimated number of recordkeepers from 600 to 915 and an increase in the number of hours per record from 2 hours to 4 hours. The estimated burden of recurring hours increased by 8 hours to 128 hours. This change is due to an increase in the estimated number of new operators (which stems from the increase in the number of initial recordkeepers), and the increase in the number of hours per record. These changes are due to additional data and analysis that FDA was able to collect in the interim.

Table 3.--Estimated Annual Recordkeeping Burden: Calorie Analysis and Recording

Type of Response	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours	Total Capital Costs for Recordkeeping
Initial hours for vending operators	810	8	6,480	4	25,920	\$1.3 million
Recurring hours for vending operators	4	8	32	4	128	\$6,400
Total					26,048	

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

The third party disclosure burden for vending machine operators is the time necessary to install calorie displays on their vending machines. In the PRIA, FDA estimates an average, recurring hourly burden of 0.17 hours per machine per year to install and maintain the displays. FDA estimates an average of 4.8 million machines are serviced by 10,800 operators, for an average number of machines per operator of 444 machines. The estimated recurring hours needed for third party disclosure is then 816,000 hours (10,800 firms x 444 machines/firm x 0.17 hours/display). This amount is recurring in every year, and is given in table 4 of this document.

These estimated annual third party disclosure burdens have changed from the burdens estimated for the OMB Control Number 0910-0665 30 day notice (76 FR 5380, (Jan. 31, 2011)). This estimate of third party disclosure hours has decreased by approximately 13.2 million hours, from the 14 million hours estimate given in the 30-day notice. In addition, we no longer estimate any growth in the number of hours, given that data shows no significant increase in the number of vending machines over the last several years. These changes are due to additional data and analysis that FDA was able to collect in the interim.

Table 4.--Estimated Annual Third Party Disclosure Burden: Calorie Content

Type of Respondent	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours	Total Capital Costs	Total Operating Costs
Recurring burden for vending operators	10,800	444	4,800,000	0.17	816,000	\$4.8 million	\$19.2 million

The current total reporting burden for menu labeling and vending machine operator registration as required by section 4205, now under review at OMB under No. 0910-0664, is 820 hours. The estimated reporting burden under the Menu Labeling proposed rule is 2,190 hours, an increase of 1,370 hours. As described in the paperwork analysis in that proposed rule, this increase is due to an increase in the estimated number of respondents. This proposed rule does not further revise those estimates.

In compliance with the PRA, the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding the information collection to OMB (see DATES and ADDRESSES sections of this document).

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe *** a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts “any requirement for nutrition labeling of food that is not identical to the requirement of section [21 U.S.C. 343(q)]” (21 U.S.C. 343-1(a)(4)), 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 [21 U.S.C. 343(q)(5)(H)(ix)].” (21 U.S.C. 343-1(a)(4)). If this proposed rule is made final, the final rule would create requirements for nutrition labeling of food under 21 U.S.C. 343(q) that would preempt certain non-identical State and local nutrition labeling requirements.

Section 4205 of the Affordable Care Act 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)].” (Public Law No. 111-148, § 4205(d), 124 Stat. 119, 576 (2010)0.

FDA interprets the provisions of Section 4205 of the Affordable Care Act related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold in vending machines that must comply with the Federal requirements of 21 U.S.C. 343(q)(5)(H), 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 21 U.S.C. 343(q)(5)(H)(viii) or (2) from vending machines operated by a person not subject to the requirements of 21 U.S.C. 343(q)(5)(H)(viii) who voluntarily elects to be subject to those requirements by registering biannually under 21 U.S.C. 343(q)(5)(H)(ix).

Otherwise, for food sold from vending machines not subject to the nutrition labeling requirements of 21 U.S.C. 343(q)(5)(H)(viii), States and localities may impose nutrition labeling requirements. Under FDA’s interpretation of the Rule of Construction in section 4205(d)(1) of the Affordable Care Act, nutrition labeling for food sold from these vending machines would not be “nutrient content disclosures of the type required under [21 U.S.C. 343(q)(5)(H)]” 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 21 U.S.C. 343(q)(5). This interpretation is consistent with the fact that Congress included vending machine operators in the voluntary registration provision of 21 U.S.C. 343(q)(5)(H)(ix). 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.

An alternative to FDA's interpretation of the provisions of section 4205 of the Affordable Care Act related to preemption 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 "nutrition content disclosures of the type required under [21 U.S.C. 343(q)(5)(H)]" and would not fall within the exception to preemption in 21 U.S.C. 343-1(a)(4) ("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 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 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 issued by FDA on August 25, 2010 ("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)). Federal law provides that, upon petition, FDA may exempt State or local requirements from the express

preemption provisions of 21 U.S.C. 343-1(a) under certain conditions. 21 U.S.C. 343-1(b). FDA has promulgated regulations at 21 CFR 100.1 describing the petition process that is available to State and local governments to request such exemptions from preemption. Under the interpretation being proposed by FDA, for food sold from vending machines that is not subject to the nutrition labeling requirements of 21 U.S.C. 343(q)(5)(H), States and localities may establish or continue to impose nutrition labeling requirements. Under the alternative interpretation described above, there would be vending machines for which the Federal government has not required nutrition labeling and for which States and localities would also 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. 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 in the event states petition for exemption.

FDA requests comments on the Agency's interpretation of the provisions of section 4205 of the Affordable Care Act related to preemption, as well as on the alternative interpretation described in the Federalism section. FDA also requests comments on the use of the petition process in the context. In addition, the Agency requests comments on other potential interpretations that interested persons identify as appropriate given both the preemption-related language of section 4205 and the statutory goals.

In addition, the express preemption provisions of 21 U.S.C. 343-1(a)(4) do not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food. This is clear from both the

literal language of 21 U.S.C. 343-1(a)(4) with respect to the scope of preemption and from the Rule of Construction at section 4205(d)(2) of the Affordable Care Act.

VIII. Environmental Impact

The Agency has 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.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

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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, it is proposed that 21 CFR parts 11 and 101 be 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

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(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 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)) with FDA for purposes of paragraph (d) of this section.

Vending machine means 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.

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 dispensed from a vending machine are not covered vending machine food if:

(1) The prospective purchaser can view the entire Nutrition Facts Panel on the label of the vended food without an obstruction. The Nutrition Facts Panel must be the information in the format required in § 101.9(c) and (d). The Nutrition Facts Panel must be 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. 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.

(2) An article of food sold from a vending machine provides visible nutrition information at the point of purchase. The visible nutrition information at the point of purchase includes the total number of calories for the article of food, as dispensed, at the point of purchase. This visible nutrition information must appear on the food label itself. This visible nutrition information must 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.

(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:

(A) 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);

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

(C) Is a vending machine with a selection button; or

(ii) 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 the FDA under the provisions of paragraph (d) of this section

(2) Calorie declaration. (i) The number of calories must be clear and conspicuous for a covered vending machine food and 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) For calorie declarations in or on the vending machine, 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, 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.

(D) 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.

(E) The number of calories for packaged foods that contain multiple servings must include the total calories present in the covered vending machine food. The vending machine

operator may voluntarily disclose calories per serving in addition to the total calories for the food.

(ii) Calorie information for covered vending machine food must be placed prominently in the following manner:

(A) This calorie information 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 sign is visible at the same time as the food, its name, price, or selection button or selection number is visible.

(B) 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.

(C) When the calorie information is declared on a sign adjacent to the vending machine, 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.

(D) 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.

(E) 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.

(F) For vending machines with limited choices, e.g., 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.

(d) Voluntary provision of calorie labeling for foods sold from vending machines.

(1) Applicability. An authorized official of 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 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 e-mail 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. 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, White Oak Building 22, Rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(vi) Authorized officials of a vending machine operator who elects to be subject to the Federal requirements can register by visiting <http://www.fda.gov/menulabeling>. 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) 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.

Date: __March 28, 2011_____

Margaret A. Hamburg,
Commissioner of Food and Drugs.

Kathleen Sebelius,
Secretary of Health and Human Services.

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