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21 CFR Parts 11 and 101
Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0172]

RIN 0910–AG57

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: To implement the menu 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 certain nutrition information for standard menu items in certain chain restaurants and similar retail food establishments. The Affordable Care Act, in part, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), among other things, to require restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Under provisions of the Affordable Care Act, restaurants and similar retail food establishments not otherwise covered by the law may elect to become subject to the Federal requirements by registering every other year with the FDA. Providing calorie and other nutrition information in restaurants and similar retail food establishments would assist consumers in making healthier dietary choices.

DATES: Submit either electronic or written comments on the proposed rule by June 6, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 6, 2011 (see the "Paperwork Reduction Act of 1995" section of this document). See section III.G of this document for the proposed effective date of any rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–F–0172 and/or RIN 0910–AG57, 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, Docket No. FDA–2011–F–0172, and RIN 0910–AG57 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.

FOR FURTHER INFORMATION CONTACT: Claudine Kavanaugh, Office of Foods, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 3234, Silver Spring, MD 20993, 301–796–4647.

SUPPLEMENTARY INFORMATION:

I. Background

A. Public Health Impacts of Overconsumption of Calories and Poor Nutrition

The U.S. Centers for Disease Control and Prevention (CDC) identifies as overweight an adult whose body-mass index, or BMI, (defined as weight in kilograms divided by the height in meters squared) is between 25 and 29.9. CDC defines an obese adult as a person 20 years of age or older whose BMI is 30 or above (Ref. 1). Data published by CDC indicate that 68 percent of the adult U.S. population is overweight or obese under this definition, including 34 percent who are considered obese (Ref. 1). For adults, being overweight or obese increases the risk for a number of chronic diseases, including coronary heart disease, type 2 diabetes, stroke, hypertension, arthritis, and certain types of cancer (Refs. 1 and 2). A BMI over 35 is associated with excess mortality, primarily from cardiovascular disease, diabetes, and certain types of cancer (Refs. 1, 3–5). Cardiovascular disease, cancer and diabetes are the leading causes of death and disability in the US, accounting for 70 percent of all deaths in the U.S. (Ref. 6). In 2005, 133 million Americans (almost one out of every two adults) had at least one chronic illness (Ref. 6). As noted previously, overweight and obesity are important contributors to the morbidity and mortality associated with these diseases.

CDC defines obesity in children as a BMI at or above the 95th percentile plotted on CDC BMI-for-age and sex growth charts. Overweight in children is defined as BMI-for-age from the 85th up to the 95th percentile (Ref. 7). Using this definition, CDC data indicate that about 32 percent of children and adolescents, aged 2 to 19, are overweight or obese (Ref. 8). Overweight and obesity in childhood is associated with a risk for obesity in adulthood, with the associated health risks. In addition, children with high BMI face health problems even in childhood, including elevated lipid concentrations and blood pressure (Ref. 8).

The primary risk factors for overweight and obesity in the general population are overconsumption of calories (*i.e.,* eating more calories than are needed to maintain body weight) and physical inactivity (*i.e.,* getting an amount of exercise below the amount required to burn excess calories consumed over the amount needed to maintain body weight) (Ref. 9 at pp. 1, 8, 9). Americans now consume an estimated one-third of their total calories on foods prepared outside the home (Ref. 10) and now spend almost half of their annual food dollars on foods prepared outside the home (Refs. 11 and 12.). Consumers are generally unaware of, or inaccurately estimate, the number of calories in restaurant foods (Ref. 13). In one survey of 193 adults, the participants underestimated the calorie content in foods prepared outside of the home they perceived to be "healthier" food choices by nearly half, an average of almost 650 calories per item (Ref. 14).

B. 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), 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)). In general, when a food is in package form, the required nutrition labeling information (Nutrition Facts) must appear on the label of the food. (Title 21 of the Code of Federal Regulations (CFR) § 101.9 (21 CFR 101.9). FDA's final regulations establishing nutrition labeling requirements were published in 1993 (58 FR 2079, January 6, 1993) and are found at § 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 must include information about the levels of 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, vitamins, and minerals. Research conducted by FDA and others shows that many consumers use the Nutrition Facts to make their food choices (Ref. 15). However, this nutrition information is generally not available for foods sold in restaurants and similar retail food establishments, which make up an increasing proportion of the American diet.

C. The Exemption From Federal Nutrition Labeling Requirements for Food Sold in Restaurants and Other Retail Food Establishments Under NLEA

The NLEA amendments to the FD&C Act included an exemption for 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" (403(q)(5)(A)(i)) (21 U.S.C. 343(q)(5)(A)(i)). The NLEA amendments to the FD&C Act also included an exemption for food of the type described in section 403(q)(5)(A)(i) that is primarily processed and prepared in a retail establishment, ready for human consumption, "offered for sale to consumers but not for immediate human consumption in such establishment and which is 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. Current provisions in § 101.10 require restaurants and other establishments in which food is offered for human consumption that make either a nutrient content claim (defined in § 101.13) or health claim (defined in § 101.14) to provide certain nutrition information upon request. For example, if a menu lists an entrée as being low in fat, information about the amount of fat in the entrée must be available upon request. FDA notes that this requirement is and will still be in place if this proposed rule is finalized.

FDA provided examples of restaurants or other establishments in which food is offered for human consumption, in which food sold generally was exempted from nutrition labeling requirements under NLEA, in § 101.9(j)(2). The agency also provided in § 101.9(j)(3) examples of food sold in establishments in which food is processed and prepared, ready for human consumption, offered for sale to consumers but not for immediate consumption, and not offered for sale outside of the establishments. These regulations are further discussed in section III.A of this document.

In recent years, there has been growing support among public health experts for providing calorie and other nutrition information on restaurant menus in order to help consumers make more informed food choices. (Refs. 13, 16–18) There is also evidence of consumer preference for calorie information on menus. For example, more than 70 percent of respondents to a national telephone survey of 580 adults supported the idea of listing calorie information on restaurant menus (Ref. 19). In a subset of 150 individuals from an experimental study in Minneapolis-St. Paul, MN about the influence of nutritional labeling on fast-food meal choices, 79 percent of respondents said they would use calorie information if it was provided (Ref. 20).

Some State and local jurisdictions have enacted laws or regulations requiring calorie declaration for food offered for sale at restaurants and other establishments. However, the requirements of these laws differed among the States and local jurisdictions. For example, some laws applied to retail food establishments with 15 or more locations, while others applied to retail food establishments with 20 or more locations. Some jurisdictions required only calories on menus and menu boards while others required additional nutrient declarations (*e.g.,* variations of the following: total grams of *trans* fat, grams of saturated fat, grams of carbohydrates, and milligrams of sodium). Some State and local laws required a statement on menus and menu boards regarding daily intake amounts for calories and other nutrients and other laws did not require such a statement. The wording of those required statements varied (Refs. 21 and 22).

D. Requirements of Section 4205 of the Patient Protection and Affordable Care Act

On March 23, 2010, the Affordable Care Act (Pub. L. 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, which governs Federal preemption of State and local food labeling requirements. As amended, section 403(q) requires restaurants and similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items ("chain retail food establishments") to provide calorie information for standard menu items, including food on display and self-service food, and to provide, upon consumer request, additional written nutrition information for standard menu items. Such food is deemed to be misbranded if these requirements are not met. More specifically, the following information must be provided for standard menu items that are sold in chain retail food establishments:

- The number of calories contained in each standard menu item as usually prepared and offered for sale on a menu or menu board (the calorie declaration must be "adjacent to" the name of the standard menu item, so as to be "clearly associated with" the item);
- A succinct statement concerning suggested daily caloric intake posted prominently on the menu or menu board designed to enable the public to understand in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards;
- Additional nutrition information for standard menu items in a written form ("written nutrition information"), available on the premises, which must be made available to consumers upon request;
- A "prominent, clear, and conspicuous" statement on the menu or menu board regarding the availability of the written nutrition information; and
- The number of calories (per item or per serving) on a sign adjacent to self-service food and food on display. This food includes food sold at salad bars, buffet lines, cafeteria lines or similar self-service facilities, and self-service

beverages and food on display that is visible to consumers.

Section 4205 of the Affordable Care Act became effective on the date the law was signed, March 23, 2010; however, some provisions depend on FDA to issue rules before they can be required. With respect to chain retail food establishments, the provisions that became requirements upon enactment are:

- Disclosing the number of calories contained in each standard menu item as usually prepared and offered for sale on menus and menu boards;
- Providing written nutrition information to consumers upon request;
- Providing a "prominent, clear, and conspicuous" statement on menus and menu boards about the availability of the written nutrition information; and
- Providing calorie information (per serving or per food item) for self-service items and food on display, on a sign adjacent to each food item.

The law also specifies that FDA must issue regulations that:

- Establish requirements for a succinct statement concerning daily caloric intake, posted prominently on the menu or menu board, designed to enable the public to understand in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards;
- Establish standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item; and
- Specify how an authorized official of any restaurant or similar retail food establishment not subject to the requirements of section 403(q)(5)(H) may elect to be subject to the requirements by registering biannually the name and address of such restaurant or similar retail food establishment with FDA.

Although these provisions became requirements at the time the law was signed, FDA has previously announced that we intend to exercise our enforcement discretion until the final rule is published and in effect. *See* 76 FR 4360 (Jan. 25, 2011). FDA believes that this approach to implementing section 4205 will minimize uncertainty and confusion among all interested persons. The agency also believes that expeditious completion of the rulemaking process will most rapidly lead to full and consistent availability of the newly required nutrition information for consumers.

Given that FDA does not intend to enforce the self-executing provisions at this time, we encourage our State and local partners to proceed in a similar way. We do, however, encourage establishments that already have calorie and nutrition information available to continue to provide that information to consumers.

Section 403(q)(5)(H)(x) requires that FDA propose implementing regulations no later than one year after enactment of the ACA (21 U.S.C. 343(q)(5)(H)(x)). In addition, section 4205 authorizes FDA to require, by regulation, chain retail food establishments to disclose information about a nutrient, not explicitly required to be disclosed by section 4205, in the written nutrition information, if FDA determines that such information should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices (21 U.S.C. 343(q)(5)(H)(vi)).

Section 403(q)(5)(H)(viii)(I) establishes calorie disclosure requirements for certain articles of food sold from a vending machine that is operated by a person who is engaged in the business of owning or operating 20 or more vending machines (21 U.S.C. 343(q)(5)(H)(viii)(I)). Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal related to calorie declaration for food sold in vending machines.

Section 4205 required FDA to publish a notice in the **Federal Register** specifying the terms and conditions under which restaurants or similar retail food establishments and vending machine operators not subject to the requirements of section 4205 could elect to be subject to requirements by registering with FDA (21 U.S.C. 343(q)(5)(H)(ix)). FDA has published this notice. See 75 FR 43182, July 23, 2010. Voluntary registration is discussed in section III.C. of this document.

E. FDA Activities Related to Implementation of Section 4205

On July 7, 2010, FDA published a notice in the **Federal Register** 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. Comments to the docket were due September 7, 2010. In response to this docket notice, FDA received approximately 875 responses, each containing one or more comments. Many of these comments, in general, supported the nutrient disclosure requirements in chain retail food establishments and for food sold from vending machines, whereas some comments opposed such requirements.

On July 23, 2010, FDA published a **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 (July 23, 2010)). In response to this notice, FDA received seven responses, 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) that became requirements upon enactment. Our current thinking on the preemptive effect of section 4205 is set out in section IX. of this document.

Also on August 25, 2010, FDA published a "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010" ("draft implementation guidance") (75 FR 52426, August 25, 2010). The draft implementation guidance described which provisions became requirements upon enactment of the law and which provisions FDA would implement through rulemaking. FDA received approximately 80 responses to this draft implementation guidance, each containing one or more comments. On January 25, 2011, FDA published in the **Federal Register** a notice withdrawing the draft implementation guidance (76 FR 4360 January 25, 2011)). FDA now intends to complete the notice and comment rulemaking process for section 4205 before initiating enforcement activities. In the course of developing this proposed rule, we have considered the comments received on the draft guidance.

We describe in more detail and respond to the comments to the notices and guidance documents, including the withdrawn draft implementation guidance, in this proposal. Some of the comments to the notices and guidances are duplicative. Therefore, in this document, when responding to

comments from the docket notice, the registration notice, or the draft implementation guidance, we will generally refer to them simply as "comments" without identifying to which document these were submitted. Comments that are outside the proposed scope of this rulemaking, such as those concerning labeling of ingredients, allergen labeling, and labeling of genetically engineered foods, will not be discussed.

II. Legal Authority

As stated in section I.D. of this document, on March 23, 2010, the Affordable Care Act (Pub. L. 111–148) was signed into law. Section 4205 amended section 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), which requires, in relevant part, covered establishments to provide certain nutrient declarations for standard menu items. Under section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)), such declarations must be truthful and nonmisleading. Because food that is not in compliance with section 403 is deemed misbranded, 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 a 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 that the Secretary of Health and Human Services (Secretary) issue proposed regulations no later than one year after enactment. Section 701(a) (21 U.S.C. 371(a)) vests the Secretary with the authority to issue regulations for the efficient enforcement of the FD&C Act. Thus, FDA has the authority to issue this proposed rule under sections 201(n), 403(a)(1), 403(q)(5)(H), and 701(a) of the FD&C Act.

FDA is proposing requirements that covered establishments provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Also, FDA is proposing the terms and conditions for voluntary registration by establishments that are not automatically subject to the requirements of section 4205 that elect to become subject to the requirements. FDA is proposing to set out these provisions in new § 101.11.

III. The Proposal

A. Summary

This proposal would add a new section 101.11 to 21 CFR and make additional changes to FDA's regulations as needed to conform existing regulations to the new statutory requirements. In this section, we explain the provisions of the new proposed section 101.11, beginning with the definitions of several key terms in the proposal.

B. Definitions

The menu labeling requirements of section 4205 apply to standard menu items offered for sale in "covered establishments":

1. "Restaurants or similar retail food establishments" that are
   - Part of a chain with 20 or more locations,
   - "doing business under the same name", and
   - "offering for sale substantially the same menu items"; and
2. Other restaurants or similar retail food establishments that have been voluntarily registered to be subject to the Federal requirements by an "authorized official".

Covered establishments must provide calorie information on "menus" and "menu boards," and other nutrition information upon request, for "standard menu items," including "combination meals," "food on display," "self-service food," and "variable menu items." The new nutrition labeling requirements do not apply to "custom orders," "daily specials," "food that is part of a customary market test," and "temporary menu items."

To establish the scope of establishments, labeling, and food covered by section 4205, FDA must define these and other key terms. Therefore, we are proposing in the introductory paragraph of § 101.11(a) that the definitions of terms in section 201 of the FD&C Act (21 U.S.C. 321) are applicable to these terms when used in proposed § 101.11. Additional terms are defined alphabetically in the proposed codified. Here, they are discussed in the order they are mentioned in the outline above, organized into three categories: (1) Terms related to the scope of establishments covered, (2) the terms menu and menu board, and (3) terms related to foods covered.

1. Scope of Establishments Covered

The menu labeling requirements in section 4205 of the Affordable Care Act apply to foods "offered for sale in a restaurant or similar retail food establishment that is 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 substantially the same menu items." They also apply to restaurants or similar retail food establishments that voluntarily register to become subject to the Federal requirements. Some of the questions related to the scope of establishments covered are very complex, and FDA offers several alternatives for public comment.

Covered Establishment

We are proposing in § 101.11(a) that the term "covered establishment" means a restaurant or similar retail food establishment that is a 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, as well as restaurants or similar retail food establishments that voluntarily register to become subject to the Federal requirements. FDA derived this proposed definition from the criteria in sections 403(q)(H)(i) and (ix)(I) of the FD&C Act. Section 403(q)(H)(i) describes which restaurants and similar retail food establishments must meet the new requirements: Restaurants and similar retail food establishments that are 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. Section 403(q)(H)(ix)(I) allows restaurants or similar retail food establishments not otherwise subject to the requirements in section 403(q)(H) to register voluntarily to be subject to them (see section III.C below). Both restaurants and similar retail food establishments described in section 403(q)(H)(i) and those that register under section 403(q)(ix)(I) are subject to, or "covered" by, the nutrition labeling requirements of section 4205.

Terms within the definition of "covered establishment" are discussed below. We note that we have not proposed a definition for the statutory criterion, "part of a chain with 20 or more locations." For the purposes of this proposal, FDA is assuming the common meanings of the words in that phrase. However, FDA requests comment on whether the phrase should be defined in the final rule. In particular, we request comment on the terms "chain" and "location" in the context of the various types of corporate or other business arrangements or structures that might be relevant, including contracting arrangements.

Restaurant and Similar Retail Food Establishment

While the core coverage may seem clear, the relevant statutory term

("restaurants and similar retail food establishments") is ambiguous. It is possible to imagine a range of interpretations, calling for relatively narrow coverage (including only restaurants and those establishments that are closely analogous to restaurants) or relatively broad coverage (including a range of establishments that sell food retail). FDA offers here a proposed interpretation alongside several alternatives for public comment. Under the proposed interpretation, explained in detail below, a retail food establishment is "similar" to a restaurant, and hence, covered, if it offers for sale restaurant or restaurant-type food and its primary business activity is the sale of food to consumers. FDA gives examples of included and excluded establishments below.

Statutory context. As a starting point for developing a regulatory definition, we look to statutory context. As noted earlier, the 1990 NLEA amendments exempted two categories of food relevant for this discussion: (1) Food "which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or used in such establishments," and (2) food "which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is the type described in [(1)] and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment." 21 U.S.C. 343(q)(5)(A)(i) and (ii). These are referred to in this document as "restaurant food" and "restaurant-type food," respectively.

When promulgating regulations in 1993 to implement NLEA, FDA interpreted the categories of restaurant and restaurant-type food broadly. The agency provided the following examples of restaurant food: Food sold in institutional food service establishments, transportation carriers, delicatessens and retail confectionery stores where there are facilities for immediate consumption on the premises, food service vendors such as mall cookie counters, and sidewalk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices. 21 CFR 101.9(j)(2)(ii). The agency included the following examples of restaurant-type food: Ready-to-eat foods that processed and prepared on-site and sold by independent delicatessens, bakeries, or retail confectionary stores where there are no facilities for immediate consumption; by in-store delicatessen, bakery, or candy departments; or at self-service food bars such as salad bars. FDA also issued guidance on the labeling of foods sold in restaurants and other retail establishments selling restaurant or restaurant-type foods (Ref. 23).

Section 4205 amended the statutory exemption from Federal nutrition labeling requirements for restaurant and restaurant-type food. In determining the scope of section 4205, FDA considered which restaurant and restaurant-type foods should remain exempt from the Federal nutrition labeling requirements and which should be covered by the new Federal nutrition labeling requirements of section 4205.

Public comments. In response to the docket notice and other **Federal Register** notices published in 2010, described in section I.E. above, FDA received numerous comments on the types of establishments that should be covered under section 4205. Some comments that were submitted to FDA supported the inclusion of a broad list of establishments such as those that had been exempted from nutrition labeling in FDA's implementing regulations of the NLEA. Some of these comments stated that concession stands at bowling alleys, amusement parks, stadiums, casinos, miniature golf courses, and other entertainment venues should be covered as well. These comments asserted that such establishments should be covered because consumers need to have access to calorie and other nutrition information for foods sold from such concession stands, and requiring nutrition information in all of these establishments provides a level playing field. A few of these comments maintained that establishments such as grocery stores and convenience stores contain facilities such as bakeries or cafes that are indistinguishable from their stand-alone counterparts and, therefore, should be covered by section 4205.

Other comments opposed the inclusion of concession stands at entertainment venues such as movie theaters, and restaurants at hotels, stating that the primary purpose of going to these establishments is not to buy food, but instead for entertainment or lodging. A few comments suggested that FDA adopt a definition that excludes establishments whose sale of prepared food (excluding pre-packaged snacks that already list nutritional information) is less than 35 percent of gross revenue. One comment suggested that FDA examine the percentage of sales derived at a particular retail location from food served for immediate consumption on the premises, and that, if more than 25 percent of total sales at a retail location are derived from the sale of food served for immediate consumption on the premises, the retail outlet is similar to a restaurant and should fall within the scope of § 4205.

Some comments opposed the inclusion of convenience stores and some grocery stores. The comments stated that not all chain convenience stores have menus or sell the same food items at all locations. The comments asserted that food in convenience stores is not standardized and that the foods differ depending on the techniques and preferences of the store employees preparing the foods. By contrast, according to the comments, food sold in restaurant chains is typically standardized and prepared in a homogeneous manner as dictated by corporate policy. The comments stated that some grocery stores have cafes, food courts, or otherwise sell restaurant food directly to consumers. Some comments contended that only grocery stores with seating areas should be covered. Other comments stated that FDA does not have authority under section 4205 to regulate individual departments or operations within a retail food establishment unless that establishment as a whole is similar to a restaurant.

FDA received a few comments regarding the possible inclusion of food-service contractors, which the comments described as companies that provide managed food and facility services to a variety of institutions, including hospitals, schools, stadiums/arenas and businesses, as covered establishments. Some of these comments stated that menus at establishments operated by food service contractors can vary from day-to-day and month-to-month. However, if food-service contractors have quick-service restaurants, the comments support calorie labeling in these establishments.

We considered these comments, in addition to the language and purpose of the statute, when deliberating on how to define restaurants and similar retail food establishments for purposes of this rulemaking. We also noted the existence of hybrid establishments, such as chain coffee vendors operating in retail bookstores and soup and sandwich counters, cafes, and food courts in grocery or convenience stores. For example, a grocery store may have a salad bar from which consumers select various foods that are ready for human consumption, processed and prepared primarily in the grocery store, and not offered for sale outside of the grocery

store. In addition, many establishments, such as certain coffee shops in bookstores, operate in or consist of multipurpose businesses, where entertainment, restaurant food and other goods and services are offered together or in close proximity.

Proposed definition. FDA tentatively concludes that a retail food establishment is an establishment whose primary business activity is the sale of food to consumers. FDA also tentatively concludes that in order for a retail food establishment to be "similar" to a restaurant, it must offer for sale restaurant or restaurant-type food. Although there are many types of establishments where consumers come into contact with food for purchase, FDA notes that the statutory text focuses explicitly on restaurants and retail food establishments that are "similar" to restaurants, rather than on all establishments where food is sold (often incidentally to or quite separately from the establishment's primary purpose). In light of the statutory language, FDA is proposing in 101.11(a) that the term "restaurant or similar retail food establishment" means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment. FDA acknowledges that the statutory language is not entirely clear, and invites comments on various alternatives, but currently believes that the proposed definition fits best with the natural meaning of the language and its proper scope.

The sale of food would be considered to be a retail establishment's primary business activity if either (1) the establishment presents or has presented itself publicly as a restaurant (*e.g.,* through consumer-, industry- or investor-oriented materials) or (2) greater than 50 percent of a retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of food. Examples of when an establishment is presenting itself as a restaurant could include calling itself a restaurant on a consumer-oriented Web site, listing itself under "Restaurants" in the phone book, and using the term "restaurant" in its signage. Note that if a portion of the establishment were to present itself publicly as a restaurant (*e.g.,* a "café car" on a train), the first criterion would not necessarily be satisfied; the question would be how the establishment as a whole presents or has presented itself. See the discussion of facilities within establishments below. For the second criterion, gross floor area would include all floor space, wall to wall, including areas under built-in counters, cooking equipment, seating, and similar furniture. Multi-purpose seating areas used substantially for activities other than food consumption, such as seating in entertainment venues (*e.g.,* shows, sport stadiums), would not be counted in the share of floor space devoted to the sale of food. FDA notes that some establishments may have seating outside for the consumption of food (*e.g.,* outdoor cafes). We seek comment on whether this space should be considered in determining gross floor area.

As an alternative to using percentage of gross floor area as an indicator of the primary business activity of an establishment, FDA is seeking comment on an approach based on the percent revenue of the business. Under this alternative approach, the sale of food would be considered to be a retail establishment's primary business activity if either (1) the establishment presents or has presented itself publicly as a restaurant or (2) more than 50 percent of the establishment's revenues are generated by the sale of food. FDA requests comment on this alternative means of determining an establishment's primary business activity. We specifically seek comment on whether 50 percent is the appropriate threshold or whether it should be higher or lower. We also welcome comment on other suggested alternative criteria for identifying the primary business activity of an establishment.

Under the proposal that includes gross floor space, restaurants and similar retail food establishments would likely include table service and quick-service (or fast food) dining establishments, cafeterias,[1] pastry and retail confectionary stores, coffee shops, snack bars, and ice cream parlors, as well as grocery stores and convenience stores that sell restaurant or restaurant-type food. In addition, multi-purpose establishments that offer restaurant or restaurant-type food and include areas for entertainment (*e.g.,* games or children's shows) would be restaurants or similar retail food establishments if they present themselves or have presented themselves publicly as restaurants, regardless of whether the amount of floor space dedicated to the sale of food is greater than 50 percent of the venue's gross floor space.

Correspondingly, establishments that do not sell restaurant or restaurant-type food or whose primary business activity is not the sale of food would not be considered restaurants or similar retail food establishments and would not have to comply with the menu labeling provisions of 403(q)(5)(H). For example, where a multi-purpose establishment has never presented itself publicly as a restaurant and the percentage of the establishment's gross floor area devoted to the sale of food is less than 50 percent, the establishment would not be a restaurant or similar retail food establishment under this proposal. FDA expects that most movie theaters, amusement parks, general merchandise stores with in-house concession stands, hotels, and transportation carriers such as trains and airplanes will not be considered restaurants or similar retail food establishments under this proposal, because, in general, they do not present themselves to the public as restaurants, nor are they likely to meet the floor space (or revenue) threshold.

The following table provides examples of establishments that FDA expects would be considered restaurants or similar retail food establishments under the proposal and those that would not. Note that whether a specific establishment would be considered a restaurant or similar retail food establishment would depend on whether that specific establishment met the proposed regulatory criteria. In addition, a restaurant or similar retail food establishment is covered by the new menu labeling requirements if it is part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items, or it voluntarily registers with FDA.

[1] Many cafeterias located within other establishments, *e.g.,* most school and hospital cafeterias, would be considered part of larger establishments they are situated within and would not be covered by the proposed rule. See the discussion of facilities located within larger establishments below.

TABLE 1—ARE THE FOLLOWING ESTABLISHMENTS "RESTAURANTS OR SIMILAR RETAIL FOOD ESTABLISHMENTS" UNDER THE PROPOSED RULE?

Generally yes	Generally no
Table service dining establishments	Movie theaters
Quick service (fast food) establishments	Amusement parks
Cafeterias	General merchandise stores
Pastry and retail confectionary stores	Hotels
Coffee shops	Trains
Snack bars	Planes
Ice cream parlors	
Multi-purpose establishments that have presented themselves publicly as restaurants	
Establishments within larger establishments that are part of a chain with locations outside of the larger establishment's chain (*e.g.,* chain coffee shop in a bookstore; see discussion below)	
Grocery stores	
Convenience stores	

Note: While the appropriate categorization will often be straightforward, the word "generally," used in the headings, is an important qualification. For example, some grocery and convenience stores may meet the definition of "restaurants or similar retail food establishments" under this proposed rule, while others may not.

Many facilities that sell restaurant or restaurant-type food are located within larger retail establishments, such as a coffee shop in a bookstore, a hot dog stand in a stadium, a quick-service counter in an establishment selling a range of packaged foods and household products ("Superstore XYZ"), or a concession stand in an entertainment venue. Some of these facilities would be considered separate retail establishments, while others would be considered part of their larger retail establishments.

If a facility selling restaurant or restaurant-type food is part of a chain with locations outside of the chain of the larger retail establishment, the facility would be considered a separate retail establishment. For example, if a coffee shop in a bookstore is part of a chain of coffee shops with locations outside of the chain of bookstores, the coffee shop would be considered a separate retail establishment. When determining the primary business activity of the coffee shop, only the representations of the coffee shop itself and the coffee shop's floor area would be considered. The coffee shop in the bookstore would most likely meet the proposed definition of a restaurant or similar retail food establishment.

If, by contrast, a facility selling restaurant or restaurant-type food is not part of a chain with locations outside of the chain of the larger retail establishment, the facility would be considered part of the larger retail establishment. For example, if Superstore XYZ has a café that appears only in other locations of the Superstore XYZ chain, the café would be considered part of Superstore XYZ. When determining the primary business activity of Superstore XYZ, the agency would ask whether the superstore as a whole presents or has presented itself as a restaurant and what percentage of the gross floor area of the superstore as a whole, including the café, is dedicated to the sale of food. Because the café would not be considered an "establishment," it would not be eligible for being a "restaurant or similar retail food establishment" under this proposal. As a result, whether the cafe independently presents itself as a restaurant (*e.g.,* by listing itself in the phone book under "Restaurants") or has greater than 50% of its floor space devoted to the sale of food would be irrelevant.

As another example, a movie theater concession stand that appears only in other movie theaters in that particular chain of movie theaters would not be considered a separate establishment for the purposes of this proposed rule. Because movie theaters usually do not present themselves as restaurants and do not dedicate more than 50 percent of their gross floor area to the sale of food, they generally would not fall within the definition of restaurant or similar retail food establishment in this proposed rule.

FDA requests comment on whether such facilities within larger establishments should be included within the definition of restaurants and similar retail food establishments in the final rule. FDA particularly requests comment on this approach with respect to movie theaters, other entertainment-type venues, and Superstores that offer restaurant or restaurant-type food.

An alternative. One alternative to our proposed definition is to define "restaurant or similar retail food establishment" to mean a retail establishment where the sale of restaurant or restaurant-type food—as opposed to food in general—is the primary business activity of that establishment. Restaurant or restaurant-type food here would not include packaged food that is required to bear Nutrition Facts. Under this alternative, the agency would consider the sale of restaurant or restaurant-type food to be a retail establishment's primary business activity if either (1) the establishment presents itself or has presented itself publicly as a restaurant, or (2) a total of more than 50 percent of a retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of restaurant or restaurant-type food or its ingredients. As with the proposed definition, multi-purpose seating areas used substantially for activities other than food consumption, such as seating in entertainment venues (*e.g.,* shows, sport stadiums) would not be counted in the share of floor space devoted to the sale of restaurant or restaurant-type food. Under this alternative, FDA solicits comment on whether a percent revenue approach to determining an establishment's primary business activity is the sale of restaurant or restaurant-type foods.

Under this alternative, "restaurant or similar retail food establishment" would include table service and quick-service (or fast food) dining establishments, cafeterias, pastry and retail confectionary stores, coffee shops, snack bars, and ice cream parlors. Establishments where the primary business activity is not the sale of restaurant or restaurant-type food would not be considered restaurants or similar retail food establishments. In contrast with the proposed definition, establishments that are unlikely to be considered restaurants or similar retail food establishments under this alternative include grocery and convenience stores, in addition to hotels and transportation carriers such as trains and airplanes. The option would

not cover grocery and convenience stores because it would not count the floor space used to sell food that is not restaurant or restaurant-type food (*e.g.,* packaged food) in determining the primary business activity.

The following table provides examples of establishments that FDA expects would be considered restaurants or similar retail food establishments under the alternative and those that would not. Note that whether a specific establishment would be considered a restaurant or similar retail food establishment would depend on whether that establishment met the alternative regulatory criteria. In addition, a restaurant or similar retail food establishment is only covered by the new menu labeling requirements if it is part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items.

TABLE 2—ARE THE FOLLOWING EESTABLISHMENTS "RESTAURANTS OR SIMILAR RETAIL FOOD ESTABLISHMENTS" UNDER THE ALTERNATIVE TO THE PROPOSED DEFINITION?

Generally yes	Generally no
Table service dining establishment	Movie theaters
Quick service (fast food) establishments	Amusement parks
Cafeterias	General merchandise stores
Pastry and retail confectionary stores	Hotels
Coffee shops	Trains
Snack bars	Planes
Ice cream parlors	Grocery stores
Multi-purpose establishments that have presented themselves publicly as restaurants	Convenience stores
Establishments within larger establishments that are part of a chain with locations outside of the larger establishment's chain (*e.g.,* chain coffee shop in a bookstore; see discussion below)	

Note: While the appropriate categorization will usually be straightforward, the word "generally," used in the headings, is an important qualification. For example, some grocery and convenience stores will qualify as similar retail food establishments under the rule, while others may not. The answer depends on the definition proposed in this section.

Requests for comment. We request comment on the proposed definition and on the alternatives. We are also interested in comments on whether we should use "primary business activity," or a different test, as a basis for determining whether an establishment is a restaurant or similar retail food establishment. We also request comment on whether we should choose a different number for the cutoff for the percent of gross floor area for determining the primary business activity of the retail establishment or whether we should choose the percent revenue approach discussed above or different criteria for determining primary business activity, such as whether the consumer pays for admission to the establishment.

As we have noted, some comments have urged a broader test on public health grounds. Any such test must explain how it is consistent with statutory language. For example, if FDA adopted a percentage revenue threshold test for determining primary business activity and set the threshold at 25%, as some comments suggested, would chain movie theater concessions be included? If so, would this test be appropriate, given the statutory language? We are also interested in comments on the impact of the proposed definition and alternatives on the sale of restaurant or restaurant-type food by large chain "Superstores" or by contractors servicing similar food outlets in 20 or more locations. FDA notes that one food contractor commented that it offers quick service or fast food concepts in some of its locations. The comment further stated that menus in these locations are highly standardized and consistent across locations. The comment supported calorie labeling on menus and menu boards and the availability of additional written nutrition information for these types of locations. Comments supporting or opposing the possible definitions discussed here should include a rationale and should explain the impact of the recommendation on the implementation of section 4205.

Doing Business Under the Same Name

The menu labeling requirements apply to restaurants and similar retail food establishments that are part of a chain with 20 or more locations "doing business under the same name." We are proposing in § 101.11(a) that the term "doing business under the same name" means sharing the same name, where the term "same name" includes names that are either exactly the same, or are slight variations on each other due, for example, to the region, location or size.

In some cases, a chain retail food establishment's name may vary slightly from the names of other establishments in the same chain, often reflecting the location or size of the establishment. For example, a quick-service restaurant, "Joe's Burgers New York Ave.," located on New York Avenue, might have another location on Pennsylvania Avenue called "Joe's Burgers Pennsylvania Ave." As another example, a dine-in restaurant with the name "ABC" might have an outlet in an airport called "ABC Express" that offers take-out. FDA is proposing that the term "same name" includes names that are slight variations on each other, for example, based on region, location or size (*e.g.,* "Joe's Burgers New York Ave." and "Joe's Burgers Pennsylvania Ave." or "ABC" and "ABC Express"). FDA requests comment on this definition. Specifically, we request comment on whether the relevant term should be understood instead to refer to the underlying name of ownership, such as the name of a parent company, or the name of the entity conducting corporate business on behalf of the establishment, such as the name of a contractor operating an establishment, regardless of the public name used by individual establishments.

Offering for Sale Substantially the Same Menu Items

We are proposing in § 101.11(a) that the term "offering for sale substantially the same menu items" means offering for sale menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies. For example, a chain restaurant may make a sandwich and call it "Bay View Crab Cake," whereas another restaurant in that chain that makes the same sandwich prepared the same way and with the same ingredients may call it "Ocean View Crab Cake." These two restaurants would be offering for sale the same menu item. In addition, restaurants and similar retail

food establishments that are part of a chain can still be offering for sale substantially the same menu items if the availability of some menu items varies within the chain. For example, a covered restaurant in a chain may have a limited menu and not carry all the standard menu items as another restaurant in the chain. However, if most of the standard menu items in the restaurant with the limited menu are sold in the restaurant with the more extensive menu, these two restaurants would be offering for sale substantially the same menu items. As another example, a chain retail food establishment might offer standard menu items that are mostly the same, except for a few that are unique to that chain retail food establishment. That chain retail food establishment would still be offering for sale substantially the same menu items as the other establishments in the chain. In this proposed definition, the term "menu items" refers to food items that are offered for sale in a restaurant or similar retail food establishment.

Authorized Official

Restaurants and similar retail food establishments that are not automatically covered by the new menu labeling requirements can voluntarily register to be subject to them. Section 403(q)(5)(H)(ix) provides that "[a]n authorized official of any restaurant or retail food establishment * * * not subject to the requirements of this clause may elect to be subject to the requirements of such clause, by registering biannually the name and address of such restaurant or similar retail food establishment * * * with the Secretary, as specified by the Secretary by regulation." We are proposing in § 101.11(a) that the term "authorized official of a restaurant or similar retail food establishment" means the owner, operator, agent in charge, or any other person authorized by the owner, operator, or agent in charge of a restaurant or similar retail food establishment not subject to the requirements of section 4205 to voluntarily register the establishment with FDA to become subject to the requirements of section 4205. FDA tentatively concludes that it is appropriate for the owners, operators, or agents in charge to be able to authorize other persons to register on their behalf.

Summary of Proposed Scope of Covered Establishments

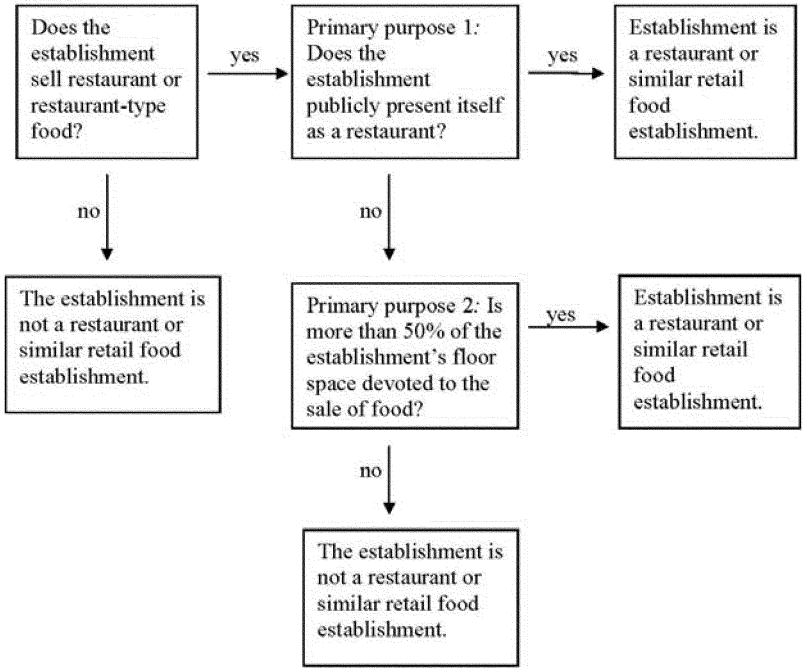
When is an entity an establishment? If an entity is free-standing, it would be an establishment. If an entity is inside an establishment, then the entity could be considered a separate establishment or it could be considered part of the establishment in which it is situated. If the entity is part of a chain with locations outside of the chain of the larger establishment, then the entity would be a separate establishment. If not, the entity would be considered part of the larger establishment.

TABLE 3—WHEN IS AN ENTITY AN ESTABLISHMENT?

	Is the entity an establishment?
The entity is free-standing.	Yes.
The entity is inside an establishment and:	
• It only appears in locations of the larger establishment's chain (*e.g.,* Superstore XYZ Café in Superstore XYZ).	No.
• It is part of a chain with locations outside of the larger establishment's chain (*e.g.,* coffee shop in a bookstore that is part of a chain of coffee shops with locations that are free-standing).	Yes.

When is an establishment a restaurant or similar retail food establishment? To be a restaurant or similar retail food establishment, an establishment must sell restaurant or restaurant-type food. In addition, the sale of food in general must be the establishment's primary purpose. The sale of food is an establishment's primary purpose if (1) the establishment publicly presents itself or has publicly presented itself as a restaurant, or (2) the establishment dedicates more than 50% of its floor space to the sale of food. This is demonstrated in following flow chart:

Figure 1.



When is a restaurant or similar retail food establishment a covered establishment? A restaurant or similar retail food establishment is a "covered establishment" if (1) it is part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items, or (2) it has voluntarily registered with FDA to be subject to the Federal requirements. FDA refers to the first category as "chain retail food establishments."

TABLE 4—STATUTORY CRITERIA FOR CHAIN RETAIL FOOD ESTABLISHMENTS:

Statutory criteria	Proposed interpretation
Part of a chain with 20 or more locations	The restaurant or similar retail food establishment is part of a chain with at least 19 other establishments.
Doing business under the same name	Establishments in the chain share the same name or have names that are slight variations on each other, due to, for example, region or size (e.g., ABC and ABC Express, Joe's Burgers New York Ave. and Joe's Burgers Pennsylvania Ave).
Offering for sale substantially the same menu items	Establishments in the chain offer for sale menu items that use the same general recipes and are prepared in substantially the same ways with substantially the same food components, even if the name of the menu item varies. Establishments can be offering for sale substantially the same menu items even if the availability of some menu items varies within the chain.

Voluntary registration. If a restaurant or similar retail food establishment is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items, the establishment may voluntarily elect to be subject to the new Federal requirements by registering with FDA.

2. Menu and Menu Board

Covered establishments are required to post calories and other information on menus and menu boards. Section 403(q)(5)(H)(xi) provides that "the term 'menu' or 'menu board' means the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection." We are proposing in § 101.11(a) to essentially codify this definition. The proposed regulatory definition also clarifies that menus include breakfast, lunch and dinner menus; dessert menus; beverage menus; children's menus; other specialty menus; electronic menus; and menus on the Internet. Menus may be in different forms, *e.g.,* booklets, pamphlets, or single sheets of paper. Menu boards include drive-through menu boards as well as display boards above ordering counters.

In developing this proposed definition, FDA considered comments expressing various opinions on what constituted a menu or menu board. According to several comments, FDA should allow electronic devices, such as Internet-enabled smart phones, text messaging, and kiosks, to serve as primary writings. One comment requested that FDA clarify whether a writing posted on the Internet would only be considered a menu if a consumer may place an order online. Several comments asserted that marketing materials (*e.g.,* banners, table tents) should not be considered menus.

FDA tentatively concludes that "menu" or "menu board" includes any writing of the covered establishment that is the primary writing from which a consumer makes an order selection.

FDA considered whether "primary" should be from the perspective of the establishment or the consumer. If covered establishments were only required to label the writing they consider to be their primary writing from which consumers make order selections, only one writing would be required to be labeled. For example, at a quick service restaurant that has two menu boards, one above a counter inside and one outside at a drive-through, the one the restaurant considers its "primary writing" would be labeled, but the other might not. Given the importance for all consumers to have access to nutrition information when making order selections, FDA proposes that "primary writing" should be interpreted from a consumer's vantage point. For example, while a printed menu may be the "primary writing" of a restaurant used by a customer ordering food while dining inside the restaurant itself, a menu mailed as a flyer mailed to another customer's home could be the "primary writing" of the restaurant used by that customer ordering take-out or delivery from the same restaurant. Both the printed menu and the menu flyer would meet the definition of "menu" or "menu board" under proposed § 101.11(a). We recognize that some establishments may send menus as a form of advertising. FDA tentatively concludes advertisements for food fall outside the scope of section 4205. However, take-out and delivery menus, which include all or a significant portion of items offered for sale and serve as the primary writing from which consumers make their order selections, would be menus under the proposed rule. FDA requests comment on these tentative conclusions.

FDA notes that many consumers order restaurant or restaurant-type food from restaurants or similar retail food establishments over the phone or Internet. FDA tentatively concludes that if consumers can order from a covered establishment online, over the phone, or by fax, using a writing of the covered establishment on the Internet as the primary writing from which he or she makes his or her order selection, then the writing on the Internet is a menu for the purposes of section 403(q)(5)(H).

3. Food Covered

Section 4205 requires covered establishments to provide calorie and other nutrition information for "food that is a standard menu item," including combination meals, variable menu items, self-service food, and food on display. The new requirements do not apply to custom orders, daily specials, food that is part of a customary market test, and temporary menu items.

Food

The term "food" is defined in section 201(f) of the FD&C Act, in relevant part, as "articles used for food or drink for man * * * chewing gum, and articles used for components of any such article." 21 U.S.C. 321(f). Under section 201 of the FD&C Act, this definition applies "for purposes of this Act." Therefore, articles of food that are offered for sale in covered establishments as standard menu items, including food on display and self-service foods would generally be subject to section 403(q)(5)(H). The term "food" includes foods that are also regulated by other U.S. Government agencies, such as meat, poultry, and processed egg products, which are also regulated by the United States Department of Agriculture (USDA), and alcoholic beverages regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) within the United States Department of the Treasury.[2] Comments submitted to FDA supported the position that meat, poultry, processed egg products, and alcoholic beverages are considered "articles of food" subject to the requirements of amended section 403(q) because they are foods as defined in the FD&C Act and they provide a significant amount of calories.

Other comments stated that TTB, which regulates the labeling of certain alcohol beverages pursuant to the provisions of the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. 201 *et seq.*), does not currently require nutrition labeling for the alcoholic beverages it regulates, as required for packaged food regulated by FDA. The comments stated further that while TTB requires a statement of average analysis on labels that make calorie or carbohydrate claims, this statement includes only calories, carbohydrates, protein, and fat. See TTB Ruling 2004–1. *http://www.ttb.gov/rulings/2004-1.pdf.* The comments noted that TTB does not require the declaration of sugar, fiber, sodium, or cholesterol content on a beer label. As a result, these comments stated that beer brewers would have to undertake a substantial testing program to be able to provide that nutrition information for consumers. In addition, one comment expressed concern with obtaining nutrition information, stating that beers produced by small brewers have greater variation in alcohol content and ingredients than beers within the existing "regular beer" category in USDA's nutrition database. However, this comment stated that general classifications can be established that will provide industry members and consumers with accurate calorie and nutritional information. The comment further stated that industry members could work with USDA to develop easily measured criteria, such as original gravity measurement, that would provide a consistent benchmark for brewers and accurate information for consumers. The comment also maintained that, absent agreement between FDA and TTB with respect to labeling formats, action by small brewers to provide nutrition information pursuant to amended section 403(q) would contradict current TTB guidance and create uncertainty when a pending TTB rulemaking on "serving facts" is completed.[3] Accordingly, the comment urged FDA to delay the application of the new requirements to alcohol beverages pending agreement between FDA and TTB on a consistent methodology.

FDA has considered these comments and consulted with TTB and USDA in developing this proposed rule. Section 4205 amends section 403(q) of the FD&C Act (21 U.S.C. 343(q)), which generally provides nutrition labeling requirements for certain foods. Section 4205 provides nutrition labeling requirements directed specifically toward standard menu items sold in covered establishments. FDA tentatively concludes that the nutrition disclosure requirements in amended section 403(q)(5)(H) for standard menu items offered for sale in covered establishments apply to foods for human consumption, including meat, poultry, and processed egg products, even though they are also regulated by USDA. This tentative conclusion is consistent with FDA's position that FDA has jurisdiction under the FD&C Act over meat, poultry, and

[2] FDA exclusively regulates the labeling of alcoholic beverages that are not under TTB's jurisdiction, including beers that do not meet the definition of a "malt beverage" under the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. 201 *et seq.*) and wine beverages containing less than 7 percent alcohol by volume. See, *e.g.,* FDA, "Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Draft Guidance." August 2009. *Available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm166239.htm.* Malt beverage is defined in section 117(a)(7) of the FAA Act (27 U.S.C. 211(a)(7)) and TTB regulations at 27 CFR 7.10.

[3] In the **Federal Register** of July 31, 2007 (72 FR 41860), TTB published a proposed rule to amend its regulations to require a statement of the percentage of alcohol on all alcoholic beverages and a serving facts panel, which would include a statement of calories, carbohydrates, fat and protein. This proposed rule has not been finalized.

processed egg products in interstate commerce.

While alcohol beverages are "food" under the FD&C Act, FDA recognizes that at least one court has held that TTB has exclusive jurisdiction over the labels of the alcohol beverages it regulates under the FAA Act. *Brown-Forman Distillers Corp.* v. *Mathews,* 435 F. Supp. 5 (W.D.Ky. 1976). Providing nutrition information required in section 4205 for alcohol beverages should result in a similar public health benefit as providing the information for a food for which the labeling is exclusively regulated by FDA. However, it is not clear that Congress intended for the nutrition information disclosures required by section 4205 to apply to alcohol beverages, given that the labels of the majority of alcohol beverages are regulated by TTB. For the purposes of this proposal, FDA tentatively concludes that the new menu labeling requirements do not apply to alcohol beverages. Therefore, proposed § 101.11(b)(1)(ii) provides that the labeling requirements do not apply to alcohol beverages. We request comment on whether alcohol beverages should be within the scope of the requirements of section 4205 and proposed 21 CFR 101.11. In any case, the provisions of section 4205 do not apply to and have no effect on the labels of food products sold in packaged form, including meat, poultry and processed egg products that are regulated by USDA or on the labels of alcoholic beverages regulated by TTB under the FAA Act.

Restaurant Food

We are proposing in § 101.11(a) that "restaurant food" means food that is served in restaurants or other establishments in which food is served for immediate human consumption, *i.e.,* to be consumed either on the premises where the food is purchased or while walking away, or that is sold for sale or use in such establishment. This definition corresponds to the way the agency uses the term "restaurant food" in § 101.10, "Nutrition labeling of restaurant foods." See 61 FR 40320 (Aug. 2, 1996). It also reflects the food described in section 403(q)(5)(A)(i) of the FD&C Act.

Restaurant-Type Food

We are proposing in § 101.11(a) that "restaurant-type food" means food of the type described in the definition of "restaurant food" that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment. This definition reflects the food described in section 403(q)(5)(A)(ii).

Standard Menu Item

We are proposing in § 101.11(a) that the term "standard menu item" means a restaurant or restaurant-type food that is routinely included on a menu or menu board or that is routinely offered as a self-service food or food on display. FDA notes that, unlike the term "menu," the term "standard menu item" is not defined in section 4205. In developing this proposed definition, FDA considered the relationships between sections 403(q)(5)(H)(i), (ii), and (iii). Section 403(q)(5)(H)(i), entitled "General requirements for restaurants and similar retail food establishments," requires covered establishments to "disclose the information described in subclauses (ii) and (iii)," "in the case of food that is a standard menu item." Sections 403(q)(5)(H)(ii)(I)(aa) and (II)(aa) require calorie declarations on menus and menu boards, respectively, and section 403(q)(5)(H)(iii) requires calorie declarations for self-service food and food on display.

FDA considered whether only self-service food and food on display that appear on menus or menu boards should be covered. However, the examples Congress provides for self-service food and food on display in section 403(q)(5)(H)(iii) ("food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers") generally do not appear on menus or menu boards—customers often simply pick up their selections and pay a cashier. In addition, in certain establishments where customers do order self-service food or food on display, *e.g.,* where "salad bar" or "breakfast buffet" is listed on a printed menu at a sit-down restaurant, the individual items on the salad bar or the breakfast buffet generally are not listed on the printed menu. Any signs identifying the individual foods on the salad bar or buffet are intended to be viewed after the customer orders.

These examples—salad bars, buffet lines, and cafeteria lines—are explicitly named in section 403(q)(5)(H)(iii), so they must fall within the scope of the new law. Therefore, FDA proposes to interpret "standard menu item" to mean a food that is routinely listed on a menu or menu board or that is routinely offered as self-service food or food on display. For example, a hamburger, a combination meal, and a specific type of pizza (*e.g.,* "deluxe pizza") that regularly appear on a restaurant menu would be considered standard menu items. Potato salad that is routinely offered at a salad bar, pancakes that are routinely offered at a buffet, and pudding that is routinely offered at a cafeteria line would be considered standard menu items, as well. This interpretation allows for the types of foods on display and self-service foods described in section 403(q)(5)(H)(iii) to be covered and gives meaning to the reference in section 403(q)(5)(H)(i) to section 403(q)(5)(H)(iii) ("in the case of food that is a standard menu item * * * the [covered establishment] shall disclose the information described in subclauses (ii) and (iii)."). Correspondingly, FDA tentatively concludes that "menu item" should be considered a food item that is listed on a menu or menu board or that is offered as a self-service food or food on display. FDA requests comment on the proposed definition of standard menu item.

Multiple Servings

Some comments contended that foods sold in multiple servings such as a bucket of chicken pieces, rotisserie chicken, and full rack of ribs are not standard menu items because they are not sold for immediate consumption. Other comments stated that bakery items such as individually sold bagels or cookies also should not be covered. Other comments did not oppose a requirement for providing some calorie and other nutrition information for these multiple-serving foods, but recommended that the calorie declaration for them be by serving, which, they contended, would be more meaningful. Two industry comments stated that they received consumer complaints when the calories were declared for whole pizzas, as was required by some jurisdictions. The comments stated that the consumers claimed that this type of declaration was confusing and impractical, and they asserted that nutrition and calorie information should be disclosed per slice. Other comments stated that the calories should be declared for the food offered for sale and not for each serving.

FDA disagrees with the comments that stated that multi-serving foods are not standard menu items. Section 403(q)(5)(H) requires that calories be disclosed for standard menu items at covered establishments, regardless of how many servings included in the item. Multi-serving foods that are routinely included on a menu or menu board (*i.e.,* the primary writing of the restaurant or similar retail food establishment from which a customer makes an order selection) or routinely offered as a self-service food or food on

display would meet FDA's proposed definition of standard menu item. FDA requests comments on this issue.

Combination Meal

We are proposing in § 101.11(a) that the term "combination meal" means a standard menu item that consists of more than one food item; for example, a meal that includes a sandwich, a side item, and a drink would be a combination meal. A combination meal may be represented on the menu or menu board in narrative form, numerically, or pictorially. A combination meal may include one or more variable items and may itself be a variable menu item, as that term is defined in this section. For example, the side item may have several options (*e.g.,* fries, salad, or onion rings) or the drink may vary (*e.g.,* soft drinks, milk, or juice), and the customer selects which of these items will be included in the meal.

Variable Menu Item

We are proposing in § 101.11(a) that the term "variable menu item" means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item. As examples, variable menu items may have flavoring options, (*e.g.,* a milkshake that is available in vanilla, chocolate, or strawberry flavors) or topping options (*e.g.,* pizza prepared with a selection of toppings).

Self-Service Food

We are proposing in § 101.11(a) that the term "self-service food" means restaurant or restaurant-type food that is offered for sale at a salad bar, buffet line, cafeteria line, or similar self-service facility, and self-service beverages. This definition covers food that the customer serves himself or herself, such as food at hot and cold food bars or beverages in a self-service beverage machine in a restaurant. FDA considers the term "facility" as it is used in section 403(q)(5)(H)(iii) to refer to a self-service fixture in a covered establishment, and not necessarily to the entire establishment. For example, a salad bar in a pizzeria would be a self-service facility, while the pizzeria as a whole would be a covered establishment if it as part of a chain of 20 or more locations doing business under the same name and offering for sale substantially the same menu items. Self-service foods are a subset of food on display.

Food on Display

We are proposing in § 101.11(a) that the term "food on display" means restaurant or restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption. Under the proposed definition, food on display would include food packaged at the customer's request, such as a slice of pizza sold at a counter or an entrée item served on a buffet line, or pre-wrapped by the establishment for direct customer selection, such as a sandwich prepared on the premises and displayed in a case. FDA tentatively concludes that this term includes food that is behind a glass counter or another viewing apparatus for the purposes of showing a serving or meal suggestion. Food on display would not encompass meats and cheeses sold at delicatessens in grocery stores, given that there is an ordinary expectation that the consumer will further prepare those foods before consumption, *e.g.,* by using the meat and cheese to make a sandwich.

Custom Order

We are proposing in § 101.11(a) that the term "custom order" means a food order that is prepared in a specific manner based on an individual consumer's request, which requires the restaurant or similar retail food establishment to deviate from its usual preparation of a menu item. For example, a club sandwich ordered without the bacon would be considered a custom order if the establishment usually includes bacon in its club sandwich.

Daily Special

We are proposing in § 101.11(a) that the term "daily special" means a menu item that is prepared and offered for sale on a particular day, that is not routinely listed on a menu or offered by the covered establishment, and that is promoted by the covered establishment as a special menu item for that particular day. Often, such items are added to the menu on a particular day through inserted slips of paper or written on erasable menu boards. However, an item that is offered for sale every week on Mondays is routinely offered and therefore would not be considered a daily special. In addition, if a standard menu item is offered at a discounted price on a particular day, the item would not be considered a daily special. For example, if a turkey club sandwich is a standard menu item at a restaurant and normally costs 5 dollars, but on Fridays the same turkey club sandwich is specially advertised as costing only 4 dollars, FDA tentatively concludes that the nutrient content disclosure requirements for standard menu items would still apply to the turkey club sandwich on Fridays; the sandwich would not be considered a "daily special" under § 101.11(a) merely because it is specially discounted. Similarly, if a covered establishment offers individual menu items together at a discount on a particular day, they would also not be a daily special. FDA requests comment on this definition.

Food That Is Part of a Customary Market Test

We are proposing in § 101.11(a) that the term "food that is part of a customary market test" means food that is marketed in a covered establishment for fewer than 90 consecutive days in order to test consumer acceptance of the product.

Some comments from industry stated that the 90-day time period should be calculated per market, not per chain, and asked that we clarify when the 90-day time period begins. These comments also stated that 90 days may not be long enough for a test market.

FDA points out that the 90-day time period is a statutory requirement. FDA proposes to interpret the 90-day time period to mean consecutive days beginning when the menu item is first offered for sale in the specific location. This interpretation is based on FDA's understanding of how test marketing is ordinarily done. FDA requests comment about our interpretation of a 90-day consecutive time frame on the test marketing of products.

Temporary Menu Item

We are proposing in § 101.11(a) that the term "temporary menu item" means a food that appears on a menu or menu board for less than a total of 60 days per calendar year. As with the 90-day time period for food that is part of a customary market test, the 60-day time period for temporary menu items is a statutory requirement. To provide flexibility, the 60 days includes the total of consecutive and non-consecutive days the item appears on the menu.

C. Requirements for Covered Establishments

1. Applicability

FDA is proposing in § 101.11(b)(1)(i) that menu labeling requirements apply to standard menu items offered for sale in covered establishments. As discussed in section I.D., under 403(q)(5)(H)(i), menu labeling requirements apply to food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same

name and offering for sale substantially the same menu items. Whether a chain has 20 or more locations does not depend on the type of ownership of its locations (*e.g.,* whether owned by the corporate owner of the chain or individual franchisees).

As discussed in section III.C. of this document, section 403(q)(5)(H)(ix) includes a provision that permits restaurants and similar retail food establishments not subject to the requirements of section 403(q)(5)(H) (*e.g.,* a restaurant that is part of a chain with fewer than 20 locations) to register with FDA to voluntarily elect to become subject to the requirements of section 403(q)(5)(H). Consequently, FDA is proposing in § 101.11(b)(1) (ii) that the menu labeling requirements apply to foods that are standard menu items offered for sale in chain retail food establishments and restaurants or similar retail food establishments that voluntarily register with FDA.

2. Foods to Which the Requirements of Section 4205 Do Not Apply

Section 4205 provides that the menu labeling requirements do not apply to certain foods. These foods are "items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use); daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or such other food that is part of a customary market test appearing on the menu for fewer than 90 days, under terms and conditions established by the Secretary" (21 U.S.C. 343(q)(5)(H)(vii)).

FDA received several comments on these foods to which the menu labeling requirements in section 4205 are nonapplicable. Some comments stated that these foods should not be exempt from the requirements of section 4205. Some of these comments stated that condiments that come with meals should be included as part of the calorie declaration. One comment stated that if the condiment is non-nutritive, it should be excluded from the calorie labeling requirement, but if the condiment contains more than 10 calories per serving (*e.g.,* salad dressing, mayonnaise, pickles, olives, maple syrup, or honey), calorie labeling requirements should apply. Another comment suggested that FDA remove the calorie declaration exemption for 60–90-day temporary items so that restaurants cannot continually change their menus to avoid calorie labeling.

We note that section 403(q)(5)(H)(vii)(I)(aa) provides that the nutrient content disclosure requirements in sections 403(q)(5)(H)(i)–(vi) do not apply to "items not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use)." (21 U.S.C. 343(q)(5)(H)(vii)(I)(aa)). FDA tentatively concludes that this provision should be read narrowly, based on the parenthetical language. If the provision is read broadly to deem all "items not listed on a menu or menu board" beyond the scope of the law, then most self-service food and food on display would not be covered, including food at salad bars, buffet lines, and cafeteria lines. Given that Congress explicitly named these as examples of self-service facilities to which the calorie disclosure requirements in section 403(q)(5)(H)(iii) apply, the current proposal narrowly interprets this provision.

Given the phrase "for general use," FDA tentatively concludes that it is reasonable to interpret this provision to apply to food, such as many condiments, that are available for use by any customer in the covered establishment, regardless of the customer's particular order or food selection. Examples include salt and pepper placed on tables for use by whomever sits there, large ketchup and mayonnaise dispensers placed on a counter to be used by any customer, and lemons placed near a drink station. In contrast, the nutrient content disclosure requirements in section 403(q)(5)(H) would apply to salad dressing at a salad bar that is only available to customers who order the salad bar. The labeling requirements would also apply to salad dressing at salad bars where customers pay for salad by weight, where the weight of the salad dressing affects the price of the item.

FDA tentatively concludes that section 403(q)(5)(H)(vii)(I)(aa) does not refer to condiments that are part of a standard menu item, as it is usually prepared and offered for sale (*e.g.,* mustard, mayonnaise, and ketchup that are part of a hamburger or sandwich as usually prepared and offered for sale). Sections 403(q)(5)(H)(ii)(I)(aa) and (II)(aa) specify that covered establishments must provide, on menus and menu boards, "the number of calories contained in the standard menu item, as usually prepared and offered for sale." 21 U.S.C. 343(q)(5)(H)(ii)(I)(aa) and (II)(aa). Caloric value of these condiments must be included as part of the total caloric declaration for a standard menu item, because the condiments are a part of the standard menu item as it is usually prepared and offered for sale.

As discussed in III.B. of this document, FDA proposes to define a temporary menu item as one that appears on a menu or menu board of a covered establishment for less than 60 days per calendar year. For example, a pumpkin-flavored latte that only appears on the menu of a coffee shop in November would be a temporary menu item. FDA tentatively interprets the 60-day calendar limit to mean less than 60 days per year in total; the 60 days do not have to be consecutive.

Also discussed in III.A. of this document, FDA proposes to define a food that is part of a customary market test to be a food appearing on a menu or menu board for less than 90 days for which the covered establishment wishes to test consumer acceptance. For example, many restaurants advertise "for a limited time only" sandwiches that have new components. FDA recognizes that in some cases, a chain of restaurants or similar retail food establishments tests a new product in different locations within the chain and in more than one region of the country at different times. FDA tentatively concludes that "a customary market test," for the purposes of this section, refers to a test in a single covered establishment. Based on FDA's understanding of how test marketing is generally conducted, FDA proposes that a food that is part of a market test is an item that appears on a menu or menu board of a covered establishment for less than 90 consecutive calendar days. A food may be part of a customary market test at more than one location of a chain at a time. A food might also be a standard menu item at one location while being part of a customary market test at another.

Note that self-service food and food on display that do not appear on menus or menu boards would not be considered temporary menu items or food that is part of a customary market test. Based on the statutory language, both of these categories of nonapplicability only capture food "appearing on the menu" for a limited amount of time. Therefore, even if a self-service food or food on display that does not appear on a menu or menu board is only offered by a covered establishment for a limited time, such as a pumpkin-spice muffin available only in November, the nutrition information declaration requirements in section 403(q)(5)(H) would still apply. Self-service foods or foods on display in covered establishments that do not appear on menus can still belong to other categories of food to which the nutrition information declaration requirements do not apply, such as daily specials or custom orders.

Based on the reasons above, FDA is proposing in § 101.11(b)(1)(ii) that the requirements in § 101.11(b)(2) shall not apply to condiments and other items placed on the table for general use; daily specials; temporary menu items; custom orders; or food that is part of a customary market test. In addition, as discussed in III.B. of this document, FDA is proposing that the requirements in § 101.11(b)(2) shall not apply to alcohol beverages.

3. Information That Must Be Declared by Covered Establishments

a. Calorie declaration on menus and menu boards. Section 403(q)(5)(H)(ii) requires covered establishments to disclose on menus and menu boards, in a clear and conspicuous manner, the number of calories contained in standard menu items as usually prepared and offered for sale. The covered establishment must provide the calorie information adjacent to the name of the standard menu item so as to be clearly associated with the standard menu item (*e.g.,* 21 U.S.C. 343(q)(5)(H)(ii)(I)(aa)).

Some comments stated that the statutory requirements for menu labeling should apply only to the menu that most consumers use the most; for example, one national pizzeria chain stated that most of its customers order through the Internet and that therefore the information should only be required to be posted there. Another comment suggested that each company should be permitted to select its own "primary" menu on which calories must be disclosed, based on technological capabilities and customer ordering patterns. FDA disagrees with these comments. Based on section 403(q)(5)(H)(ii), FDA tentatively concludes that these calorie declarations must be provided on all menus and menu boards of the covered establishment. For example, section 403(q)(5)(H)(ii)(I)(aa) states that a calorie disclosure must appear "on the menu listing the item for sale." The same standard menu item could be listed on multiple menus, *e.g.,* a 12" cheese pizza at a pizzeria might appear on the menu for customers dining in and also on the online menu for customers ordering over the Internet. The calorie declaration for each standard menu item must appear on each menu that lists the standard menu item, in accordance with section 403(q)(5)(H)(ii). FDA requests comments on this approach to calorie declarations and multiple menus.

Some comments stated that FDA should allow flexibility for drive-through menu boards and allow calorie disclosures on stanchions (free-standing boards, generally placed next to drive-through menu boards, used to post calorie information) because of lack of space. These comments stated that the drive-through menu boards are not large enough to add calorie labeling and that some local zoning laws do not permit restaurants with drive-through windows to build larger menu boards.

FDA tentatively concludes that stanchions inadequately convey calorie information. A situation in which customers need to look to one board (the menu board) for important food-selection information, such as price, and another (the stanchion) for calories, is likely to be more difficult for customers attempting to use the declared calorie information at the point of selection. This is particularly true in the drive-through context, where customers have a restricted field of vision from their car windows, and they may have a relatively short time to consider the menu board prior to ordering, because customers often cannot view the full menu while waiting in line. Moreover, we note that 403(q)(5)(H)(II)(aa) requires the number of calories contained in standard menu items to be disclosed on the menu board itself. Therefore, we have not included separate stanchions as an option for displaying calories at drive-through restaurants and similar retail food establishments. FDA requests comment on how the use of stanchions would enable customers to use calorie information when they are making selections from a drive-through menu board.

In the draft implementation guidance that was subsequently withdrawn, FDA recommended that calories be declared in a type size at least as large as the name of the standard menu item or price, whichever is larger, and with the same prominence, *i.e.,* the same color and contrasting background as the standard menu item.

Some comments supported FDA's draft guidance on type size, color, and background. Other comments stated that these recommendations were too prescriptive and went beyond the statutory requirement that calorie information must be disclosed in a clear and conspicuous manner. Some comments stated that having the calories in the same color makes the calorie declaration less prominent. Other comments suggested different colors or the use of check marks based on calorie content, *e.g.,* for particular foods, check marks may be made by the food to inform consumers how many times a day or week they should consume that food. One comment suggested that FDA require that the calories be "easily readable, in a typeface similar to other information about each standard menu item, and in a font no less than nine points."

FDA recognizes that menus and menu boards come in a variety of sizes. Therefore, it would not be appropriate to require a specific type size and font for all menus and menu boards. However, if the calorie declarations on menus and menu boards are not declared in a clear and conspicuous manner, the declarations would not be in compliance with the requirements in section 403(q)(5)(H)(ii). FDA tentatively concludes that a calorie declaration on a menu or menu board would not be disclosed in a clear and conspicuous manner if the declaration is too light in color or is presented in a color that does not sufficiently contrast with the background. FDA agrees with the comments asserting that the agency should provide more flexibility with regard to calorie declarations than was suggested in the draft implementation guidance. FDA proposes in § 101.11(b)(2)(i)(A)(*1*) that a calorie declaration must be made in the same color, or in a color at least as conspicuous as, the color of the name of the associated standard menu item on the menu or menu board. Further, FDA proposes that a calorie declaration must have the same contrasting background as the background used for the name of the associated standard menu item on the menu or menu board. In addition, the calorie declaration must be in a font size large enough to be "clear and conspicuous." We understand that menus and menu boards often have limited space. We think that it is important to provide flexibility to businesses while, at the same time, fulfilling the requirements of the statute and providing consumers with easily readable information. FDA is proposing that a calorie declaration must be no smaller than the type size of the name or price of the associated standard menu item on the menu or menu board whichever is smaller. We request comment on this tentative conclusion.

FDA is proposing in § 101.11(b)(2)(i)(A)(*3*) that the term "Calories" or "Cal" must appear as a heading above a column listing the number of calories for each standard menu item on that menu or menu board, or adjacent to the number of calories for each standard menu item. If a column is used for the listing of calories, the term "Calories" or "Cal" must appear in a type size no smaller than the smallest type size of the name or price of any menu item and in the same color, or in a color at least as conspicuous as and in the same contrasting background as that name or price. If the term "Calories" or

"Cal" appears adjacent to the number of calories for the standard menu item, the term "Calories" or "Cal" must appear in the same type size and in the same color and contrasting background as the number of calories.

We tentatively conclude that permitting the flexibility of using the abbreviation "Cal" would assist covered establishments that have limited space on their menus or menu boards in meeting the requirements of section 403(q)(5)(H). Allowing calories to be stated as a header of a column would provide additional flexibility.

One comment asserted that drive-thru menu boards are limited in size and space as compared to interior menu boards, thus making it challenging to list calories in a clear and conspicuous manner. The comment recommended that FDA only should require the statement "Nutrition information is available upon request" on the drive-through menu boards of a covered establishment and require the establishment to have brochures available at the drive-through window. However, FDA notes that section 403(q)(5)(H)(ii)(II) expressly requires covered establishments to post calorie declarations on menu boards, including drive-through menu boards. Therefore, proposed § 101.11(b)(2)(i)(A) would apply to all menu boards at covered establishments, including drive through menu boards.

FDA is proposing in § 101.11(b)(2)(i)(A)(*2*) to require that covered establishments declare calories on menus and menu boards to the nearest 5-calorie increment up to and including 50 calories, and to the nearest 10-calorie increment above 50 calories. For foods that have fewer than 5 calories, the 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).

b. Determination of calories for standard menu items that come in different flavors, varieties, or combinations. Section 403(q)(5)(H)(v)) requires that FDA establish, by regulation, standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, that are listed as single menu items (21 U.S.C. 343(q)(5)(H)(v)). This section includes as examples of these foods soft drinks, ice cream, pizza, doughnuts, and children's combination meals. As discussed in section II.A. of this document, FDA proposes to define these items as variable menu items. Section 403(q)(5)(H)(v) states that FDA may establish these standards as averages, ranges, or other methods.

FDA recognizes that, under this proposal, some combination meals as discussed in section III. A. of this document would be variable menu items, while others would not. The calorie declaration on a menu or menu board for a combination meal that consists of a fixed combination, where the customer has no choice as to which flavors, varieties, or combinations of items are included, would be governed by proposed § 101.11(b)(2)(i)(A) and (B). Such a combination meal would not be considered a variable menu item.

Some standard menu items come in different varieties, such as a single scoop of ice cream that comes in different flavors and a medium soft drink that comes in a variety of sodas. For some of these variable menu items, the difference between the number of calories in the lowest calorie variety and the highest could be wide. For example, calories for a large soft drink could range from zero calories for a diet soft drink to more than 400 calories for a non-diet soft drink. For combination meals, the difference in caloric value has the potential to be especially large, given that multiple items in the combination meal might vary. A combination meal may contain a sandwich, side dish and drink. The side dish may be fries, onion rings, or a salad. The number of calories may be much fewer if the consumer chooses the salad with light dressing and bottled water or a diet drink than if the consumer chooses the fries and a sweetened drink. On the other hand, for other variable menu items, the range of calories in the possible varieties is likely small (*e.g.,* donuts with different flavors of icing), such that a calorie or other nutrient difference among the varieties is not nutritionally significant.

Section 403(q)(5)(H)(v) specifically states that we must establish standards for determining and disclosing the nutrient content information for standard menu items that come in different flavors, varieties, or combinations, through means determined by FDA, including averages, ranges, or other methods. Some comments supported the use of ranges because, they asserted, displaying an average calorie content when the lower and upper limits are so dissimilar would be misleading. Other comments suggested that FDA require median values for calories if the values for all flavors, varieties, or combinations are within 20 percent of the median and require ranges if calories are not within 20 percent of the median. Some comments maintained that sugar-free (no calorie or very low calorie) should be listed separately from sugar-sweetened beverages. A few comments recommended that FDA allow covered establishments to pick among ranges, medians, and averages. Some comments disagreed with permitting ranges and suggested that the foods must be labeled individually. One comment suggested that FDA require covered establishments to group similar items where the item of greatest caloric value contains less than 5 percent more calories that the item of lowest caloric value and display items separately if the calorie difference is greater than 5 percent. A few comments recommended that the calorie information for items such as sandwiches, pizza, or burritos that are intended to be prepared in a large number of different ways be displayed for the standard preparation of the item, with the standard preparation of the item clearly noted on the menu, menu board, or food tag or next to the food on display. The calorie content for each additional food component, according to the comment, should then be displayed on the menu, menu board, food tag, or next to the food on display for each food component.

FDA is proposing in § 101.11(b)(2)(i)(A)(*4*) that the calories must be declared as a range for standard menu items that come in different flavors, varieties, or combinations but are listed as a single menu item. For example, the calories for different flavors of ice cream or combination meals would be disclosed in the format "xx-yy" where "xx" is the caloric content of the lowest calorie flavor or combination, and "yy" is the caloric content of the highest calorie flavor or combination. However, we considered a number of other options in developing this proposal.

Option 1: Single value. We considered requiring calorie values for all variable menu items to be presented as single values, either in the form of an average (obtained by summing up the calorie content of all options and then dividing by the number of options) or a median of all options (obtained by determining the "middle" number of calories from the list of options). For example, if there were three options for a sandwich, one with 400 calories, one with 450 calories, and one with 600 calories, the average would be 483 calories ((400+450+600)/3 = 483) (which would be rounded to 480 for the calorie declaration), and the median would be 450. The tradeoff between using an average or median value is between closer reflection of the distribution of possible choices and simplicity of calculation. If the median

is declared, a change in this number would change the declared calories, even if no other variation had a change in calorie content and even if the overall range of calories did not change. On the other hand, changes in numbers other than the middle number would not generally affect the median. Taking the example above, if the calories in the middle option for the sandwich changed from 450 to 420 (*e.g.,* because the covered establishment changed the cheese in that sandwich to lower fat cheese), then the number of calories disclosed would be 420, because 420 is the new median. In contrast, if the calories in the middle option stayed 450, but the calories in the highest option changed from 600 to 750 (*e.g.,* because the establishment changed the sandwich's sauce formulation and changed the bun on the sandwich to a bun with higher fat content), number of calories disclosed would be 450, because 450 remains the median.

If the average is declared, the calorie declaration would likely change in response to a calorie change in any option. As a result, the reported number is less prone to manipulation. For example, if the calories in the middle option in the sandwich above changed from 450 to 420, the average would change from 483 (rounded to 480 for the calorie declaration) to 473 (rounded to 470 for the calorie declaration). If the highest option for the sandwich above changed from 600 to 750, the average would change from 483 (rounded to 480 for the calorie declaration) to 533 (rounded to 530 for the calorie declaration).

Presenting calorie declarations of variable menu items as single values—whether as averages or median values—offers the benefit of maximizing space on a menu or menu board. However, single values have a drawback in that they fail to convey to consumers the nutrient content of the specific choices available within that variable menu item group. Posting an average or median value may also mask dramatic differences that can exist in caloric intake for certain variable menu items, especially where calorie ranges are large.

Option 2: Range. We considered requiring calories for all variable menu items to be reported in the form of a range. FDA recognizes that there may be some cases where disclosing a range may be more difficult than disclosing a single value, such as when menu space is limited. In addition, a range is arguably less useful to consumers in cases where calorie ranges are very small or where calorie ranges are very large and consumers cannot distinguish which varieties or combinations of items may offer lower calories or determine the exact amount of calories in their specific choice. However, a range format provides consumers with more information about the caloric content of the options available within a given variable menu item group; it provides the lowest value, the highest value, and therefore the window within which a consumer's choice will fall.

Option 3: Hybrid combining averages and ranges. We considered a number of approaches that would require declaration of a single average value for variable menu items whose calorie ranges fall within specified bounds and declaration of a range for variable menu items whose calorie ranges fall outside those bounds. This option has the benefit of allowing single values to be used on a menu or menu board for variable items that have relatively narrow ranges, while ensuring that the full range of calories is provided for wider ranges.

Within this option, we considered different approaches for determining when a range and when an average value should be reported. First, we considered requiring an average value unless the highest calorie option contains over 25 percent more calories than the lowest calorie option. At that point, a range would be disclosed instead. For example, if the lowest calorie item contains 400 calories, the calorie declaration would be an average unless the highest calorie item exceeds 500 calories ($400 \times 25\% = 100$; $400 + 100 = 500$). Taking a variable menu item that has 400, 430, or 490 calories, the number of calories in the highest calorie item (490) is less than 25% more than the number of calories in the lowest calorie item ($490 < 500$), so the calorie declaration would be the average: 440 ($(400+430+480)/3 = 440$). Taking a variable menu item that has 400, 430, or 550 calories, the highest calorie item (550) has more than 25% more calories than the lowest calorie item ($550 > 500$), so the calorie declaration would be a range: 400–550.

Our rationale for considering the 25 percent is based in our nutrient content claim regulations. FDA permits a "reduced calorie" claim on a food if the food contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference food. In the preamble for the regulations on nutrient content claims (58 FR 2302 at 2348), FDA stated that the terms "less" and "reduced" should be used only when a nutritionally significant reduction in the level of the nutrient has been reached so as not to mislead consumers into believing that a product would provide a nutritionally significant reduction in the level of a nutrient when it would not. FDA concluded that an appropriate minimum reduction for the terms "reduced" and "less" is 25 percent based on various factors.

Second, we considered an approach that would require an average value to be reported for all variables that fall within 20 percent of the average value; a range would otherwise be required. Using 20 percent as a cutoff for determining whether to use an average or a range would be consistent with the number used for compliance purposes. See § 101.9(g). For example, if the calories for a variable menu item are 400, 430 or 490, the highest calorie option has 22.5% more calories than the lowest calorie option, so the calorie declaration under the 20 percent cutoff approach would be the range: 400–490 calories.

An additional approach could be to have a special rule for low calorie foods. The number of calories in low calorie foods, i.e., those with 40 or fewer calories, could be declared by an average even if the difference in the calories between the lower and higher calorie variable menu item is greater than 25 or 20 percent. For example, if the calories for flavored teas ranged from 5 to 20 calories, a difference of 300 percent ($(20–5)/5 \times 100$), the range would not be necessary, and an average, *e.g.,* 12.5 calories could be used. In addition, consistent with calorie declaration of packaged food, calories less than 5 would be declared as 0. Therefore, the average calories for the flavored tea would be 10 ($(20+0)/2$). The rationale for using 40 calories as the cutoff is that foods that contain 40 calories or less are eligible to bear a "low calorie" claim (§ 101.60(b)(2)).

We note that a difference of 20 or 25 percent may translate into a substantial amount of calories where the calorie values are high (*e.g.*, for some combination meals), resulting in the reporting of single values for some large calorie ranges. So, we also considered using a fixed 100 calorie maximum range as a cutoff. Using this approach, variable items with large numbers of calories in all options would declare the range of calories more often than if we used a percentage cutoff. Variable items with smaller numbers of calories for all options would declare a range less often. For example, a hamburger combination meal that ranges from 1,000 to 1,200 calories would be listed as a single calorie value (1,100 calories) under the 25 percent approach, but as a range (1,000–1,200 calories) under the 100 calorie cutoff approach, since the

difference between the two values is greater than 100 calories. On the other hand, under the 25 percent approach, calories for a single ice cream scoop that varies from 240 to 320 calories depending on the flavor would be displayed as a range, because the highest calorie option is 33 percent more caloric than the lowest calorie option ((320–240)/240 = 33%). But because the difference is only 80 calories, under the 100 calorie rule, the average, *i.e.* 280 calories, would be disclosed.

Option 4. If only 2 options are available for an item (*e.g.*, a sandwich with fries or with fruit), provide both numbers with a forward slash between (*e.g.*, 450/350). If three or more options are available, provide the range in calories. We considered this option because some variable menu items may have only two choices and the use of a slash may be more reflective of the fact that there are two choices than the use of a dash. For example, for a chicken sandwich that comes in grilled and crispy versions, with 470 and 610 calories, respectively, declaring the calories as 470/610 may better reflect the two discrete choices than declaring the calories as 470–610. On the other hand, the calorie declaration for a combination meal that comes with a choice of sides, *e.g.*, tater tots or French fries, and various soft drinks would be a range (*e.g.*, 1380–1810).

Option 5. If only 2 options are available for an item (*e.g.* a sandwich with fries or with fruit), provide both numbers with a forward slash between (*e.g.* 450/350). For foods with 3 or more options, use one of the hybrid approaches outlined in Option 3.

Since many of these options could result in menus with different formats and wide variations in the ranges, we intend to conduct consumer research to evaluate how well consumers understand the caloric information presented in each of the formats and whether mixed formats on a single menu or menu board might be confusing to consumers. FDA intends to make the results of our consumer research available to the public prior to publication of the final rule and will allow sufficient time for interested stakeholders to comment on the results of our research.

FDA is proposing that the calorie declaration be in a range for all variable menu items (Option 2). Requiring a range for all variable menu items gives consumers a consistent format across all items. FDA recognizes that in some instances, the calorie range may be so wide that the consumer may still need the calorie information for the particular menu item before he or she can make a fully informed purchase decision. We want to ensure that the calorie declaration is understood by consumers and will help them make better food choices. We seek comment on whether the proposed method of declaring calories is appropriate and would not be misleading to consumers. We are especially interested in any consumer research on the issue. We are also interested in comment and research on the options that we considered but did not propose and whether any of the other options individually or in combination would be preferable and why. In developing the final rule on this proposal, we will consider the results of our research and all relevant comments and data.

FDA also requests comment on complexities that may be raised by certain variable menu items. For example, some menus with combination meals list an option to increase the size of components of those meals for a discounted additional price. FDA is considering whether those listings should be labeled with the number or range of calories they add to the standard combination meal, and requests comment. FDA also recognizes that the Internet may allow for the use of different methods for disclosing calories. For example, interactive menus online may present opportunities for more innovative ways of providing tailored calorie information, *e.g.,* providing a calorie tracker in the ordering frame that tallies calories as customers make order selections. FDA requests comment on this issue. While this may be especially suitable for ordering certain variable menu items, such as when selecting a crust and toppings for pizza, FDA requests comment on whether different methods should be used for nutrient content declarations for interactive internet menus in general.

4. Succinct Statement Concerning Suggested Daily Caloric Intake Required on Menus and Menu Boards

Sections 403(q)(5)(H)(ii)(I)(bb) and (II)(bb) require that chain retail food establishments post a succinct statement concerning suggested daily caloric intake ("succinct statement") on menus and menu boards, as specified by the Secretary by regulation, that is designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu and menu board (21 U.S.C. 343(q)(5)(H)(ii)(I)(bb) and (II)(bb)). Some comments stated that the succinct statement should take into account the different caloric needs of individuals based on age, gender, and physical activity. Comments suggested various statements including:

- "2,000 calories meets the daily caloric needs of most adults; however, individual dietary needs may vary."
- "A 2,000 calorie diet is being used as a basis for general nutrition advice. However, individual calorie needs may vary."
- "This is ____ percent of a 2,000 calorie diet."
- "To maintain a healthy weight, most adults need no more than 2,000 calories per day."

Some comments stated that a different statement should be used on children's menus because children have different caloric needs. According to one comment, if 2,000 calories is used as a reference point, parents may overestimate the caloric needs of their children. One comment suggested the following for a children's menu:

> The recommended caloric intake for a day varies from ____ to ____ for adolescents and adults, from ____ to ____ for school-age children, and from ____ to ____ for pre-school children above age two years.

Caloric declarations on menus and menu boards in covered establishments that provide the number of calories contained in standard menu items will give consumers information that is useful in selecting more healthful food choices. FDA recognizes that individual daily caloric needs may differ based on several factors including gender, age, and activity level (Ref. 9 at page 13). For this reason, it is important that consumers be able to place the calorie declarations in the context of their individual dietary needs. As described in section I. B of this document, nutrition labeling on packaged foods has been required for approximately 20 years, and consumers are familiar with and use this information. The Nutrition Facts on packaged foods uses 2,000 calories as a reference amount on which to base recommended intake for macro- and micronutrients for individuals 4 years of age and older (§ 101.9(c)(9)). A 2,000-calorie reference value is close to the midpoint of the range of energy requirements for sedentary adults (1,600–2,600 cals) (Ref. 9 at page 14).

FDA initially proposed a reference value of 2,350 for the Nutrition Facts (55 FR 29476 at 29486); in response to comments, however, FDA selected 2,000 as the reference value in the 1993 final rule. As stated in the preamble to the final rule: "The rationale for selecting 2,000 calories as opposed to other lower values varied, but reasons given included the fact that it is consistent with widely used food plans, it

approximates the caloric requirements for postmenopausal women who are at-risk for excessive intake of calories and fat, and it is a "rounded down" value for 2,350 calories." FDA also noted in the preamble to the final rule that some comments noted that "2,000 calories is easier to use in quick, mental calculations compared to other calorie levels such as 1,900 or 2,350 calories." 58 FR 2206 at 2217.

FDA tentatively concludes that 2,000 calories is an appropriate reference value to include in the succinct statement. However, not everyone should eat 2,000 calories per day. Individual caloric needs differ depending on various factors such as age, gender, and physical activity. For example young children and sedentary adults may have caloric needs below 2,000 calories (1,200–1,600 calories) whereas some adult men and active adults of either sex may need more than 2,000 calories (2,200–3,200). Considering the statutory directive and current nutrition advice (Ref. 9), FDA tentatively concludes that, to help ensure that the succinct statement is designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards, certain principles should be met:

- The statement should be succinct;
- The statement should be in plain language that consumers can understand;
- The total caloric value should be framed appropriately so that it is not viewed as a recommendation for daily intake for every consumer;
- The statement should give consumers a means to compare the calorie declaration for a menu item to total calories and;
- The statement should inform consumers that individual needs vary.

Using these principles and considering suggestions from the comments, FDA developed the following statements:

- "Using 2,000 calories per day as a reference point, consider how the menu item you select fits within your total daily calorie needs, which may be higher or lower depending on age, physical activity, gender."
- "A 2,000 calorie daily diet is used as a general reference point for nutrition advice. Individual calorie needs vary depending on age, physical activity, gender."
- "Typical daily caloric intake for women is 1,600 to 2,000 calories, for men is 2,000 to 3,000 calories and for children (ages 4 to 14) is 1,800 to 2,500 calories. Be sure to include the calories of the menu item you select as a part of your total daily caloric intake." [4]

We have also included the following statement that was suggested from comments because we tentatively concluded that the statement satisfied the principles described above.

- "A 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual calorie needs may vary."

FDA concludes that the above statements satisfy the principles developed by the Agency to ensure that the succinct statement is designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards. FDA seeks comment on the principles developed by the agency, including whether all the principles are needed to help consumers understand the significance of the calorie information provided on menus and menu boards. In addition, we have concerns about whether consumers will understand the statements, especially those statements that use terms such as "reference point," "fits within," and "calorie needs vary."

When deliberating on which of the four (4) bulleted statements listed above should be required on menu and menu boards, FDA considered the language in each statement, our previously noted concerns with certain phrases, the availability of space on menu boards, and the statutory directive regarding the succinct statement. Given these considerations, we tentatively conclude that the statement that best addresses these considerations is "A 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual calorie needs may vary." We are proposing in § 101.11(b)(2)(i)(B) to require this statement be posted on menus and menu boards.

FDA seeks comment on whether this proposed statement is adequately designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information provided on menus and menu boards. FDA is particularly interested in comments with alternative suggested statements that are consistent with the principles identified above and requests that any such statements be accompanied by data, such as consumer research.

Some comments stated that FDA should consider a different succinct statement on children's menus and reference the calorie needs for children in specific age ranges. We seek comment on whether FDA should require a different statement on menus that are targeted to children. Such a statement may include language such as "The daily caloric intake for children ____ years of age is ____ to ____ depending on whether they are boys or girls as well as their age and level of physical activity." (The blanks are to be filled in with information on current dietary guidelines.) Comments submitted to the agency on whether a different statement should be required or recommended for children's menus should provide a rationale, data (*e.g.* consumer research), or other information supporting such statement. The agency is particularly interested in any consumer research that demonstrates that the statement is understood by consumers.

We intend to conduct consumer research to evaluate consumer response to these statements. FDA intends to make the results of our consumer research available to the public prior to publication of the final rule and to allow sufficient time for interested stakeholders to comment on the results of our research.

Section 4205 requires that the succinct statement be posted on menus and menu boards prominently and in a clear and conspicuous manner. We are proposing in § 101.11(b)(2)(i)(B)(1) that the required succinct statement appear in a type size no smaller than the smallest type size for any calorie declaration appearing on the same menu or menu board with the same color, or in a color at least as conspicuous, as the caloric declaration and with the same contrasting background as the caloric declarations. FDA is proposing in § 101.11(b)(2)(i)(B)(2) that for menus, the succinct statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement regarding the availability of the written nutrition information described in section III.C.5. of this document, the succinct statement must appear directly above that statement of availability. FDA is proposing in § 101.11(b)(2)(i)(B)(3) that the succinct statement appear on the bottom of menu boards, directly above the statement of availability. FDA tentatively concludes that these requirements will help ensure that the succinct statement is prominent, clear, and conspicuous, as required by sections 343(q)(5)(H)(ii)(I)(bb) and (II)(bb) (21

[4] This statement was developed for focus group testing based on the data upon which the 2,000 calorie reference value used in the Nutrition Facts was derived. The aim was to test a data-derived statement that provided specific calorie ranges for various subpopulations. More recent data from the 2010 Dietary Guidelines suggest that these ranges should be revised; however, the difference in numbers does not impact the objective of testing the utility and comprehension of the statement by the focus group participants.

U.S.C. 343(q)(5)(H)(ii)(I)(bb) and (II)(bb)).

5. Nutrition Information That Must Be Made Available in a Written Form

Section 403(q)(5)(H)(ii)(III) requires that covered establishments must provide, in a written form and upon consumer request, the nutrition information required under clauses (C) and (D) of section 403(q)(1) of the FD&C Act. 21 U.S.C. 343(q)(5)(H)(ii)(III). The written nutrition information must be available on the premises of the establishment and the establishment must post on the menu or menu board a prominent, clear and conspicuous statement regarding the availability of the information (21 U.S.C. 343(q)(5)(H)(ii)(III) and (IV)). FDA requests comment on interpreting the phrase "on the premises" for menus appearing on the Internet.

a. *Statement of availability.* Section 403(q)(5)(H)(ii)(IV) requires that covered establishments post on menus and menu boards a prominent, clear, and conspicuous statement regarding the availability of the written nutrition information (21 U.S.C. 343(q)(5)(H)(ii)(IV)). Therefore, FDA is proposing in § 101.11(b)(2)(i)(C) to require the following statement regarding the availability of the written form of additional nutrition information proposed in § 101.11(b)(2)(ii)(A) on menus and menu boards in covered establishments:

Additional nutrition information available upon request.

FDA is also proposing in § 101.11(b)(2)(i)(C) that this statement ("statement of availability") appear in a type size no smaller than the smallest type size for any calorie declaration appearing on the same menu or menu board, with the same prominence, *i.e.,* the same color, or in a color as least as conspicuous as and in the same contrasting background as the calorie declarations. FDA is proposing that for menus, the statement of availability must appear on the bottom of the first page with menu items in the same type size and font as the calorie declaration and must appear immediately below the succinct statement proposed in § 101.11(b)(2)(i)(B). For menus with more than two (2) pages, the statement must appear either on every page with menu item, or on the first page, so long as a symbol (*e.g.,* asterisk) follows the term "Calories" or "Cal" where it first appears on each subsequent page, clearly referring to the statement of availability appearing on the first page of the menu. FDA is proposing that the statement appear on the bottom of menu boards, immediately below the succinct statement required in § 101.11(b)(2)(i)(B). FDA tentatively concludes that this manner of providing the statement of availability will satisfy the requirements in amended section 403(q)(5)(H)(ii)(IV) that the statement be prominent, clear, and conspicuous. We seek comment on whether the statement of availability will adequately inform consumers about the availability of the written nutrition information. In addition, we seek comment on whether the placement, font, and background requirements are appropriate to ensure that the statement of availability is prominent, clear, and conspicuous.

FDA recognizes that some restaurants or similar retail food establishments have relatively few standard menu items, and, as a result, may have menu boards that list relatively few items in very large font. FDA requests comment on whether it is appropriate in these cases to tie the font size of the two statements required to appear at the bottom of menu board to the calorie disclosures.

b. Required nutrients. Section 403(q)(5)(H)(ii)(III) specifies that the written form must provide "the nutrition information required under clauses (C) and (D) of subparagraph (1) [21 U.S.C. 343(q)(1)(C) and (D)]," which require declaration of the following nutrition information:

- The total number of calories derived from any source, and the total number of calories derived from the total fat;
- The amount of each of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein.

FDA is proposing in § 101.11(b)(2)(ii)(A) to require that the nutrition information in written form contain the information listed above, with two changes. The nutrition labeling requirements under sections 403(q)(1)(C) and (D) were added to the FD&C Act by NLEA and are the nutrients originally required to be provided in the mandatory nutrition information for packaged foods. FDA has since revised by regulation the nutrients required to be provided on the label or labeling of food in relevant part by removing the complex carbohydrates requirement from section 403(q)(1)(D) and requiring that information regarding the amount of *trans* fats be included in the label or labeling of food subject to section 403(q)(1). FDA proposes to make analogous revisions with respect to the written form required by section 403(q)(5)(H)(ii)(III). These are explained further below.

In addition, we note that, because section 403(q)(5)(H)(ii)(IV) refers only to clauses (C) and (D) of section 403(q)(1), covered establishments are currently not required to provide the information about vitamins and minerals required to be on the labels and labeling of foods pursuant to clause (E) of section 403(q)(1).

c. Removal of complex carbohydrates from the requirements of 403(q)(1)(D). Section 403(q)(2)(B), which was added to the FD&C Act by NLEA, provides that "[i]f the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement." Pursuant to this authority, FDA removed the requirement for bearing the amount of complex carbohydrates in the label or labeling of food, based on a determination that for complex carbohydrates "there was no consensus on a clear definition for the term 'complex carbohydrates' as it relates to physiological effects, health benefits, or dietary guidelines," there was a "lack of methods for reliably determining the amounts present," and without a specific definition for "complex carbohydrates it [was] not possible to include quantitative information in the nutrition label that would assist consumers in maintaining healthy dietary practices." (58 FR 2079 at 2101, Jan. 26, 1993); See § 101.9(c)(1) (no regulation requiring that labeling bear nutrition information regarding complex carbohydrates). Because the agency removed the requirement that the label or labeling of food include information regarding "complex carbohydrates" from section 403(q)(1)(D), declaration of complex carbohydrates is no longer a requirement under section 403(q)(1)(D). As a result, this proposed rule does not include complex carbohydrates among the nutrients that must be included in the written form required to be available to consumers under section 403(q)(5)(H)(ii)(III). FDA also received a comment stating that FDA should not include complex carbohydrates in the nutrition information in written form because, among other reasons, the amount of complex carbohydrates is not required to be included on the Nutrition Facts of packaged foods.

d. Addition of trans fat to the requirements of 403(q)(5)(H)(ii)(III). Section 403(q)(5)(H)(vi) provides that "if the Secretary determines that a nutrient,

other than a nutrient required under [section 403(q)(5)(H)(ii)(III)], should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, declaration of such nutrient in the written form" (21 U.S.C. 343(q)(5)(H)(vi)). Similarly, section 403(q)(2)(A) (21 U.S.C. 343(q)(2)(A)) provides that "[i]f the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for [the] purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient to be included in the label or labeling of such food." 21 U.S.C. 343(q)(2)(A).

In 2003, FDA amended its regulations on nutrition labeling, through rulemaking (68 FR 41434, July 11, 2003), to require in § 101.9(c)(2)(ii) that *trans* fatty acids be declared in the label or labeling of conventional foods subject to section 403(q)(1) of the FD&C Act. In that rulemaking, FDA determined that the current scientific evidence consistently showed that *trans* fats are associated with increased low density lipoprotein (LDL)-cholesterol levels and, therefore, that lower intakes of both saturated and *trans* fats are important dietary factors in reducing the risk of coronary heart disease (CHD) in the general population and for those at increased risk for CHD. Further, FDA stated that the current authoritative reports at that time, such as the 2000 Dietary Guidelines for Americans (Ref. 24 at p. 30), recommended that Americans cut back or limit the intake of *trans* fats. Thus, the agency concluded that persons interested in following these recommendations and maintaining optimal LDL-cholesterol levels must be able to determine levels of both saturated and *trans* fats in food products. Information on saturated fat content was already available in the Nutrition Facts on the labels of certain foods. The agency determined that the most practical way to inform consumers of the level of *trans* fat in these foods was for that information to be included in the Nutrition Facts. In the time since the final rule on *trans* fat labeling was published in 2003, the scientific evidence on *trans* fat has continued to support the relationship between *trans* fat and risk of CHD. Authoritative reports published since 2000 have included recommendations on the reduction of intake of *trans* fat. For example, the Institute of Medicine (IOM) has stated that *trans* fat consumption should be kept as low as possible while consuming a nutritionally adequate diet (Ref. 25). Additionally, the 2010 Dietary Guidelines for Americans recommended that *trans* fat intake be as low as possible (Ref. 9 at pp. x and 25). Therefore, for the same public health reasons that supported the requirement that the amount of *trans* fat be declared on the label or labeling of conventional foods subject to 403(q)(1) of the FD&C Act, we are proposing to require covered establishments to declare the amount of *trans* fat in standard menu items in the written form required by section 403(q)(5)(H)(ii)(III).

e. Nutrients in insignificant amounts. FDA recognizes that some standard menu items may contain insignificant amounts of the nutrients required to be disclosed in the written form. See 21 U.S.C. 343(q)(5)(H)(ii)(III). Section 403(q)(5)(C) of the FD&C Act states that: " * * * If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary."

As directed by this statutory provision, FDA determined that "[a]n 'insignificant amount' shall be defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram." § 101.9(f)(1). Further, FDA established regulations at § 101.9(j)(4) that exempt foods that contain insignificant amounts of all the nutrients required to be included in the declaration of nutrition information on the label and labeling of food, provided that the food bears no nutrition claims or other nutrition information in any context on the label, labeling or advertising. FDA tentatively concludes that if a standard menu item contains insignificant amounts of all of the nutrients required to be declared in the written form pursuant to section 403(q)(5)(H)(ii)(II) (i.e., the nutrition information required under clauses (C) and (D) of section 403(q)(1)), a covered establishment is not required to include nutrition information regarding such food in the written form provided that the food does not make a nutrient content claim as defined in § 101.13 or Subpart D of part 101 or a health claim as defined in § 101.13 and permitted by regulation in Subpart E in part 101.

In addition, FDA established regulations at § 101.9(f)(1) that allow for the use of a simplified form of nutrition information labeling if a food contains insignificant amounts of more than one-half of the nutrients required to be disclosed in the label or labeling of food in sections 403(q)(1) and (2) of the FD&C Act. Specifically, § 101.9(f) provides that the declaration of nutrition information may be presented in the simplified format, set forth in the regulation, when a food contains insignificant amounts of eight (8) or more of the following fourteen (14) nutrients: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron. In addition, § 101.9(f)(2)(i) requires that the simplified format must include information on the following nutrients: Total calories, total fat, total carbohydrate, protein, and sodium. In the preamble to the 1993 final rule on nutrition labeling for packaged food, FDA explained that this nutrition information is "essential to aid consumers in learning about the relative nutritional qualities of all foods, and it allows them to judge the consequences of the food selections they make." (58 FR 2079, 2142 (Jan. 6, 1993)).

Section 4205 provides that section 403(q)(5)(C) shall apply to any regulations promulgated by FDA regarding the written nutrition information required by section 403(q)(5)(H)(ii)(II). However, section 403(q)(5)(C) and § 101.9(f) address some nutrients that are not required to be declared in the written nutrition information, specifically vitamin A, vitamin C, calcium, and iron. A covered establishments only is required to declare, in the written form, the nutrition information required under clauses (C) and (D) of 403(q)(1), which does not include vitamins and minerals. See 21 U.S.C. 343(q)(5)(H)(ii)(III). Consequently, at this time, FDA tentatively concludes that a covered establishment is required only to declare, in the written nutrition information, ten of the fourteen nutrients specified in § 101.9(f), specifically: Calories (derived from any

source, and derived from the total fat), total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, and protein. As a result, FDA tentatively concludes that if a standard menu item contains insignificant amounts of more than one-half of the nutrients required to be declared in the written nutrition information under proposed § 101.11(b)(2)(ii)(A), this nutrition information may be presented in a simplified format for that standard menu item. FDA is proposing in § 101.11(b)(2)(ii)(B) that the written nutrition information for a standard menu item offered for sale in a covered establishment may be presented in a simplified format when the standard menu item contains insignificant amounts of six (6) or more of the following ten (10) nutrients: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars and protein. In addition, we are proposing that the simplified format must include information on the nutrients required in § 101.9(f)(2)(i) and (ii) (*i.e.,* total calories, total fat, total carbohydrate, protein, and sodium). The statement "Not a significant source of ____ (with the blank filled in with the names of the nutrients required to be declared in the written nutrient information and calories from fat that are present in insignificant amounts) must appear following the written nutrition information. (See example in section III.B.3.e. of this document.) FDA tentatively concludes that this nutrition information is essential to aid consumers in learning about the relative nutritional qualities of all foods, and it allows them to judge the consequences of the food selections they make.

f. Standards for determining and disclosing the nutrient content of foods for variable menu items. Section 403(q)(5)(H)(v) requires that FDA establish, by regulation, standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children's combination meals (21 U.S.C. 343(q)(5)(H)(v)) (proposed to be called "variable menu items"). Further, this section provides that FDA may establish these standards through means determined by the agency, including averages, ranges or other methods. Consequently, we considered these means in developing standards for disclosing nutrition information in the written form for standard variable menu items, as well as the comments. FDA considered the following options:

Option 1. List the nutrition information for each nutrient in the variable menu item as a range.

For example, nutrition information for a meal that consists of a cheeseburger, side dish (fries or salad with fat-free dressing), and medium soft drink (diet or regular) would be provided in a written form that provides the following information:

- Total calories: 620–1,150 calories
- Calories from fat: 220–410 calories
- Total fat: 24–46 g
- Saturated fat: 8–15 g
- Trans fat: 0–1 g
- Cholesterol: 75–90 mg
- Sodium: 1,240–1,560 mg
- Total carbohydrates: 70–155 g
- Sugars: 21–66 g
- Dietary fiber: 4–7 g
- Protein: 29–34 g

For variable menu items with variations that contain calorie amounts and levels of nutrients that vary widely, this type of nutrient declaration minimally assists consumers in maintaining healthy dietary practices, since it does not provide them with a way to determine the nutrient levels of the particular variations they are choosing between. The consumer may not be able to determine how to make a selection to get fewer of the nutrients the consumer wishes to avoid and more of the nutrients that the consumer wants to consume.

Option 2. List the nutrition information for each component in the variable menu item.

Using the example described above in option 1, for a meal that consists of a cheeseburger, side dish (fries or salad with fat-free dressing), and medium soft drink (diet or regular), under option 2, the covered establishment would be required to provide information for the required nutrients for each component of the meal, *i.e.,* the cheeseburger, the fries, the salad with fat-free dressing, a medium soft drink, and a diet soft drink. The declaration may appear as follows, which includes the proposed simplified formats for the medium cola and diet cola:

Cheeseburger:

- Total calories 470 calories
- Calories from fat 190 calories
- Total fat 21 g
- Saturated fat 8 g
- Trans fat 1 g
- Cholesterol 75 mg
- Sodium 880 mg
- Total carbohydrate 43 g
- Sugars 10 g
- Dietary fiber 2 g
- Protein 26 g

Medium fries:

- Total calories 420 calories
- Calories from fat 180 calories
- Total fat 20 g
- Saturated fat 3.5 g
- Trans fat 0 g
- Cholesterol 0 mg
- Sodium 500 mg
- Total carbohydrate 54 g
- Sugars 0 g
- Dietary fiber 6 g
- Protein 5 g

Garden salad with fat-free dressing:

- Total calories 150 calories
- Calories from fat 30 calories
- Total fat: 3 g
- Saturated fat 0 g
- Trans fat 0 g
- Cholesterol 0 mg
- Sodium 340 mg
- Total carbohydrate 27 g
- Sugars 11 g
- Dietary fiber 2 g
- Protein 3 g

Medium Cola:

- Total calories 200 calories
- Total fat 0 g
- Sodium 5 mg
- Total carbohydrate 56 g
- Sugars 56 g
- Protein 0 g
- Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, and dietary fiber.

Medium Diet Cola:

- Total calories 0 calories
- Total fat 0 g
- Sodium 40 mg
- Total carbohydrate 0 g
- Sugars 0 g
- Protein 0 g
- Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, and dietary fiber

This option provides the consumer with all the required nutrient information for each component of the combination meal in a format that facilitates quick comparisons between different menu items. This option also likely reduces duplication, particularly for combination meals, since most items in combination meals are likely to be available as individual standard menu items.

In addition, when the nutrition information for different flavors, varieties, or components of combinations are the same, the nutrition information for these food items would need only be listed once, with the food items grouped together. For example:

Raspberry or Peach Flavored Iced Tea (14 ounces):

- Total calories 5 calories
- Total fat 0 g
- Sodium 15 mg
- Total carbohydrate 1 g
- Sugars 0 g
- Protein 0 g

- Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, and dietary fiber

For some variable menu items, the number of possible variations is so large that providing the nutrient information required in proposed § 101.11(b)(2)(ii)(A) in written form would be impractical if FDA required the information to be disclosed for each conceivable option. For example, a pizza with a choice among many toppings has a very large number of possible permutations. FDA tentatively concludes that it is more reasonable to require written nutrition information for the basic preparation of the pizza (*e.g.,* plain, deep- dish 12" pizza) and then provide the additional written nutrition information for each possible topping. Therefore, FDA proposes that the nutrition information required in § 101.11(b)(2)(ii)(A) must be provided for the basic preparation of the item and, separately, for each topping or other variable component.

Option 3. If a standard menu item only has two variations (*e.g.* a sandwich with fruit or with fries), provide both numbers for each nutrient in each option with a forward slash between (*e.g.* 450/700). If three or more options are available, provide the range in calories. For example, for a grilled chicken sandwich with either small fries or fruit the nutrients would be declared as:

- Total calories: 450/700 calories
- Calories from fat: 70/200 calories
- Total fat: 7/23 g
- Saturated fat: 1.5/4.5 g
- Cholesterol: 90/90 mg
- Trans fat: 0/0 g
- Sodium: 1160/1430 mg
- Total carbohydrate 63/87 g
- Sugars 27/9 g
- Dietary fiber 3/6 g
- Protein 35/38 g

This option could result in a mixed format within the written nutrition information, *i.e.,* two different types of declarations, one with numbers separated by slashes and one with numbers separated by dashes. We question whether this approach has the potential to be confusing to consumers due to the mixed format and if consumers would be able to distinguish that the nutrient declarations separated by a slash represent the actual amount of nutrients in the two options and that the nutrients declarations separated by a dash actually represents a range of nutrients where the actual amount of nutrients for the item they decide to choose could be anywhere within that range.

For the reasons described above in this section, FDA tentatively concludes that Option 2 provides the most direct and clear information for consumers. Consequently, we are proposing in § 101.11(b)(2)(ii)(C) that for foods that come in different varieties, flavors, and combinations, the nutrient information in the written form required in § 101.11(b)(2)(ii)(A) must be declared for each variety, flavor, and each food component of the combination meal. For those foods that come in different varieties, flavors, and combinations where the number of possible variations is so large that providing the nutrition information in written form for each permutation would be impractical (e.g., pizza, ice cream), FDA is proposing that the nutrition information required in § 101.11(b)(2)(ii)(A) must be provided for the basic preparation of the item and, separately, for each topping or other variable component. The nutrition information in written form may also be provided for every possible variation. FDA specifically requests comment on this proposed requirement as well as alternatives that would provide clear, truthful, and non-misleading information to the consumers about the specific food they purchase.

FDA is also proposing that if the calories and other nutrients are the same for different flavors, varieties, and each substitutable component of the combination meal, each variety, flavor, and substitutable component of the combination meal is not required to be listed separately. All items that have the same nutrient levels could be listed together with the nutrient levels listed only once.

g. Format and manner for the written nutrition information. FDA is proposing that the nutrition information must be presented in the order listed in proposed § 101.11(2)(ii) and that the information must be presented in a clear and conspicuous manner.

FDA is not proposing a specific manner for providing the written nutrition information. Instead, FDA is proposing in § 101.11(2)(ii)(D) that the written nutrition information may be provided on a counter card, sign, poster, handout, loose leaf binder, booklet, or electronic device, such as a computer, on a menu or in any other material that similarly permits the declaration in written form of the required nutrient content information for all standard menu items.

FDA's proposed approach is consistent with the many comments that stated that the manner in which the written nutrition information is made available should be flexible. One comment recommended that the written nutrition information should be made available electronically at kiosks in lieu of paper copies. Some comments recommended that the information appear on the register tape and others recommended that it appear on the menus themselves. A few comments stated that the information should be allowed on food wrappers or tray liners, while one comment opposed the use of liners and wrappers, stating that the information should be provided immediately prior to or at the point of purchase. FDA would not object to the use of tray liners or wrappers to be used as a means to provide nutrition information, as long as the tray liners or wrappers are available upon request to the consumers, and the tray liner or wrapper contains nutrition information for all standard menu items offered for sale at the covered establishment.

Another comment recommended that FDA provide additional nutrition information in Spanish and other languages depending on the region of the country in which the retail food establishment is located. FDA would not object to covered establishments providing information in other languages, in addition to English. FDA notes, however, that if the information is provided in other languages, all of the required information must be provided in that language. This is consistent with labeling requirements for packaged foods, except that covered establishments in Puerto Rico may provide the information in Spanish only. § 101.15(c).

Unlike the statutory requirements about calorie declarations, which must be placed on menus and menu boards, there is more opportunity for the industry to determine how best to present the written nutrition information. In determining how to present the nutrition information in written form, a covered establishment might consider the extensiveness of the menu and levels of technology capability, among other factors. Allowing flexibility in meeting the requirements of this section is consistent with the current regulation for nutrition labeling in restaurant foods in § 101.10, which permit the disclosure of nutrition information for foods that bear nutrient content or health claims by various means. We request comment on whether we should be more prescriptive in the format and manner of the declarations in order to ensure they are useful to consumers.

In considering whether to require more specific formats, FDA is particularly concerned with whether there are ways to provide information to consumers with diseases related to obesity and being overweight. For example, we seek comment on whether

FDA should require nutrients that are particularly important for consumers with obesity and diabetes to monitor in order to maintain healthy dietary practices (e.g., total calories, total fat, sodium, sugar) to be bolded or placed in a separate table of nutritional content. In addition, FDA requests comment on whether and how additional written nutrition information should be required to be available on the Internet, *e.g.,* when a covered establishment provides a menu on its Web site.

6. Requirements for Self-Service Food and Food on Display

a. General requirements for self-service food and food on display. Section 403(q)(5)(H)(iii) provides that calories per food item or per serving must be disclosed for self-service food and food on display (21 U.S.C. 343(q)(5)(H)(iii)). Covered establishments must provide this calorie information on a sign adjacent to each food offered.

As discussed in section III.B. of this document, FDA proposes to define "food on display" as food that is visible to the customer before the customer makes an order selection. FDA is proposing to define "self-service food" as food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility, and self-service beverages.

b. Display of calories for self-service foods or foods on display. Section 403(q)(5)(H)(i) and (iii) requires that covered establishments place adjacent to each standard menu item that is a self-service food and food on display a sign that lists calories per displayed food item or per serving (21 U.S.C. 343(q)(5)(H)(i) and (iii)). Some comments stated that for foods sold at salad bars or buffet lines, the calorie information must be near each item, and not, for example, in a pamphlet on or near the salad bar or buffet line. One comment asserted that the placement of signs adjacent to each food item creates a potential for insanitary conditions, and suggested that the calorie information be placed at the beginning of the self-service line and hung above self-serve stations.

FDA tentatively concludes that when a self-service food or food on display is already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, listing calories per displayed food item or per serving on that sign satisfies the requirement of section 403(q)(5)(H)(iii). Placing a separate sign with calorie information adjacent to a food that is already accompanied by a sign bearing its name, price, or both, could make it more difficult for consumers to clearly associate the calorie information with its corresponding self-service food or food on display. Therefore, given FDA's authority to specify the manner of nutrient content disclosures under section 403(q)(5)(H)(x)(bb), FDA is proposing in § 101.11(b)(2)(iii) that the calorie declaration appear on the sign with the name, price, or both, of the self-service food or food on display, if applicable.

FDA proposes that the calorie declaration on such a sign must state the number of calories and use the term "Calories" or "Cal," both in a type size no smaller than the type size of the name or the price of the food item whichever is smaller in the same color, or a color at least as conspicuous as that name or price, with the same contrasting background. FDA requests comment on whether establishments that already provide an individual sign identifying each food on display or self-service food with its name, price, or both should have the option of providing a separate individual sign for each food on display or self-service food for the calorie declaration, so long as the sign with the calorie declaration is adjacent to and clearly associated with its corresponding food.

When a self-service food or food on display is not already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, FDA proposes that the covered establishment place a sign adjacent to each food with the number of calories per serving or per item, as appropriate, and the term "Calories" or "Cal." FDA proposes that the calorie declaration on these signs be clear and conspicuous, and requests comment on whether additional or more specific formatting requirements are necessary.

Often, self-service food or food on display is displayed per item, such that the customer generally takes one item or is generally served one item (*e.g.,* a baked potato at a buffet, a cupcake at a bakery, a cup of pudding at a cafeteria). FDA tentatively concludes that for self-service food or food on display that is displayed per item, where an item represents one serving, the calorie declaration should be per item.

For self-service food or food on display that is not displayed per item (*e.g.,* potato salad at a buffet or ice cream at an ice cream parlor), FDA tentatively concludes that the calorie declaration should be per serving. Covered establishments may use the size of the serving utensil as the serving measure (*e.g.* 300 calories per single scoop of ice cream), or they may use common household measurements (*e.g.,* 400 calories per cup of potato salad. FDA requests comment on the appropriate measurement units for declaring calories per serving for self-service foods and foods on display.

With respect to multiple-serving foods, FDA tentatively concludes that if the food on display or self-service food is a discrete item such as a whole rotisserie chicken, and it is sold as such, then the calories must be displayed for the whole item. FDA would not object to the voluntary declaration of the calories per serving as well as the calories per food item, as long as such declaration is truthful and not misleading. However, if individual portions of a multi-serving food on display or self-service food are served to consumers or available for consumers to serve themselves (*e.g.,* cake by the slice or pizza by the slice), then, under this proposal, the calories must be displayed per serving.

c. Self-serve beverages. A few comments stated that calorie labeling for self-serve beverages, such as soft drinks, juices, shakes, smoothies, coffees, teas, and similar drinks is difficult because of factors including the wide range of calories per ounce of the different types of beverages; the variability in serving size within a chain and in different establishments; and the amount of ice dispensed for certain beverages. The comments also stated that there is limited space on menus and beside beverage dispensers. Some comments asserted that the calorie declaration should be on menus or menu boards, because that is where the consumer makes decisions; one of these comments stated that to the extent that it is appropriate to make calorie information available in places other than the menu or menu board, it should be provided in a consistent manner (*i.e.,* the calorie declarations on menus, menu boards, and adjacent to self-service fountain machines and other self-service beverage equipment should all be consistent and based on the same serving size or other agreed upon unit of measure).

The comments stated that FDA must work with covered establishments, as well as with the beverage industry, to determine the appropriate serving size (*e.g.,* 12 fluid ounces) or other standard (*e.g.,* ranges, averages, per cup assuming one-third ice fill, *etc.*) on which a reasonable approximation of beverage calorie content should be based. Some comments recommended that FDA exempt self-service fountain machines and other self-service beverage dispensing equipment from displaying calorie information until FDA satisfies the FD&C Act's requirement to

"establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks."

FDA recognizes that covered establishments may have different sizes for beverages that are listed on the menu as small, medium and large. Consumers may be confused when they order the same item (*e.g.,* a small cola) in two different establishments and are presented with two different calorie declarations. For example, in one establishment, a small cola may be 140 calories and in another establishment a small cola is 190 calories. The difference in the calories could be based on the fact that the two cups sold as "small" may have different volumes (*e.g.,* 12 ounces versus 16 ounces). FDA is considering whether the amount of calories declared should be based on the number of ounces. We anticipate that if we adopt this view in the final rule, we would not object to the covered establishment listing the number of ounces as part of the size declaration *e.g.,* "140 calories per 12 ounces (small)." FDA requests comment on this issue.

Similar to the ice cream parlor that lists all of its flavors on the menu board, some covered establishments list beverages individually on a menu or menu board. In such situations, calorie information must be provided in both locations, in accordance with section 403(q)(5)(H)(ii) and (iii). When a general term for a set of beverages that includes different flavors or varieties is listed on a menu or menu board (*e.g.,* "soda"), we are proposing that the calories be declared as a range, like any other variable menu item (see proposed § 101.11(b)(2)(i)(4)). The self-service beverage dispenser itself must have calorie declarations for each flavor or variety offered, such that the calorie declaration is clearly associated with its corresponding flavor or variety. For example, the restaurant may place above each dispenser for soft drinks small signs labeled with the amount of calories for each beverage. As with other self-service foods or foods on display, if a self-service beverage already has an individual, identifying sign, the calorie declaration must appear on that identifying sign, so long as it is in a type size no smaller than the type size of the name of the beverage with the same prominence.

d. Applicability of 403(q)(5)(H)(ii) to self-service food and food on display. Section 403(q)(5)(H)(i) states, "in the case of food that is a standard menu item * * * [the covered] establishment shall disclose the information described in subclauses (ii) and (iii)." The word "and" between the references to subclause (ii) and subclause (iii) indicates that for each standard menu item, including self-service food and food on display, covered establishments should follow requirements in section 403(q)(5)(H)(ii) as applicable and section 403(q)(5)(H)(iii) as applicable. FDA tentatively concludes that when these self-service foods and food on display appear on menus or menu boards, the menus or menu boards must bear the calorie declarations required by sections 403(q)(5)(H)(ii)(I)(aa) and (II)(aa). FDA also tentatively concludes that covered establishments must provide the nutrition information in written form required under 403(q)(5)(H)(ii)(III) for these self-service foods and foods on display, and the statements required by 403(q)(5)(H)(ii)(I)(bb), (II)(bb), and (IV) on their corresponding menus and menu boards.

(1) Calorie Declarations

As discussed above, FDA proposes to define "menu" or "menu board" as the primary writing of the covered establishment from which a consumer makes an order selection. Under this definition, most self-service food and food on display would not appear on menus or menu boards. However, some would. For example, an ice cream parlor might list all of its flavors on a menu board and also have bulk containers of ice cream on display and visible to customers in a display case. In this situation, calorie declarations must be provided adjacent to the ice cream flavors on the menu board under 403(q)(5)(H)(ii)(II)(aa) and on signs adjacent to the individual ice cream bulk containers themselves under 403(q)(5)(H)(iii).

As another example, a coffee shop might have baked goods identified by small signs adjacent to each food declaring the name and, often, the price of each baked good. In many cases, these baked goods on display do not appear on the establishment's menu board. Because these signs are the only writings of the establishment from which consumers select baked goods to order, FDA tentatively concludes that they are the primary writings from which consumers ordering baked goods make their order selections.

Unlike self-service beverages such as fountain drinks that have specific size and product options, for a narrow category of self-service food or food on display where a general menu item corresponds to a wide set of self-service food or food on display, a calorie declaration adjacent to the name of the general menu item on a menu or menu board might not be helpful to the consumer. For example, the food choices on buffet lines are typically extensive, and the customers have control over the portions of each food choice they serve themselves. In addition, many buffets are all-you-can-eat. FDA notes that it would be almost impossible for covered establishments to provide useful calorie information for the general menu item "lunch buffet," given that there is no clearly identifiable upper bound to the amount of calories a customer ordering the "lunch buffet" would consume. Therefore, FDA tentatively concludes that it would be most useful for consumers, and most practical for retail food establishments, if the calorie information is provided for each individual item on the lunch buffet in accordance with section 403(q)(5)(H)(iii), but not adjacent to the name "lunch buffet" on the menu or menu board. Given FDA's authority to under section 403(q)(5)(H)(v), FDA is proposing in § 101.11(b)(2)(i)(A)(*4*) to instead require covered establishments to include on the menu or menu board a statement referring customers to the self-service facility for calorie information, e.g., "See lunch buffet for calorie declarations." FDA requests comment on this tentative conclusion.

(2) Additional Written Nutrition Information for Self-Service Food and Food on Display

Section 403(q)(5)(H)(ii)(III) requires certain additional nutrition information to be available to the consumer in written form upon request. Because section 403(q)(5)(H)(i) states that covered establishments must disclose the information in section 403(q)(5)(H)(ii) for standard menu items, FDA tentatively concludes that covered establishments must provide the additional written nutrition information described in section 403(q)(5)(H)(ii)(III) for self-service foods and food on display that are standard menu items.

Similar to our tentative conclusion regarding calorie declarations for general menu items such as "lunch buffet" discussed above, FDA tentatively concludes that it would be most useful for consumers, and most practical for covered establishments, if the additional written nutrition information is provided for each individual item on the lunch buffet, not for "lunch buffet" generally. This tentative conclusion is consistent with FDA's proposal for providing additional written nutrition information for variable menu items by component. FDA requests comment on this tentative conclusion.

(3) Succinct Statement and Statement of Availability of Additional Written Nutrition Information for Food on Display

As discussed earlier, a narrow set of food on display has identifying signs adjacent to each food item that are the primary writings of the establishment from which consumers make order selections. FDA recognizes that sections 403(q)(5)(H)(ii)(I)(bb), (II)(bb), and (IV) apply to these foods under a straightforward reading of the statute. However, the obligation to provide the two statements related to suggested daily caloric intake and the availability of additional written nutrition information under 403(q)(5)(H)(ii) seem to pose difficulties, given the generally small size of these individual signs. In addition, from a consumer's perspective, it is probably unnecessary for these two statements to appear on every single individual identifying sign. Lastly, FDA is instructed to "consider * * * space on menus and menu boards" in promulgating these regulations (403(q)(5)(H)(x)).

FDA tentatively concludes that each individual sign could be considered its own menu, but that a set of signs that are in close proximity to each other, such as those that might identify items in a bakery display counter, could be viewed together as the primary writing from which consumers choose among those items to order. Therefore, FDA is proposing in § 101.11(b)(iii)(B) that covered establishments may place the statements required under 403(q)(5)(H)(ii) on the individual food-specific signs, but they also have the option of placing them on a separate, larger sign, in close proximity to food on display, that can be easily read as the consumer is making his or her order selection. Similarly, FDA tentatively concludes that signs identifying food on display that are the primary writing from which consumers select the corresponding items to order and are in close proximity to a menu board, such that the menu board can be easily read as the customer is viewing the food on display, could be considered part of that menu board. For example, some coffee shops offer baked goods in a display case directly in front of the menu board. In these situations, the statements that appear on the menu board itself under 403(q)(5)(H)(ii)(II)(bb) and (IV) would be sufficient. FDA requests comment on these conclusions and whether additional restrictions related to presenting these statements in these contexts are necessary.

e. Requirements for Self-Service Foods and Foods on Display That Are Packaged Foods That Bear the Nutrition Information Required by Section 403(q)(1) of the FD&C Act and § 101.9

Some packaged food, such as bags of chips or packages of cookies, are offered for sale in covered establishments individually or as parts of combination meals. A packaged food that is required to bear nutrition information on its label under 403(q)(1) of the FD&C Act and FDA's implementing regulations at § 101.9 would not be a restaurant or restaurant-type food, because restaurant or restaurant-type food includes only food previously exempt from those nutrition labeling requirements. Therefore, such food would not be covered by the proposed menu labeling requirements. However, FDA tentatively concludes that some packaged food offered for sale in covered establishments is "food served in restaurants or other establishments in which food is served for immediate consumption or that is sold for sale or use in such establishments." While it happens to bear Nutrition Facts, it is not required to do so. This food would meet the proposed definition of "restaurant food" and therefore would be covered by the menu labeling requirements.

Such packaged food already includes on its label the nutrition information that FDA is proposing be required to be disclosed in the written form in § 101.11(b)(2)(ii). As noted in section III.B.5. this information would include the number of calories, calories from fat, total fat, saturated fat, cholesterol, *trans* fat, sodium, total carbohydrates, sugars, dietary fiber, and total protein in the food. In some cases, the packaged food is placed on a shelf, rack, counter, or other area where the food can be accessed by a consumer before the consumer purchases the food. So long as the consumer is able to examine the nutrition information on the label of the packaged food before purchasing the food and the food complies with the nutrition labeling requirements set forth in 403(q)(1) of the FD&C Act and § 101.9, the label for the packaged food will provide to consumers, in written form, the nutrition information that FDA is proposing be required in the written nutrition information. Therefore, FDA tentatively concludes that this type of packaged food would satisfy the requirements of § 101.11(b)(2)(ii), so long as consumers are able to examine the nutrition information on the label of the packaged food before purchasing the food.

In addition, the label of such packaged food includes calorie information for the food per item or per serving. FDA tentatively concludes that a packaged food that is a self-service food or food on display that bears the nutrition information required by 403(q)(1) of the FD&C Act and § 101.9 satisfies the calorie disclosure requirement for self-service food or food on display in section 403(q)(5)(H)(iii) of the FD&C Act, so long as a consumer is able to examine the calorie information on the label prior to purchase. Covered establishments would not be required to place signs that list calories per displayed food item or per serving adjacent to such packaged foods. The agency tentatively concludes that these proposals will provide flexibility for industry without sacrificing nutrition information provided to consumers.

Covered establishments still would be required to post calorie information on menus and menu boards for packaged foods that are standard menu items listed on menus and menu boards. For example, a covered establishment may list "chips" on its menu board, referring to packaged bags of chips that are available as self-service foods or foods on display within the establishment. In this situation, the establishment would be required to disclose on the menu board calorie information for the packaged chips, even though the establishment may not be required to place a sign that lists calories per displayed food item or per serving adjacent to the packaged chips themselves.

In addition, if a covered establishment lists on its menu or menu board a combination meal that includes a packaged food, the establishment would be required to disclose the total calorie information for the combination meal, including the packaged food. For example, a covered establishment may list on its menu board a combination meal that includes a soft drink, sandwich, and packaged chips. In this case, the covered establishment would be required to disclose on the menu board the total calorie information for the combination meal, which would include the soft drink, sandwich, and packaged chips, because these food items together make up the combination meal. FDA requests comments on these proposals and tentative conclusions.

8. Determination of Nutrient Content

Section 403(q)(5)(H)(iv) requires that a covered establishment "shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in [21 CFR 101.10] (or any successor regulation) or in a related

guidance of the Food and Drug Administration." 21 U.S.C. 343(q)(5)(H)(iv). FDA is proposing in § 101.11(c)(1) that nutrient content disclosures may be determined by nutrient databases, cookbooks, laboratory analyses, and other reasonable means, including the use of labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and § 101.9. FDA notes that covered establishments must ensure that the nutrition declaration is truthful and not misleading in accordance with section 403(a)(1) under the FD&C Act. Further, FDA is proposing in § 101.11 that for compliance purposes, a covered establishment is required to upon request provide information on the reasonable basis used to determine the nutrient content disclosures for their standard menu items, self-serve foods and foods on display. This proposed requirement is discussed in more detail below in section E. In addition, because the nutrients that are required to be declared in covered establishments are a subset of those required to be declared in the labeling of food in § 101.9, FDA is proposing in § 101.11 an approach for determining compliance modeled after § 101.9(g). Proposed § 101.11(c)(2) provides for two classes of nutrients for purposes of compliance: Class I (added nutrients) and Class II (naturally occurring (indigenous) nutrients). FDA is proposing that for Class I protein or dietary fiber, the nutrient content of an appropriate composite sample must be at least equal to the value for that nutrient declared in the nutrition information in the written form. Other requirements would include that the amount of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, and sodium contained in an appropriate composite of a standard menu item must not be more than 20 percent in excess of the declared value. Additionally, the amount of protein, total carbohydrates and dietary fiber contained in an appropriate composite of a standard menu item must not be less than 80 percent of the declared value. FDA also is proposing that for variable menu items that disclose calories in ranges, the lowest calorie declaration in the range would be used to determine compliance. FDA requests comments on the appropriate variability from declared nutrition information for compliance purposes, including whether § 101.11 should mirror § 101.9 in this respect.

D. Voluntary Registration for Restaurants or Similar Retail Food Establishments That Are Not Chain Retail Food Establishments and Elect To Be Subject to the Requirements of Section 4205

Section 403(q)(5)(H)(ix) provides that restaurants and similar retail food establishments *not* automatically subject to the requirements of section 403(q)(5)(H) may elect to become subject to the requirements by registering biannually with FDA (21 U.S.C. 343(q)(5)(H)(ix)). On July 23, 2010, as required by section 403(q)(5)(H)(ix), FDA published in the **Federal Register** a notice ("registration notice") specifying the terms and conditions for implementation of voluntary registration, pending promulgation of regulations (75 FR 43182 (July 23, 2010)).

Section 4205 preempts State and local nutrition labeling requirements for chain retail food establishments that are not "identical" to the Federal requirements, as discussed more fully in section IV of this document (21 U.S.C. 343–1(a)(4)). Under amended section 403A(a)(4), restaurants and similar retail food establishments that are not chain retail food establishments but elect to become subject to the Federal requirements by registering voluntarily with FDA are not subject to State or local nutrition labeling requirements, unless those State or local requirements are "identical to" Federal requirements. Restaurants and similar retail food establishments that register are subject to the requirements of amended section 403(q) and FDA's implementing regulations to the same extent as chain retail food establishments.

FDA anticipates that registrations will primarily be submitted by restaurants and similar retail food establishments with fewer than 20 locations in States and localities that have non-identical menu labeling requirements. An authorized official would be permitted to register multiple restaurants or similar retail establishments within a chain on a single registration form, provided that the official is an authorized official for all of the restaurants or similar retail food establishments included on the form. In addition, the authorized official of an individual restaurant or retail food establishment may register that restaurant or retail food establishment on a single registration form.

FDA is proposing in § 101.11(c)(2) that the authorized official of a restaurant or similar retail food establishment as defined in § 101.11(a)(10) may register with FDA. FDA is also proposing in § 101.11(c)(2) that an authorized official may register an individual restaurant or similar retail food establishment or multiple restaurants or similar retail food establishments that are part of chain on a single registration form.

FDA is proposing in § 101.11(c)(3) that authorized officials for restaurants and similar retail food establishments must provide FDA with the following information:

- The name, address, phone number, e-mail address, and contact information for the authorized official;
- The name, address, and e-mail address of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;
- All trade names the restaurant or similar retail food establishment uses;
- Preferred mailing address (if different from location address for each establishment) 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 restaurant or similar retail food establishment will be subject to the requirements of § 101.11.

FDA has created and made available at a Web site, *http://www.fda.gov/menulabeling,* a form (OMB No. 0910–0664) that contains fields requesting this information. Authorized officials of restaurants and similar retail food establishments electing to be subject to the requirements of section 403(q)(5)(H) can obtain information to register by visiting *http://www.fda.gov/menulabeling.* Registrants must use this form to ensure that complete information is submitted.

FDA prefers that the information be submitted by e-mail by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by e-mail to *menulawregistration@fda.hhs.gov.* If e-mail is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to (301) 436–2804 or mail it to FDA, White Oak Building 22, Room 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

In section 4205, Congress provided that registration must be renewed biannually (21 U.S.C. 343(q)(5)(H)(ix)(I)). Although "biannual" is defined as occurring twice every year,

the word is also defined as occurring every other year. (Ref. 26). FDA tentatively concludes that registration every other year is a more reasonable interpretation of this requirement, because it does not seem warranted or necessary for a restaurant or similar retail food establishment to tell FDA every 6 months that the establishment wants to be subject to Federal jurisdiction. Thus, FDA is proposing in § 101.11(d)(5) that authorized officials must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA, and the registration will automatically expire if not renewed.

E. Substantiation Documentation

Covered establishments must provide nutrient content disclosures that are not false or misleading to comply with section 403(a)(1). Covered establishments also must have a reasonable basis for their nutrient content disclosures under section 403(q)(5)(H)(iv). It is clear under section 403 that covered establishments must substantiate the accuracy of their nutrient content disclosures and the fact that those disclosures have a reasonable basis. Under section 701(a), FDA has authority to issue regulations for the efficient enforcement of FD&C Act, including sections 403(a)(1) and 403(q)(5)(H)(iv).

Without access to substantiation documentation for a covered establishment's nutrient content disclosures, FDA cannot efficiently determine whether a covered establishment's nutrient content disclosures are truthful and not misleading, as required by section 403(a)(1) of the FD&C Act. Without access to substantiation documentation of the bases of nutrient content disclosures, the requirement that nutrient content disclosures have reasonable bases in particular would be unenforceable. Accordingly, FDA is proposing the substantiation requirements in § 101.11(c)(2) as necessary for the efficient enforcement of the FD&C Act.

F. Conforming Amendments

As a result of the amendments to the FD&C Act made by section 4205, conforming amendments must be made in part 101 of Title 21 of the CFR. Section 4205 amended section 403(q)(5)(A) of the FD&C Act, which provided, in part, that the nutrition labeling requirements in section 403(q)(1)–(4) did not apply to food served in restaurants or other establishments in which food is served for immediate consumption or which is sold for sale or use in such establishments. It also did not apply to food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. Based on this exemption, FDA promulgated regulations in § 101.9(j) that exempt from nutrition labeling requirements these foods, so long as they do not bear nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Section 101.10 requires nutrition labeling for a restaurant food that bears a nutrient content or health claim, except that information on the nutrient amounts that are the basis for the claim may serve as the functional equivalent of complete nutrition information.

With the new requirements of section 403(q)(5)(H) for standard menu items offered for sale in certain restaurants and similar retail food establishments, provisions in § 101.9(j) need to be amended. In particular, covered establishments with annual gross sales made or business done in sales to consumers that is not more than $500,000 or with annual gross sales made or business done in sales of food to consumers of not more than $50,000 are now required to provide nutrition information under section 403(q)(5)(H). Thus, the exemption in § 101.9(j)(1) needs to be amended to reflect that, in providing the nutrition information required under § 101.11, a covered establishment would not become subject to § 101.9. In addition, the exemptions from nutrition labeling in § 101.9(j)(2) and (3) need to be revised to exclude standard menu items sold in covered establishments and reference the special labeling requirements for those foods in § 101.11. Similarly, § 101.10 needs to be amended to include the provision that for restaurant foods sold in covered establishments, the information required in the written nutrition information required by proposed § 101.11(b)(2)(ii)(A) would meet the requirements of § 101.10, when applicable. Therefore, FDA is proposing conforming amendments in § 101.9(j) and § 101.10.

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 who voluntarily choose to register under section 403(q)(5)(H)(ix).

G. Proposed Effective Date

FDA received several comments regarding the effective date of the final rule that would issue based on this proposal. Many comments suggested that FDA provide one to two years before the effective date because covered establishments would need that much time to make the changes necessary to comply with the regulations. One comment requested an effective date of three years because this timeframe was needed to defray the costs of new menu boards. Others suggested that six months was a reasonable timeframe.

FDA is proposing that the final rule become effective six months from the date of its publication. Compliance is expected to yield significant public health benefits because consumers will have calorie and other nutrition information when they make menu choices. Because of this benefit, the agency finds that it is reasonable to make the requirements effective as soon as practicable. Based on the comments and on what covered establishments will need to do to come into compliance, the agency tentatively finds that making the final rule effective six months after publication is practicable. FDA recognizes, however, the potential difficulties of implementing the rule in this timeframe, and we request comment on whether the effective date should be extended for a greater period of time after the publication of the final rule. We request comment on whether a nine-month or one-year implementation timeframe would be more appropriate.

H. Compliance

As discussed in section II of this document, FDA is proposing these regulations under sections 201(n), 403(a), 403(q), as amended by section 4205 of the Patient Protection and Affordable Care Act of 2010, and 701(a) of the FD&C Act. Failure to comply with the regulations, if adopted by the agency, will render the food misbranded under sections 201(n), 403(a), or 403(q) of the FD&C Act. Introducing, delivering for introduction, or receiving a misbranded food in interstate commerce, or misbranding a food while it is in interstate commerce or being held for sale after shipment in interstate commerce, are prohibited acts under section 301 of the FD&C Act and subject to enforcement action.

FDA addressed the issue of enforcement of section 4205 in a draft guidance entitled, "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010." The agency announced the availability of the draft guidance in the **Federal Register** on August 25, 2010 (75 FR 52426). In that draft guidance, FDA stated that it expected to refrain from enforcing the provisions of section 4205 that became requirements immediately upon enactment of the law until a date that it would specify in final guidance. Based on extensive comments on the draft guidance, however, FDA decided to withdraw the draft guidance and to exercise enforcement discretion until after it had completed notice and comment rulemaking (76 FR 4360 (January 25, 2011)).

FDA seeks comment on how we should implement these regulations. In particular, we seek comment, supported by data, concerning how much time is needed for covered establishments to come into compliance with the final rule, including, if possible, data on whether specific provisions of the rule can be more quickly implemented than others (see section V.E., below). We seek comment on whether we should provide for staggered implementation based on the size of a chain or of a specific franchisee. Again, any suggestions should be supported by data. Given that FDA does not intend to enforce the self-executing provisions at this time, we encourage our State and local partners to proceed in a similar way.

IV. Summary of Preliminary Regulatory Impact Analysis

The summary analysis of benefits and costs included in this document is drawn from the detailed Preliminary Regulatory Impact Analysis (PRIA) that is available at *http://www.regulations.gov,* Docket No. FDA–2011–F–0172, and is also available on FDA's Web site at *http://www.fda.gov/Food/LabelingNutrition/ucm217762.htm.*

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits (both quantitative and qualitative) 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 rule has been designated an "economically" significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

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) definitions of small for industrial subsectors in accommodations, food service, recreation, and retail food stores (NAICS 72, 71, 445), FDA tentatively concludes that a significant number of firms affected by this proposed rule are small businesses.

Section 4205 of the Affordable Care Act and the proposed requirements apply to chain retail food establishments, as that term is used in this document (*i.e.,* a restaurant or similar retail food establishment that is 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), and establishments that voluntarily register with FDA to become subject to the requirements of section 4205. Some chain retail food establishments may meet the SBA definitions of: Less than $7 million in annual sales for most accommodation and food service or recreation subsectors (NAICS 72, 71); less than $20.5 million in annual sales for Food Service Contractors (NAICS 722310); or less than $27 million in annual sales for supermarkets and convenience store chains (NAICS 44510 and 445120). In addition, some chain retail food establishments are owned or operated by entities, including franchisees or cooperative members that may meet the SBA definitions described above.

Establishments that voluntarily register to be subject to the Federal requirements, which may be individually owned or part of a firm that controls establishments within a chain of less than 20 locations, may meet the SBA definition described above. While the voluntary nature of the registration implies that these latter firms see a positive net benefit from becoming subject to the Federal requirements, this does constitute a potentially significant economic impact. Therefore, the agency tentatively concludes that the rule will have a significant economic impact on a substantial number of small entities. This tentative conclusion is discussed further in section V.

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 expects this proposed rule to result in 1-year expenditures that would meet or exceed this amount. This tentative conclusion is discussed further in section VI.

FDA asks for comments about the data and the methods used for estimating the regulatory impact of the proposed rule.

B. Need for This Regulation

This proposed rule is necessary to implement Section 4205 of the Affordable Care Act, which amends sections 403(q)(5) and 403A of the FFDCA, and requires disclosure of calorie and other nutrition information by covered establishments. These nutrition labeling requirements should help consumers to make more informed choices about the nutritional content of the food they purchase. The provision of calorie and other nutrition information for restaurant and restaurant-type foods, as those terms are used in this document, offered for sale by covered establishments should help consumers limit excess calorie intake and understand how the foods that they purchase at these establishments fit within their daily caloric and other nutritional needs. FDA notes as well that Executive Order 13563 specifically directs agencies to "identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include * * * disclosure requirements as well as provision of information to the public in a form that is clear and intelligible."

Economic justifications for regulatory interventions in private markets rely on the presence of some market failure. In the case of restaurant and restaurant-type foods, the private market is particularly robust and competitive. Hundreds of thousands of retail food establishments and tens of thousands of

individual firms vie for consumer dollars across the United States. High estimates of failure rates for restaurants (Ref. 27), with relatively steady growth rates in number of establishments (Ref. 28) indicate that entry in the industry occurs often, and survival is hard fought: Restaurants must be responsive to consumer needs and desires in order to survive. The competitiveness of the industry suggests that if a sizable fraction of consumers were willing to pay for—and discriminate based on—the availability of nutrition information, then the industry would provide it to them. In fact, many retail food establishments do provide nutrition information for at least a fraction of their offerings, either through available brochures, or, increasingly, on the Internet. A 2006 study found that 34 percent of the top 300 chain restaurants (by sales volume) had nutrition information available to consumers in some form (Ref. 29).

Notwithstanding this point, and although many of the usual market failures that justify regulatory action, such as the existence of market power or public goods, cannot be found here (Refs. 30 and 31), the primary support for government intervention is an absence of sufficient nutritional information, produced by an inadequate incentive for restaurants to produce that information on their own. An absence of adequate information is of course a standard market failure, justifying disclosure requirements or provision of information in many contexts.

In terms of explaining the inadequate incentive for restaurants to provide sufficient nutrition information, a central reason involves consumer demand. There are systematic biases in how consumers weigh current or immediate benefits (from eating more, or higher calorie, foods) against future or long-term costs (higher probability of obesity and its co-morbidities). These biases are directly related to the proposed requirements: The temporal disconnect inherent between food consumption choices and their potential health costs may work against an efficient provision of nutrition information for food (Ref. 32). A primary issue here is that long-term risks may not be sufficiently salient to produce adequate consumer demand for relevant information disclosure. Without that information, consumers may fail to make informed choices and may undervalue the future costs of excessive calorie consumption, relative to the current benefits from such consumption (Refs. 29, 33 and 34).

Studies suggest that one problem involves the fact that because food decisions are made so often, and the marginal effect of any one meal on future obesity is small, the cumulative costs of a large number of relevant decisions may be neglected. These studies suggest that some or many consumers will not demand calorie information, because the issue of calories 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 latter date. This tendency may explain why consumers have not generally demanded calorie and other nutrition information for restaurant and restaurant-type food, although they do, at a later point in time, value that information. Furthermore, restaurants and similar retail establishments face costs in providing calorie and other nutrition information, including opportunity costs of limited time and space in which to convey information to the consumer. That is, just as a firm has to decide which possible menu items to leave off a menu board with limited space (thus giving up the opportunity to sell those items), it must choose which pieces of information about its menu items it wants to convey. Adding an additional piece of information means that a firm may need to downplay or remove some other valuable piece of information. In addition, providing calorie information may have complex and unintended effects on revenue and profits as consumers respond to that information. Given the costs and the uncertain reception of displayed calorie information most restaurants have chosen not to display this information at the point of purchase.

The proposed requirements respond to the apparent market failure in information provision stemming from existing restaurant incentives and present-biased preferences. Specifically, the proposed requirements provide that calorie information for standard menu items must be posted in covered establishments. Providing this nutrition information will likely increase the salience of the information and promote informed choice as well. It will also likely raise consumer awareness regarding the number of calories in restaurant and restaurant-type foods, and thus may serve to highlight the potential future costs of additional calorie consumption. This increased attention to the number of calories in food offered for sale by covered establishments 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 PRIA.

Benefits in response to the proposed requirements. Obesity and overweight are major public health concerns in the United States and among the top leading health indicators addressed by the United States Healthy People 2020 goals. Nationally representative data have consistently exhibited a steady increase in the prevalence of obesity over the past three decades (Ref. 35). As noted in section I.A., 34 percent of the adult U.S. population is obese and 34 percent is overweight (Ref. 1). In addition, about 31 percent of children and adolescents, aged 2 to 19, are overweight or obese (Ref. 8).

Excess body weight has many health (Ref. 36), social (Refs. 37 and 38), psychological (Refs. 39 and 40), and economic consequences (Ref. 41) for the affected individuals. Lower life expectancy, elevated risk of diabetes, hypertension, stroke and other cardiovascular disease has been documented to rise simultaneously with the increased prevalence of obesity (Ref. 36). The economic impact is especially evident for health-care costs in terms of greater health-care utilization and higher medical expenditures (Ref. 42). More specifically, as noted, medical expenditures attributable to overweight and obesity accounted for more than 9 percent of the total U.S. medical expenditures in 1998, or between $86 billion, and $147 billion (Ref. 42). Another estimate indicates that obesity costs American families, businesses and government approximately $117 billion in 2010 (Ref. 43).

The primary risk factors for overweight and obesity in the general population are overconsumption of calories (*i.e.,* eating more calories than are needed to maintain body weight) and physical inactivity (*i.e.,* getting an amount of exercise below the amount required to burn excess calories consumed over the amount needed to maintain body weight (Ref. 9).

One contributor out of the complex and multi-facet set of factors is food offered for sale by restaurants and similar retail food establishments. The proportion of total food expenditure spent on such foods increased from 34 percent during the 1970s up to approximately 50 percent by 2004, where it has remained through 2009 (Ref. 44). These foods are generally high in calories, fat and portion size (Ref. 45),

and they tend to be lower in fiber and other essential nutrients such as calcium as compared to home-prepared foods (Ref. 10).

Restaurant food and restaurant-type food form a significant and increasing part of U.S. diets. According to one study, "food away from home" (this term is roughly comparable to restaurant and restaurant-type foods) constituted about a third of calories consumed annually by the average adult or child in the United States in the most recent comprehensive published study (Ref. 10). Another study of adults found that "food away from home" adds an additional 130 calories per meal, on average, relative to a similar meal prepared at home (Ref. 46). The difference in calorie consumption between "food away from home" and food prepared at home was greater for study participants who were overweight or obese; among those individuals, the away-from-home meals had 240 more calories per meal relative to meals prepared at home (Ref. 46).

Although many factors contribute to obesity, to the extent that the proposed requirements would mitigate the prevalence of obesity and of co-morbidities, society would gain the opportunity cost of the averted medical expenditures and an increase in productivity from averted debilitation and death. In addition to informing consumers about the calorie content for restaurant and restaurant-type foods offered for sale by covered food establishments, major predicted elements of the consumer and industry response to this proposed rule may include:

1. Increased awareness regarding the caloric content for foods offered for sale by covered establishments, 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 regarding calorie content of menu items, which may give firms an incentive to:

a. Reduce the calorie content of existing items through reformulation or by decreasing portion size.

b. Provide additional items with lower calorie formulations.

These changes may reduce consumers' caloric intake from foods sold in covered establishments, and this reduction in caloric intake may in turn contribute to a reduction in obesity in the U.S. population. 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. This substitution of one calorie source for another has been demonstrated in the context of menu labeling (Ref. 47) and in the context of other attempts to modify food choices (Ref. 48). Because FDA lacks data on how consumers will substitute between caloric sources, as well as specific information on the responsiveness of calorie demand to new information, the benefit estimations given here may be higher or lower than those that will be realized if the rule is finalized as proposed. Finally, there may be additional benefits to the extent that consumers use the written nutrition information to make food selections.

Industry and consumer costs in response to the proposed requirements. Meeting the proposed requirements will have costs for both the industry and consumers. Typically, new costs to an industry are borne by both consumers and firms: Prices rise to reflect new costs, but generally not by enough to completely offset them. If the expense of meeting the proposed requirements cause prices to increase for some or all restaurant and restaurant-type foods offered for sale by covered establishments, then the consumption of these foods will fall, further reducing profits for some, or all, of these establishments. Consumers would need to pay more for this food, requiring some reduction in other, valued, consumption.

One difficulty in determining the cost burden stems from the relatively complicated ownership structures in some of the covered sectors. Restaurants and similar retail food establishments can be corporate-owned, franchised as part of a large or small independent chain, or cooperatively-organized and doing business under the same name. Data for separate firms operating under the same name, such as franchises of a particular brand or corporate name, are difficult or impossible to acquire. Therefore, for this analysis FDA counts affected establishments and chains, which may in fact serve one, several, or many, underlying firms. Except for some potential costs of nutrition analysis, the costs of the proposed rule are analyzed at either the chain or the establishment level, so that the overall costs are not primarily a function of the actual number of firms affected.

The major elements of cost for this proposed rule are:

1. Collecting and managing records of nutritional analysis for each standard menu item.

2. Revising or replacing existing menus, menu boards and other affected displays.

3. Training employees to understand nutrition information in order to help ensure compliance with the proposed requirements.

Although not required by the proposed requirements, some chains or establishments may respond to increased consumer interest on caloric content of restaurant and restaurant-type food by reformulating existing menu items or by introducing new, lower calorie items. While the costs associated with formulating these items have not been included in the cost estimation, FDA has included the cost associated with analyzing new or reformulated items. Because the rate at which these items are introduced may be affected by the propose requirements, FDA requests comment and data on whether the proposed requirements will accelerate the rate of new item introduction and how the cost of these items may be affected by the proposed requirements.

Finally, because they are not required by the proposal, FDA has not included any costs associated with developing online or other electronic calorie calculators for variable menu items. FDA requests comment and data on the costs of these kinds of calorie tools.

Summary of benefits and costs. We summarize the estimated costs and benefits of the proposed requirements and some regulatory options in Tables 5a–5b. The full analysis is provided in the detailed PRIA. Costs of complying with the proposed requirements have been estimated for three major areas: Cost of nutrition analysis, cost of menu and menu board replacement, and costs of training. These costs have been aggregated across an estimate of the total number of chains and establishments that would be defined as covered under the proposed rule. In the case of the proposed rule, FDA estimates that there would be approximately 278,600 covered establishments organized under 1,640 chains. The initial mean estimated cost of complying with the proposed requirements is $315.1 million, with an estimated mean ongoing cost of $44.2 million. Annualized over 10 years, the mean estimated annual cost of the proposed requirements is $76.8 million at a 3 percent discount rate, and $82.3 million at a 7 percent discount rate. FDA has estimated low and high annualized cost estimates for the proposed requirements of $33.4 million and $120.5 million with a 3 percent discount rate, and $34.9 million and $130.1 million with a 7 percent discount rate. The bases for this wide range of cost estimates and the main drivers of this uncertainty are collected and discussed in the detailed PRIA.

Initial costs are estimated to be $1,100 per covered establishment. Note

however, that this figure combines the average per establishment cost of $1,800 per limited service eating establishments—i.e., those most likely to have more than one menu board or major display serving as a menu—with full service restaurants averaging less than $1,000 per establishment. These averages do not show the very wide range of costs that individual establishments and chains will bear, based on their very different approaches to nutrition analysis, menu design and overall market niche.

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 establishment menus. 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 0.06 percent of the adult obese population would need to reach at least this benchmark in order for the rule to break even on the primary, or mean annualized cost.

TABLE 5a—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 ($millions/year)	Not quantified					
Annualized Quantified:						
Qualitative: FDA estimates that at least 0.06 percent of the adult obese population would need to reduce caloric intake by at least 100 calories per week in order for benefits from the proposed requirements to reach a break even point on annualized costs (at either 3% or 7%).						
Costs						
Annualized Monetized ($millions/year)	$82.3 76.8	$34.9 33.4	$130.1 120.5	2009 2009	7% 3%	10 10

Regulatory Options. In addition to a baseline, FDA has identified five regulatory options for this proposed rule as required by Executive Order 12866. The estimated benefits and costs of these options relative to the proposed rule are given in Table 5b.

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

(1) Option 1, the proposed rule, the definition of "restaurants or similar retail food establishments," limited to retail establishments that offer for sale restaurant or restaurant type food where the sale of food is the primary business activity of that establishment. This option encompasses limited- and full-service restaurants, snack bars (including coffee shops, pastry shops, sandwich counters and similar establishments), cafeterias, drinking places, convenience stores and grocery stores that are chain retail food establishments as defined in this proposed rule. The proposed rule has an effective date of six months after the publication of the final rule.

(2) Option 2, with requirements similar to the proposed rule, but with "restaurant or similar retail food establishment" limited to retail establishments where the sale of restaurant food or restaurant-type food is the primary business activity. This option covers all establishments included in Option 1, with the exception that grocery and convenience stores would not be subject to the proposed requirements.

(3) Option 3, with requirements similar to the proposed rule, but with scope broadened to include a wide variety of establishments that serve restaurant or restaurant-type food.

(4) Option 4, with requirements similar to the proposed rule, but with an effective date starting three months after publication of the final rule instead of six months after publication of the final rule.

(5) Option 5, with requirements similar to the proposed rule, but with an effective date starting 12 months after publication of the final rule instead of six months after publication of the final rule.

TABLE 5b—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	$76.8 82.3	$33.4 34.9	$120.5 130.1	3% 7%	0.0%	0.0%
Option 2: Smaller Scope	65.9 72.5	29.1 31.6	103.2 113.8	3% 7%	−12.5%	−5.0%

TABLE 5b—SUMMARY OF ESTIMATED ANNUALIZED COMPLIANCE COSTS FOR EACH OPTION—Continued

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
Option 3: Larger Scope	86.9 92.9	38.2 39.9	135.5 145.8	3% 7%	+13.3%	+11.2%
Option 4: Shorter Compliance Time	84.2 91.0	35.8 37.8	132.4 144.0	3% 7%	+9.4%	0.0%
Option 5: Longer Compliance Time	76.2 81.6	31.9 33.2	120.5 130.1	3% 7%	−2.4%	0.0%

FDA estimates that Option 2, which limits the scope of the proposed requirements to establishments that either present themselves as restaurants or have more than 50 percent of their floor area used for restaurant or restaurant-type food, has a ten-year annualized cost of between $29.1 million per year and $103.2 million per year with a 3 percent discount rate, with a primary estimate of $65.9 million. Averaged over primary, low and high estimates, the costs of Option 2 are 12.5 percent lower than those of the proposed requirements. Although FDA does not have adequate data on the proportion of calories consumed at different types of establishments, as a rough estimate of the coverage of Option 2 relative to the proposed requirements, we use the proportion of dollar sales of restaurant or restaurant type food relative to the establishments covered by the proposed rule. In the case of Option 2, limiting the scope of covered establishments would reduce the coverage of restaurant or restaurant-type food sales by 5.0 percent. These changes are discussed more fully in the detailed analysis.

Option 3 which considers a wider set of establishments that service restaurant or restaurant-type foods, including lodging, transport, entertainment, general retail and other establishments, has costs that are 13.3 percent higher than those of the proposed requirements and coverage of sales that is 11.2 percent higher. Option 4, which shortens the compliance time to 3 months, has costs that are 9.4 percent higher than the proposed, and Option 5, which lengthens compliance time to 12 months has costs that are estimated to be 2.4 percent lower. These options do not change the set of covered establishments relative to the proposed rule.

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 is only likely to occur to the extent that the costs of registration and compliance with Federal regulation is lower than that of State or local regulation, 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 section VII of this document. For full documentation and discussion of these estimated costs and benefits see the detailed PRIA, available at *http://www.regulations.gov,* enter Docket No. FDA–2011–F–0172.

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. Although chains with 20 or more establishments will generally have total sales in excess of SBA's small business limits, many of these establishments are actually operated by franchisees, independent operators licensing a chain store brand, or some other types of small business. The majority of the costs of the proposed rule will be borne at the establishment level, in particular, the cost of new menus and of employee training. Because of this, many of these small businesses will be directly responsible for meeting of the costs of compliance.

FDA has built substantial flexibility into the proposed rule. The wide range in cost estimates given in Section IV. of this document is a function of the variety of approaches that business may choose to take to comply with the proposed requirements. The proposed rule does not prescribe the method or materials used to disclose calorie information or other nutrition information, beyond format and style requirements. In addition, the proposed rule does not require any employee training, and it allows for a variety of approaches for nutritional analysis. Therefore, businesses may choose among a wide variety of less, or more, expensive avenues for compliance depending on their situation.

Controllers of chain level brands have significant latitude to impose lesser or greater costs on their associated establishments. Examples include the extent to which franchisors may impose more expensive menu board designs on franchisees, or the extent to which franchisors impose training requirements. Because the proposed rule provides flexibility for the disclosure of nutrition information in covered establishments, the proposed rule gives small businesses (and gives owners of chain brands) the leeway to select cheaper methods to meet the proposed requirements, such as the use of stickers or menu strips, or more expensive methods, such as menu redesign or replacement.

Tying additional flexibility to the size of the firm could mean greater confusion for customers and competitors, because individual establishments within very large chains might differ in how or when they disclosed calories. Tying additional flexibility to the size of the chain would mean that some small firms in large chains would have less flexibility, and potentially higher costs, than large firms in small chains. Rather than attempt to

make a division between large and small firms, FDA has attempted to build in substantial flexibility for all firms.

Finally, section 4205 allows restaurants and similar retail food establishments that are not subject to the proposed requirements to voluntarily register with FDA to become subject to the requirements. By voluntarily registering, such an establishment is in effect indicating that the burdens of registering, which include reporting to FDA contact information for the authorized official and the establishment, and being subject to the Federal requirements, is outweighed by the benefits.

VI. Unfunded Mandates

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 has determined that this proposed rule has met the threshold under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in the detailed PRIA, available at *http://www.regulations.gov,* enter Docket No. FDA–2011–F–0172. The other requirements under the Unfunded Mandates Act of 1995 include assessing the proposed rule's effects on:

- Future costs;
- Particular regions, communities, or industrial sectors;
- National productivity;
- Economic growth;
- Full employment;
- Job creation; and
- Exports.

Note that because restaurant and restaurant-type foods are goods that by definition are not transported over long distances, international or interstate trade issues are not relevant here: the imposition of regulatory costs will not cause firms to shift production to locations that are not chain retail food establishments as the term is used in this document. Furthermore, because the costs of the proposed rule are low relative to the revenue generated by even the smallest chain retail food establishments, the proposed rule will not significantly affect employment, economic growth or national productivity.

VII. Paperwork Reduction Act of 1995

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) (the PRA). A description of these provisions is given below with an estimate of the annual reporting, recordkeeping, and third party disclosure 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.

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.

Requirements for Nutrition Labeling for Standard Menu Items in Restaurants and Similar Retail Food Establishments (OMB Control Nos. 0910–0664 and 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 chain retail food establishments, as that term is used in this proposed rule. In particular, a restaurant or similar retail food establishment with 20 or more locations doing business under the same name and offering for sale substantially the same menu items must provide nutrition information for standard menu items. Section 4205 became effective on the date the law was signed, March 23, 2010. A restaurant or similar retail food establishment that is 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 the legislation, providing information on the terms and conditions for persons who voluntarily elect to be subject to nutrition disclosure requirements specified in the legislation.

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 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). 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 this proposed rule. With this proposed rule, FDA is submitting a revised information collection request seeking OMB approval of the changes caused by the proposed rule.

B. Revision of OMB Control Nos. 0910–0664 and 0910–0665 by the Proposed Rule

This proposed rule provides detail on how chain retail food establishments can comply with section 403(q)(5)(H)

and how restaurant or similar retail food establishments not subject to the requirements of section 403(q)(5)(H) can voluntarily register to become subject to the requirements. Certain provisions of the proposed rule revise the information collection requirements that have been approved by OMB under OMB Control Nos. 0910–0664 and 0910–0665. First, proposed § 101.11(b) would require third party disclosure to consumers of nutrition information by chain retail food establishments. Second, proposed § 101.11(d)(3) would require reporting of information by restaurants and similar retail food establishments that voluntarily register to become subject to the requirements of section 403(q)(5)(H). In addition, proposed § 101.11(c)(6) would require covered establishments to provide certain information to FDA to substantiate the nutrition information provided to consumers. The following analysis provides FDA's estimate of the changes caused by the proposed rule to the previously approved annual reporting, recordkeeping, and third party disclosure burdens.

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

This is 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, these information collection requests will be further revised by the proposal related to calorie declaration for food sold in vending machines that will be separately published in the **Federal Register**. 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."

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

The analysis of burden included in this document is drawn from the detailed PRIA that is available at *http://www.regulations.gov,* enter Docket No. FDA–2011–F, and is also available on FDA's Web site at *http://www.fda.gov/Food/LabelingNutrition/ucm217762.htm.*

Description of Respondents: The likely respondents to this information collection are covered restaurants and similar retail food establishments, including restaurants and similar retail food establishments not subject to section 4205 that voluntarily register. In this analysis, we use the term "restaurant" to refer to the subset of restaurants and similar retail food establishments, as defined in this document, that self-identify as establishments whose primary business activity is the sale of "meals and beverages for immediate consumption" in economic census surveys.

FDA estimates the burden of this collection of information as follows:

TABLE 6—ESTIMATED ANNUAL RECORDKEEPING BURDEN: NUTRITION ANALYSIS AND RECORDING FOR PROPOSED 101.11(C)(6)

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours	Capital costs
Restaurant Chains	514	80	41,088	4	164,352	$11,381,376
Restaurant Firms	11,560	5	57,800	4	231,200	16,010,600
Grocery and Convenience Store Chains	570	40	22,800	4	91,200	6,315,600
Grocery and Convenience Store Firms	2,350	5	11,750	4	47,000	3,254,750
Total initial hours					533,752	42,226,212
New/Reformulated items	1,640	12	19,680	4	78,720	5,451,360
New chains	30	80	2400	4	9,600	$664,800
Total recurring hours					88,320	6,116,160
Total burden hours					622,072	

Recordkeeping

The time burden for nutrition analysis on restaurants and similar retail food establishments is the time necessary for creating a record, managing the contracts for analysis, and communicating the results of the analysis to the establishments. FDA estimates the hourly burden per record to be 4 hours. Under the proposed requirements, FDA estimates that approximately 514 restaurant chains will be required to acquire new calorie and other nutrition information. On average, we estimate that a chain retail food establishment has 80 items on its menu. The hourly burden for restaurant chains is 164,352 hours (514 chains × 80 items/chain × 4 hours/item). FDA estimates that an average of 11,560 firms that are part of the restaurant chains may need to acquire nutrition analysis for 5 items that are specific to their establishments. The burden for these restaurant firms is 231,200 hours (11,560 firms × 5 items/firm × 4 hours/item).

FDA estimates that there are 570 covered grocery and convenience store chains with an average of 40 standard menu items per chain. The hourly burden for grocery store chains is 91,200 hours (=570 chains × 40 items/chain × 4 hours/item). FDA estimates that an average of 2,350 firms that are part of the grocery or convenience store chains may need to acquire nutrition analysis for 5 items that are specific to their establishments. The burden for these restaurant firms is 47,000 hours (2,350 firms × 5 items/firm × 4 hours/item).

FDA has estimated that each of the 1,640 chains with chain retail food establishments will introduce new items or reformulate existing items on average 12 times per year. The recurring hourly burden of recordkeeping for new items

is 78,720 hours (1,640 chains × 12 items/chain × 4 hours/item).

FDA estimated that 30 new chains will have chain retail food establishments as defined by the proposed rule each year. With an average number of menu items of 80 per chain, this would result in approximately 9,600 hours (30 chains x 80 items/chain x 4 hours/item). Adding the burden from new items to this amount gives a total recurring burden of 88,320 hours for recording nutrition information by chains associated with restaurants or similar retail food establishments. These hourly burdens are given in Table 6.

The final column of Table 6 gives the estimated capital costs associated with calorie and nutrition analysis. These are the costs of acquiring nutrition analyses. FDA has estimated that the average cost of a full analysis is $277 per menu item. These costs are calculated by multiplying this per item cost by the number of items in column 3 multiplied by the number of recordkeepers in column 2.

The current total recordkeeping burden for menu labeling as required by section 4205, now under review at OMB under No. 0910–0665, is 455,304 hours. The estimated recordkeeping burden under the proposed rule is 622,072 hours, an increase of 166,768 hours. This increase is due to a net increase in the estimated number of respondents.

The proposed rule caused several changes in our previous estimates of the recordkeeping burden. Most significantly, the proposed requirements are not extended to a variety of other establishments selling restaurant or restaurant-type foods that do not have as their primary purpose the sale of food. This change decreased the estimated burden by eliminating 67,200 hours previously estimated for other chains, and 24,000 hours previously estimated for vending operators (recordkeeping burden hours for vending operators are estimated in the separately published proposal related to calorie declaration for food sold in vending machines). In Line 1 of Table 6, total restaurant chain hours have changed from 241,488 hours to 164,352 hours, a decrease of 77,136 hours, because our estimate of the number of chains has declined by 2, from 516 to 514, due to improved data on how these sectors are organized and because our estimate of the number of standard menu items per recordkeeper has declined from 117 to 80 due to the exclusion of alcoholic beverages from the requirements of the proposed rule. Lines 2 and 4 of Table 6, reflects the addition of 11,560 restaurant firms and 2,350 grocery or convenience firms that may need to acquire nutrition analysis for 5 items that are specific to their establishments. The additional burden for these restaurant firms results in an increase of 231,200 hours and 47,000 hours respectively.

Better data on the number of new and reformulated items introduced yearly, partially offset by a substantial decrease in the set of covered sectors, also increased the estimate of this burden from 24,096 to 78,720 hours, an increase of 54,624 hours. The estimate of the burden of new chains having recurring annual costs, increased because the estimated number of menu items for these chains increased from 60 to 80. This increase occurred because the proposed rule is limited to establishments with more standard menu items. These changes increased the total recurring hours due to new chains from 7,200 to 9,600 hours, an increase of 2,400 hours. Finally, this proposed rule does not address vending machine operators, so an additional 120 hours were dropped. The net effect of these increases and decreases in the burdens estimated for different sectors is an increase in the estimated recordkeeping burden of 166,768 hours (231,200 hours + 54,624 + 2,400 + 47,000 − 67,200 hours − 24,000 hours − 77,136 hours − 120 hours = 247,221 hours).

Total initial capital costs increased from $26.9 million to $36,962,326 because of the addition of the associated restaurant and grocery or convenience firms, and the removal of other sectors, and the decrease in the number of items per chain for restaurants. Better data, which increased the estimate of the number of new items per firm from 4 to 12, led to an increase in recurring new item capital costs from $1.6 million to $5,451,360. New chain recurring capital costs increased from $0.5 million to $664,800 because of the increase in the number of items per chain.

TABLE 7—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN: NUTRIENT DISCLOSURE FOR PROPOSED § 101.11(B)

Type of respondent	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours	Capital costs
Limited Service	91,000	3	273,000	2	546,000	$150,150,000
Snack Bars and Cafeterias	25,200	1	25,200	2	50,400	13,860,000
Full Service Restaurants	23,900	1	23,900	1	23,900	4,349,800
Grocery and Convenience Chains	47,400	1	47,400	2	94,800	26,070,000
Total initial hours					715,100	194,429,800
New Chains (Recurring)	600	2	1,200	2	2,400	660,000
Total recurring hours					2,400	
Total burden hours					717,500	

Third Party Disclosure

The third party disclosure burden for restaurants and similar retail food establishments is the time necessary to display calorie information on menus, menu boards, displayed food and other required locations. In practice, this is the time necessary to change out redesigned menus, menu boards, and displays. FDA estimates two hours of time per change.

FDA has estimated that limited-service restaurant chains have an average of 3 menu boards or displays per establishment. With 91,000 establishments, the total hourly burden estimated for third party disclosure at these restaurants is 546,000 hours (91,000 establishments × 3 displays/establishment × 2 hours/display).

For the 25,200 snack bars and cafeterias, FDA estimates 1 menu board per establishment would need replacement. The total hourly burden estimated for third party disclosure at these eating places is 50,400 hours (25,200 establishments × 1 displays/establishment × 2 hours/display).

For full-service restaurants, FDA estimates that an average of 25 percent will not be able to coordinate the required menu update with an already scheduled change, so that approximately 23,900 establishments (95,500 establishments × 25%) will need to replace existing menus. With an average 1 hour to change out menus per establishment, the total burden hour estimate for full service restaurants is 23,900.

For grocery and convenience store chains, FDA estimates an average of one major menu board or display per establishment. With 47,400 establishments, the total hourly burden for these establishments is 94,800 hours (= 47,400 outlets × 1 displays/outlet × 2 hours/display).

FDA estimates that initial first year disclosure burden for restaurants or similar retail food establishments will be 620,300 hours.

FDA estimates that there will be 30 new chains each year with chain food retail establishments that will need to disclose calorie and other nutrition information under. At 20 establishments per chain, there will be 600 new chain food retail establishments each year that will need to disclose calorie and other nutrition information. Taking an average number of disclosures equal to 2, the total hourly burden for disclosure due to new chains is 2,400 hours (600 establishments × 2 displays/establishment × 2 hours/display).

The final column of Table 7 gives the estimated capital costs associated with third party disclosure. These are the costs of acquiring new menu boards or menus. FDA has estimated that the average cost of menu board to be $550. Capital costs for limited service chains and grocery or convenience chains are calculated by multiplying this per menu board cost by the frequency of disclosures in column three multiplied by the number of respondents in column two.

For full-service restaurants without menu boards, the capital costs would stem from the initial replacement of menus. With an average of 91 menus per establishment, at an average cost of $2 per menu, capital cost per disclosure is $182. The total capital cost of third party disclosure for full-service restaurants is estimated to be $4,349,800.

The current total third party disclosure burden for menu labeling as required by section 4205, now under review at OMB under No. 0910–0665, is 15,001,748 hours. The estimated third party disclosure burden under the proposed rule is 717,500 hours, a decrease of 14,284,248 hours. This decrease is due to a decrease in the estimated number of respondents.

The proposed rule caused several changes in our previous estimate of the third party disclosure burdens. Most importantly, the proposed rule covers a substantially smaller set of chains and establishments than initially estimated for section 4205. The estimate of the total initial hourly burden has decreased from 964,348 hours to 715,100 hours, a decrease of 249,248 hours, because of this change and because of a better estimate of the number of menu boards and menus in restaurants that are not limited-service restaurants. The estimated number of new chains is unchanged at 600, and the burden estimate remains at 2,400 hours. Finally, we decreased the estimated burden by eliminating 14,035,000 hours previously estimated for vending operators (third party disclosure burden hours for vending operators are estimated in the separately published proposal related to calorie declaration for food sold in vending machines). The total decrease in estimated third party disclosure burden is 14,284,248 hours (249,248 hours + 14,035,000 hours = 14,284,248 hours).

The capital costs for initial restaurant third party disclosure have dropped from $265.3 million to $194,429,800 for the same reason the hourly burden dropped: There is a lower number of estimated displays. The recurring capital costs have fallen from $0.7 million to $660,000 because of different rounding.

TABLE 8—ESTIMATED ANNUAL REPORTING BURDEN, VOLUNTARY REGISTRATION UNDER PROPOSED § 101.11(c)(3) [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Restaurants	373	1	373	2	746
Grocery and Convenience Stores	594	1	594	2	1,188
Total initial hours					1,934
New registrations	19	1	19	1	19
Re-registrations	948	0.5	474	0.5	237
Total recurring hours					256
Total burden hours					2,190

Reporting

The registration provisions of the proposed rule would require an every other year reporting to FDA by authorized officials of restaurants or similar retail food establishments that are not subject to the requirements of section 4205. FDA bases its per respondent burden on the PRA analysis for section 415 of the FFDCA (21 U.S.C. 350d) as laid out for the rule "Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Ref. 49). FDA estimates that the initial collection of the information, and presentation of it in a format that will meet the agency's registration regulations, will require a burden of approximately two hours per registration for the first year because the registration system will not be fully automated.

FDA estimates that renewal registrations after the first year will require substantially less time because chains are expected to be able to affirm or edit the existing information in an online account in a way similar to other FDA firm registration systems. Therefore, FDA estimates that re-registration will take 0.5 hours for each registrant. Because some establishments that had previously been registered will choose not to do so at some point, and some new establishments will become registered, there will also be new registrations once the system is fully

operational. FDA estimates that initial registration under the fully operational system will take one hour.

The pool of potential registrants will be restaurants and similar retail food establishments that are not subject to the requirements of section 4205, including establishments located in jurisdictions with non-identical menu labeling laws that are not preempted. Of the pre-existing state and local laws, including regulations in New York City, Seattle, Philadelphia, Oregon, Massachusetts, Maine, Vermont, Nashville, Montgomery County (MD), California, and 5 New York State counties, the minimum number of establishments in a chain to which any of them currently apply is 15, and section 4205 applies to establishments that are part of chains with 20 or more establishments (*i.e.,* locations). Therefore, some restaurants and similar retail food establishments that are part of chains with between 15–19 establishments have an incentive to register. However, chains with fewer establishments, or chains in other jurisdictions, may choose to register because they are growing quickly, or because they are concerned about possible regulation. Therefore, for the purposes of this analysis, FDA counts chains with between 10 and 19 establishments, inclusive.

From the analysis in the detailed PRIA, approximately 27 percent of restaurant establishments are in jurisdictions with State or local menu labeling laws. NPD's Spring 2010 ReCount report shows a total of 20,000 establishments are part of chains with between 10 and 19 establishments (Ref. 50). If establishments were evenly distributed geographically, then 5,414 establishments from 373 restaurant chains might have an incentive to register with the FDA. The initial hourly burden for these restaurant chains is 746 hours (373 chains × 1 responses/chain/year × 2 hours/response).

The U.S. Census Bureau's County Business Patterns data shows that 30 percent of grocery stores and 10 percent of convenience stores are in jurisdictions that have relevant menu labeling regulations (Ref. 2). Taking 30 percent of an estimated 22,000 stores yields 6,600 stores run by approximately 455 chains. Taking 10 percent of an estimated 20,100 convenience stores in the 10 to 19 segment yields 2,011 stores run by approximately 139 chains. The hourly burden associated with registration for grocery and convenience store chains is 1,188 hours (594 chains × 1 responses/chain/year × 2 hours/response).

FDA estimates that the rate of growth for chains entering the 10–19 establishment segment will match the rate of growth out of this segment, so that the number of registrants will remain constant. County Business Patterns data shows an average growth rate in the number of establishments to be two percent per year over the eight years from 1999 to 2007 for restaurants (Ref. 28). Taking the restaurant growth rate for establishments of approximately 2 percent per year, new registrants will amount to approximately 19 per year, with the remaining 948 registrants only renewing their registration every other year. The recurring yearly burden for registration will be 1 hour per new registrant and 0.25 hours for continuing registrants. This yields a recurring hourly burden of 256 hours per year (19 new small chains × 1 hour/chain + 948 returning chains × .5 hours/chain × .5 response/year). These estimates are reported in Table 8.

The current total reporting burden for menu labeling registration as required by section 4205, now under review at OMB under No. 0910–0664, is 820 hours. The estimated reporting burden under the proposed rule is 2,190 hours, an increase of 1,370 hours. This increase is due to an increase in the estimated number of respondents.

The proposed rule caused several changes in our previous estimate of the reporting burdens. The estimated number of restaurants that would submit initial registrations was increased from 362 to 868, and the burden estimate increased from 724 hours to 1,934 hours, an increase of 1,210 hours. The estimated number of new registrations increased from 7 to 19 and the burden estimate from these new registrations also increased from 7 to 19 hours, an increase of 12 hours. The estimated number of restaurants that would submit re-registrations was increased from 362 to 948, and the burden estimate increased from 89 hours to 237 hours, an increase of 148 hours. Thus, the total increase in estimated reporting burden is 1,370 hours (1,210 hours + 12 hours + 148 hours = 1,370 hours).

FDA received comments on the initial proposed collection of information related to section 4205 in Docket No. FDA–2010–N–0567; Agency Information Collection Activities; Proposed Collection; Comment Request; 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. Several comments were submitted on the accuracy of the information collection burden analysis for convenience stores.

In compliance with the PRA, the agency has submitted the revised 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).

VIII. 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 (ACA) also included a Rule of Construction providing that "Nothing in the amendments made by [section 4205] shall be construed—(1) to preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)] (as added by subsection (b)) and is expressly preempted under subsection (a)(4) of such section; (2) to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or

component of the food; or (3) except as provided in section 403(q)(5)(H)(ix) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(H)(ix)] (as added by subsection (b)), to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of such Act [21 U.S.C. 343(q)(5)(H)(i)]." Public Law 111–148, § 4205(d), 124 Stat. 119, 576 (2010).

FDA interprets the provisions of Section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold in restaurants and similar retail food establishments ("R/SRFEs") 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) in R/SRFEs that are "part of a chain with 20 or more locations doing business under the same name * * * and offering for sale substantially the same menu items" ("chain R/SRFEs") or (2) in R/SRFEs that voluntarily elect to be subject to the requirements of 21 U.S.C. 343(q)(5)(H) by registering biannually under 21 U.S.C. 343(q)(5)(H)(ix).

Otherwise, for certain food that is not subject to the nutrition labeling requirements of 21 U.S.C. 343(q), States and localities may impose nutrition labeling requirements. First, States and localities can have nutrition labeling requirements for food sold in non-chain R/SRFEs that have not registered under 21 U.S.C. 343(q)(5)(H)(ix). This exception to preemption is clear from the language of 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 * * * unless such [R/SRFE] complies with the voluntary provision of nutrition information requirements under [21 U.S.C. 343(q)(5)(H)(ix)").

Second, States and localities can have certain nutrition labeling requirements for other food that is exempt from nutrition labeling under 21 U.S.C. 343(q)(5)(A)(i) or (ii) provided that such food is not required to have nutrition labeling under 21 U.S.C. 343(q)(5)(H). For example, certain food sold in schools, hospitals, and movie theaters would not, under the proposal, be required to have nutrition labeling under 21 U.S.C. 343(q)(1)–(4)(see 21 U.S.C. 343(q)(5)(A)(i) and (ii) and 21 CFR 101.9(j)(2) and (3)) or under 21 U.S.C. 343(q)(5)(H), as interpreted by FDA in the proposed rule, because these establishments would not be R/SRFEs. Under FDA's interpretation of the Rule of Construction in Section 4205(d)(1), nutrition labeling for food in these non-R/SRFEs 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. This interpretation of section 4205 of the ACA does not alter the ability of the States and localities to regulate nutrition labeling except with respect to the chain R/SRFEs and the non-chain R/SRFEs that voluntarily register. Therefore, under this interpretation, States and localities would be able to continue to require nutrition labeling for food sold by entities determined not to be R/SRFEs (*e.g.,* for movie theaters and transportation carriers).

An alternative to FDA's interpretation of the provisions of Section 4205 of the ACA related to preemption, which is not being proposed, could leave less room for States and localities to require nutrition labeling on food exempt from Federal nutrition labeling requirements under 21 U.S.C. 343(q)(5)(A)(i) or (ii). Under this alternative interpretation, State or local nutrition labeling requirements for food sold in establishments that are not "restaurants or similar retail food establishments," as defined in the proposed rule if made final, would be ineligible for the exception to preemption in 21 U.S.C. 343–1(a)(4), because that exception by its literal terms only covers nutrition labeling requirements for food offered for sale in covered R/SRFEs (*i.e.,* those not part of a chain of 20, *etc.*). Under this alternative interpretation, the Rule of Construction would simply clarify that the scope of 21 U.S.C. 343–1(a)(4) does not extend beyond the limits expressly identified in 343–1(a)(4). "Nutrition content disclosures of the type required under [21 U.S.C. 343(q)(5)(H)]" would mean, generally, requirements to disclose calories and/or other nutrition information (*e.g.,* fat, saturated fat, sodium, protein) in written form, on menus or elsewhere.

Under this alternative interpretation, States and localities could not have nutrition labeling requirements covering certain foods in non-R/SRFEs, such as schools and hospitals unless they successfully petitioned FDA. 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 certain food 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 restaurant and restaurant-type food in non-R/SRFEs, such as schools, hospitals, and movie theaters, 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 ACA related to preemption, as well as on the alternative interpretation, described in this Federalism section. FDA also requests comments on the use of the petition process in this 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. For example, could 21 U.S.C. 343–1(a)(4), as amended by Section 4205, be interpreted as not preempting State or local nutrition labeling requirements if 21 U.S.C. 343(q) and FDA's implementing regulations do not directly impose nutrition labeling requirements on food in an establishment?

In addition, the express preemption provisions of 21 U.S.C. 343–1(a)(4) do not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food. This is clear from both the literal language of 21 U.S.C. 343–1(a)(4) with respect to the scope of preemption and from the Rule of Construction at Section 4205(d)(2) of the ACA.

IX. 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.

X. 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.

XI. 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**.)

1. Flegal K.M., M.D. Carroll, C.L. Ogden, and L.R. Curtin. "Prevalence and Trends in Obesity Among U.S. Adults 1999–2008." *Journal of the American Medical Association,* 303:235–241, 2010.
2. CDC, Obesity and Overweight for Professionals Internet Webpage: "Health Consequences." Available at *http://www.cdc.gov/obesity/causes/health.html,* accessed on July 15, 2010.
3. Malnick S.D. and H. Knobler. "The Medical Complications of Obesity." *QJ Med,* 99:565–579, 2006.
4. Flegal K.M., B.I. Graubard, D.F. Williamson, and M.H. Gail. "Cause-Specific Excess Deaths Associated with Underweight, Overweight, and Obesity." *Journal of the American Medical Association,* 298:2028–2037, 2007.
5. Orpana H.M., J-M. Berthelot, M.S. Kaplan, D.H. Feeny, B. McFarland, and N.A. Ross. "BMI and Mortality: Results from a National Longitudinal Study of Canadian Adults." *Obesity,* 18(1):214–218, 2010.
6. CDC, Chronic Disease Overview Internet Webpage: "Chronic Diseases and Health Promotion." Available at *http://www.cdc.gov/chronicdisease/overview/index.htm,* accessed on February 18, 2011.
7. Ogden, C.L. and K.M. Flegal 2010. CDC. "Changes in Terminology for Childhood Obesity and Overweight." National Health Statistics Reports, Number 25, June 25, 2010. Available at *http://www.cdc.gov/nchs/data/nhsr/nhsr025.pdf,* accessed on July 10, 2010.
8. Ogden, C.L., M.D. Carroll, L.R. Curtin, M.M. Lamb, and K.M. Flegal, "Prevalence of High Body Mass Index in US Children and Adolescents, 2007–2008," *Journal of American Medical Association,* 303(3):242–249, 2010.
9. U.S. Department of Health and Human Services (DHHS) and USDA, "Dietary Guidelines for Americans, 2010," 7th ed., U.S. Government Printing Office, Washington DC, 2010. Available at *http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm*, accessed on March 25, 2011.
10. Lin, B-H., J. Guthrie and E. Frazão. "Nutrient Contribution of Food Away From Home." In Chapter 12 of *America's Eating Habits: Changes and Consequences,* Elizabeth Frazão (ed), USDA Agriculture Information Bulletin No. (AIB–750), pp. 213–242, May 1999.
11. FDA Reports & Research Internet Webpage: "Backgrounder—Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity Report," Keystone Center, June 2006.
12. USDA, Economic Research Service. "Table 10: Food away from home as a share of food expenditures." Food CPI and Expenditures: Food Expenditure Tables. Available at *http://www.ers.usda.gov/Briefing/CPIFoodAndExpenditures/Data/,* accessed on February 18, 2011.
13. Burton, S., E.H. Creyer, J. Kees, and K. Huggins, "Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants." *American Journal of Public Health,* 96(9):1669–1675, September 2006.
14. Burton, S. and E.H. Creyer. "What Consumers Don't Know *Can* Hurt Them: Consumer Evaluations And Disease Risk Perceptions Of Restaurant Menu Items." *Journal of Consumer Affairs,* 38:121–145, 2004.
15. Chonière, C.J. and A. Lando. Reported Results of the "2008 Health and Diet Survey." FDA, Consumer Research Internet Webpage: "2008 Health and Diet Survey." Available at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm193895.htm,* accessed on March 28, 2011.
16. Parker, L., A.C. Burns, and E. Sanchez (editors), IOM, National Research Council. *Local Government Actions to Prevent Childhood Obesity.* National Academies Press, Washington, DC, pp. 1–12, 2009.
17. Roberto C.A., M.B. Schwartz, and K.D. Brownell. "Rationale and Evidence for Menu-Labeling Legislation." *American Journal Preventive Medicine,* 37(6):546–551, 2009.
18. Dumanovsky T, C.Y. Huang, M.T. Bassett, and L.D. Silver. "Consumer Awareness of Fast-Food Calorie Information in New York City After Implementation of a Menu Labeling Regulation." *American Journal of Public Health,* 2010:e1–e6.
19. Kolodinsky, J., T. W. Reynolds, M. Cannella, D. Timmons, and D. Bromberg. "U.S. Consumer Demand for Restaurant Calorie Information: Targeting Demographic and Behavioral Segments in Labeling Initiatives." *American Journal of Health Promotion,* 24(1):11–14, 2009.
20. Fitch, R. C., L. J. Harnack, D. R. Neumark-Sztainer, M. T. Story, S. A. French, J. M. Oakes, and S. A. Rydell. "Providing Calorie Information on Fast-Food Restaurant Menu Boards: Consumer Views." *American Journal of Health Promotion,* 24(2):129–32, 2009.
21. Stein, K. "A National Approach to Restaurant Menu Labeling: The Patient Protection and Affordable Health Care Act, Section 4205." *American Journal of the American Dietetic Association,* 110:1280–1289, 2010.
22. City of Philadelphia, Bill No. 080167–A, November 19, 2008.
23. DHHS, FDA. "Guidance for Industry: A Food Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods, April 2008. Available at *http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/InformationforRestaurantsRetailEstablishments/default.htm,* accessed on March 29, 2011.
24. DHHS and USDA. *Dietary Guidelines for Americans, 2005,* 6th ed., U.S. Government Printing Office, Washington, DC, January 2005.
25. IOM, Food and Nutrition Board. *Dietary Reference Intakes for Energy, Carbohydrate, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids,* Summary, The National Academies Press, Washington, DC, pp. 1–19, 2005.
26. *Merriam Webster Collegiate Dictionary,* Tenth Edition, pp. 110 and 111, 1993.
27. Parsa, H.G., John T. Self, David Njite and Tiffany King. "Why Restaurants Fail." *Cornell Hotel and Restaurant Administration Quarterly,* 46(3):304–322, August 2005.
28. U.S. Census Bureau. *County Business Patterns, United States NAICS 722 2000–2008.* Available at *http://www.census.gov/econ/cbp/index.html,* accessed October 18, 2010.
29. Wootan, M. and M. Osborn. "Availability of Nutrition Information from Chain Restaurants in the United States." *American Journal of Preventive Medicine,* 30(3):266–268, March 2006.
30. Finkelstein, E.A. and K.L. Strombotne. "The Economics of Obesity." *American Journal of Clinical Nutrition,* 91(5):1520S–1524S, May 2010.
31. Philipson, T. and R. Posner. "Is the Obesity Epidemic a Public Health Problem? A Decade of Research on the Economics of Obesity." *NBER Working Paper Series,* 14010, May 2008.
32. Downs, J.S., G. Loewenstein, and J. Wisdom. "Strategies for Promoting Healthier Food Choices." *American Economic Review: Papers and Proceedings,* 99(2): 1–10, 2009.
33. O'Donoghue, T. and M. Rabin. "The Economics of Immediate Gratification." *Journal of Behavioral Decision Making,* 13(2): 233–250, 2000.
34. O'Donoghue, T. and M. Rabin. "Doing it Now or Later." *American Economic Review,* 89(1): 103–124, 1999.

35. Ogden, C.L. and M.D. Carroll. "Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, Trends 1976–1980 Through 2007–2008." National Center for Health Statistics, June 2010. Available at *http://www.cdc.gov/NCHS/data/hestat/obesity_adult_07_08/obesity_adult_07_08.pdf.,* accessed on October 17, 2010.
36. Sullivan, P.W., V. Ghusheyan, and R.H. Ben-Joseph. "The Effect of Obesity and Cardiometabolic Risk Factor on Expenditures and Productivity in the US." *Obesity,* 16: 2155–2162, 2008.
37. Ali, M.M., A. Amialchuk, and F. Renna, "Social Network and Weight Misperception among Adolescents." *Southern Economic Journal,* Forthcoming, 2010a.
38. Cawley, J., K. Joyner, and J. Sobal. "Size Matters: The Influence of Adolescent's Weight and Height on Dating and Sex." *Rationality and Society,* 18(1): 67–94, 2006.
39. Ali, M.M., H. Fang, H. and J. Rizzo (2010b). "Body Weight, Self-Perception and Mental Health among Adolescents." *Journal of Mental Health Policy and Economics,* 13(2): 53–63, 2010b.
40. Puhl, R., and K.D. Brownell. "Bias, Discrimination, and Obesity." *Obesity Research,* 9(12): 788–805, 2001.
41. Cawley, J. "The Impact of Obesity on Wages." *Journal of Human Resources,* 39(2): 451–474, 2004.
42. Finkelstein, E.A., J.G. Trogdon, J.W. Cohen, and W. Dietz. "Annual Medical Spending Attributable to Obesity: Payer- and Service-Specific Estimates." *Health Affairs,* 28(5):w822–w831, 2009.
43. Wang, Y., M.A. Beydoun, L. Liang, B. Cabellero, and S.K. Kumanyika. "Will all Americans become Overweight or Obese? Estimating the Progression and Cost of the US Obesity Epidemic." *Obesity,* 16(10):2323–2330, 2008.
44. USDA, ERS "Table 1: Food and alcoholic beverages: Total expenditures." Food CPI and Expenditures: Food Expenditure Tables. *http://www.ers.usda.gov/Briefing/CPIFoodAndExpenditures/Data/* , accessed on January 6, 2011.
45. McCrory, M.A., P.J. Fuss, E. Saltzman, and S.B. Roberts. "Dietary Determinants of Energy Intake and Weight Regulation in Healthy Adults." *Journal of Nutrition,* 130:2765–95, 2000.
46. Mancino, L., J. Todd, and B.H. Lin. "Separating what We Eat from where: Measuring the Effect of Food Away from Home on Diet." Food Policy, 34:557–562, 2009.
47. Robert Wood Johnson Foundation. "Menu Labeling: Does Providing Nutrition Information at the Point of Purchase Affect Consumer Behavior?" *Healthy Eating Research,* 2009.
48. Smith, T.A., B.-H. Lin. and J.-Y. Lee. "Taxing Caloric Sweetened Beverages: Potential Effects on Beverage Consumption, Calorie Intake, and Obesity." *Economic Research Report,* ERR–100, July 2010.
49. Food and Drug Administration. 2003. "Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." **Federal Register** 68(197):5392–5403.
50. NPD Group. "FDA Report," *ReCount Restaurant Census.* Spring 2010.

List of Subjects

21 CFR Part 11

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

21 CFR Part 101

Food Labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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 (g) to read as follows:

§ 11.1 Scope.

* * * * *

(g) This part does not apply to electronic signatures obtained under § 101.11(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 101.9 is amended by revising paragraph (j)(1)(i) and paragraphs (j)(2) introductory text and (j)(3) introductory text to read as follows:

* * * * *

(j) * * *

(1)(i) Food offered for sale by a person who makes direct sales to consumers (*e.g.,* a retailer) who has annual gross sales made or business done in sales to consumers that is not more that $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, provided, that the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section, § 101.10, or § 101.11, as applicable.

* * * * *

(2) Except as provided in § 101.11, food products that are:

* * * * *

(3) Except as provided in § 101.11, food products that are:

* * * * *

5. Section 101.10 is revised to read as follows:

§ 101.10 Nutrition labeling of restaurant foods whose labels or labeling bear nutrient content claims or health claims.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (*e.g.,* "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition information as described in § 101.9. For standard menu items that are offered for sale in covered establishments (as defined in § 101.11(a)), the information in the written nutrition information required by § 101.11(b)(2)(ii)(A) will serve to meet the requirements of this section. Nutrient levels may be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

6. Section 101.11 is added to subpart A to read as follows:

§ 101.11 Nutrition labeling of standard menu items in covered establishments.

(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 purposes of this section:

Authorized official of a restaurant or similar retail food establishment means the owner, operator, agent in charge, or other person authorized by the owner, operator, or agent in charge to register the restaurant or similar retail food establishment, which is not otherwise subject to section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act, with FDA for the purposes of paragraph (d) of this section.

Combination meal means a standard menu item that consists of more than one food item, for example a meal that includes a sandwich, a side dish, and a drink. A combination meal may be represented on the menu or menu board

in narrative form, numerically, or pictorially. Some combination meals may include a variable menu item (or be a variable menu item as defined in this paragraph where the components may vary. For example, the side dish may vary among several options (*e.g.,* fries, salad, or onion rings) or the drinks may vary (*e.g.,* soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal.

Covered establishment means a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.,* individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is registered to be covered under section 403(q)(5)(H)(ix) of the Federal Food, Drug, and Cosmetic Act.

Custom order means a food order that is prepared in a specific manner based on an individual customer's request, which requires the restaurant or similar retail food establishment to deviate from its usual preparation of a menu item, *e.g.,* a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich.

Daily special means a menu item that is prepared and offered for sale on a particular day, that is not routinely listed on a menu or offered by the covered establishment, and that is promoted by the covered establishment as a special menu item for that particular day.

Doing business under the same name means sharing the same name. The term "same name" includes names that are either exactly the same, or are slight variations of each other, for example, due to the region, location or size (*e.g.,* "New York Ave. Burgers" and "Pennsylvania Ave. Burgers" or "ABC" and "ABC Express").

Food on display means restaurant or restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.

Food that is part of a customary market test means food that is marketed in a covered establishment for fewer than 90 consecutive days in order to test consumer acceptance of the product.

Gross floor area means all space, wall to wall, including areas under built-in counters, cooking equipment, seating, and similar furniture.

Menu or *menu board* means the primary writing of the restaurant or similar retail food establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch and dinner menus; dessert menus; beverage menus, children's menus, other specialty menus, electronic menus, and menus on the Internet. The menus may be in different forms, *e.g.,* booklets, pamphlets, or single sheets of paper. Menu boards include those inside a restaurant or similar retail food establishment as well as drive-through menu boards at restaurants or similar retail food establishments.

Offering for sale substantially the same menu items means offering for sale menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies, (*e.g.* "Bay View Crab Cake" and "Ocean View Crab Cake"). "Menu items" in this definition refers to food items that are listed on a menu or menu board or that are offered as self-service food or food on display. Restaurants and similar retail food establishments that are part of a chain can still be offering for sale substantially the same menu items if the availability of some menu items varies within the chain.

Restaurant or similar retail food establishment means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment. The sale of food is the retail establishment's primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of food.

Restaurant food means food that is served in restaurants or other establishments in which food is served for immediate human consumption, *i.e.,* to be consumed either on the premises where that the food is purchased or while walking away; or which is sold for sale or use in such establishments.

Restaurant-type food means food of the type described in the definition of "restaurant food" that is ready food human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment.

Self-service food means restaurant or restaurant-type food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility and that is served by the customers themselves. Self-service food also includes self-service beverages.

Standard menu item means a restaurant or restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display.

Temporary menu item means a food that appears on a menu or menu board for less than a total of 60 days per calendar year. The 60 days includes the total of consecutive and non-consecutive days the item appears on the menu.

Variable menu item means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.

(b) Requirements for nutrition labeling for food sold in covered establishments.—(1) *Applicability.* (i) The labeling requirements in this paragraph (b) apply to standard menu items offered for sale in covered establishments.

(ii) The labeling requirements in this paragraph (b) do not apply to alcohol beverages; items such as condiments that are placed on the table for general use; daily specials; temporary menu items; custom orders; and food that is part of a customary market test.

(2) *Nutrition information.* (i) The following must be provided on menus and menu boards:

(A) The number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale must be declared in the following manner:

(*1*) The number of calories must be listed adjacent to the name or the price of the associated standard menu item, in a type size no smaller than the name or the price of the associated standard menu item, whichever is smaller, in the same color, or a color at least as conspicuous as the name of the associated standard menu item, and with the same contrasting background as the name of the associated standard menu item.

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

(*3*) The term "Calories" or "Cal" must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item. If the term "Calories" or "Cal" appears as a heading above a column of calorie declarations, the term must be in a type size no smaller than the smallest type size of the name or price of any menu item on that menu or

menu board in the same color or a color at least as conspicuous as that name or price and in the same contrasting background as that name or price. If the term "Calories" or "Cal" appears adjacent to the number of calories for the standard menu item, the term "Calories" or "Cal" must appear in the same type size and in the same color and contrasting background as the number of calories.

(*4*) For variable menu items, the calories must be declared as a range, in the format "xx–yy" where "xx" is the caloric content of the lowest calorie variety, flavor, or combination, and "yy" is the caloric content of the highest calorie variety, flavor, or combination. If the variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, e.g., all-you-can-eat buffet, then the menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, e.g., "See buffet for calorie declarations." This statement must appear in a type size no smaller than the name or price of the variable menu item, whichever is smaller, and in the same color or a color at least as conspicuous as that name or price, with the same contrasting background as that name or price.

(B) The following statement designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards: "A 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual calorie needs may vary."

(*1*) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as the calorie declarations and with the same contrasting background as the calorie declarations.

(*2*) For menus, this statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement regarding the availability of the written nutrition information required in paragraph (b)(2)(i)(C) of this section, this statement must appear directly above the statement required in paragraph (b)(2)(i)(C).

(*3*) For menu boards, this statement must appear on the bottom of the menu board, immediately above the statement required in paragraph (b)(2)(i)(C) of this section.

(C) The following statement regarding the availability of the additional written nutrition information required in paragraph (b)(3)(i) of this section must be on all forms of the menu or menu board: "Additional nutrition information available upon request."

(*1*) This statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the smallest calorie declaration appearing on the same menu or menu board and in the same color or in a color at least as conspicuous as the caloric declarations, and with the same contrasting background as the caloric declarations.

(*2*) For menus, the statement must appear on the bottom of the first page with menu items. For menus with more than two pages, the statement must appear:

(*i*) At the bottom of every page with menu items; or

(*ii*) At the bottom of only the first page with menu items, as long as a symbol (*e.g.,* asterisk) clearly referring to the required statement appearing on the first page of the menu follows the term "Calories" or "Cal", where the term first appears on each page after the page with the statement.

(3) For menu boards, the statement must appear on the bottom of the menu board immediately above or below the succinct statement required in paragraph (b)(2)(i)(B) of this section.

(ii) The following nutrition information for a standard menu item must be available in written form on the premises of the restaurant or similar retail food establishment and provided to the customer upon request. This nutrition information must be presented in the order listed and using the measurements listed, except as provided in paragraph (b)(2)(ii)(B) of this section. Rounding of these nutrients must be in compliance with § 101.9(c). The information must be presented in a clear and conspicuous manner:

(A)(*1*) Total number of calories derived from any source (cal),
(*2*) Total number of calories derived from the total fat (fat cal),
(*3*) Total fat (g),
(*4*) Saturated fat (g),
(*5*) *Trans* fat (g),
(*6*) Cholesterol (mg),
(*7*) Sodium (mg),
(*8*) Total carbohydrate (g),
(*9*) Dietary fiber (g),
(*10*) Sugars (g),
(*11*) Protein (g).

(B) If a standard menu item contains insignificant amounts of all the nutrients required to be disclosed in paragraph (b)(2)(ii)(A) of this section, the establishment is not required to include nutrition information regarding the standard menu item in the written form. However, if the covered establishment makes a nutrient content claim or health claim, the establishment is required to provide nutrition information on the nutrient that is the subject of the claim in accordance with § 101.10. For standard menu items that contain insignificant amounts of six or more of the required nutrients, the declaration of nutrition information required by paragraph (b)(2)(ii)(A) of this section may be presented in a simplified format.

(*1*) An insignificant amount is defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, it must be an amount that allows a declaration of "less than one gram."

(*2*) The simplified format must include information on the following nutrients: Total carbohydrates, total fat, protein, and sodium, calories from fat, and any other nutrients identified in paragraph (b)(2)(ii)(A) of this section that are present in more than insignificant amounts. These nutrients may be in a column, list, or table. If the simplified format is used, the statement "Not a significant source of ____" (with the blank filled in with the names of the nutrients required to be declared in the written nutrient information and calories from fat that are present in insignificant amounts) must be included at the bottom of the list of nutrients.

(C) For variable menu items, the nutrition information listed in paragraph (b)(2)(ii)(A) of this section must be declared as follows for each size offered for sale:

(*1*) The nutrition information required in paragraph (b)(2)(ii)(A) of this section must be declared for the basic preparation of the item and, separately, for each topping, flavor, or variable component.

(*2*) If the calories and other nutrients are the same for different flavors, varieties, and substitutable components of the combination meal, each variety, flavor and substitutable component of the combination meal is not required to be listed separately. All items that have the same nutrient levels could be listed together with the nutrient levels listed only once.

(D) The written nutrition information required in paragraph (b)(2)(ii)(A) of this section may be provided on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device such as a computer, or in a menu, or in any other form that similarly permits the written declaration of the required

nutrient content information for all standard menu items. If the written information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer/consumer to review the written nutrition information upon request.

(iii) The following must be provided for food that is self service or on display.

(A) When a self-service food or food on display is already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, the calories per item or per serving must be provided on the sign. When a self-service food or food on display is not already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, the covered establishment must place a sign adjacent to each food with the number of calories per serving or per item in a clear and conspicuous manner.

(*1*) For purposes of § 101.10(b)(2)(ii)(A), "per item" means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, a muffin, or a multi-serving food such as a whole cake.

(*2*) For purposes of § 101.10(b)(2)(ii)(A), "per serving" means:

(i) Per each common household measure, *e.g.,* cup, scoop, tablespoon, offered for sale as dispensed using a serving instrument such as a scoop, ladle, cup, or measuring spoon; or

(ii) Per unit of weight offered for sale, *e.g.,* per half pound or pound.

(*3*) The calories must be declared in the following manner:

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

(ii) If the food is not already accompanied by a sign with the food's name, price or both, the calorie declaration, accompanied by the term "Calories" or "Cal", must appear on a sign adjacent to the standard menu item in a clear and conspicuous manner if the food is not already accompanied by a sign with the food's name, price or both. If the food is already accompanied by a sign with the food's name, price, or both, the calorie declaration and the term "Calories" or "Cal" must appear on that sign in a type size no smaller than the name or price of the menu item, whichever is smaller, in the same color or a color that is at least as conspicuous as that name or price using the same contrasting background.

(B) For food on display identified by a menu adjacent to the food itself, the statement that puts the calorie information in the context of a recommended total daily caloric intake as required by paragraph (b)(2)(i)(B) of this section and the statement regarding the availability of the additional written nutrition information required by paragraph (b)(2)(i)(C) of this section. These two statements may appear either on the sign adjacent to the standard menu item or on a separate, larger sign, in close proximity to the food on display, that can be easily read as the consumer is making order selections. This requirement is satisfied if the two statements appear on a large menu board that can be easily read as the consumer is viewing the food on display.

(C) The nutrition information in written form required by paragraph(b)(2)(ii) of this section, except for packaged food that bears nutrition labeling information required by § 101.9 if the packaged food, including its label, can be examined by a consumer before purchasing the food.

(c) *Determination of nutrient content.* (1) A restaurant or similar retail food establishment must have a reasonable basis for its nutrient disclosures. Nutrient levels may be determined by nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in § 101.10.

(2) Two classes of nutrients are defined for purposes of compliance:

(i) *Class I.* Added nutrients in standard menu items; and

(ii) *Class II.* Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a standard menu item, the total amount of such nutrient in the standard menu item is subject to class II requirements unless the same nutrient is also added.

(3) A standard menu item with a nutrient declaration of protein, total carbohydrate, or dietary fiber, shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act unless it meets the following requirements:

(i) *Class I protein or dietary fiber.* The nutrient content of the appropriate composite is at least equal to the value for that nutrient declared in the nutrition information in written form.

(ii) *Class II protein, total carbohydrate, or dietary fiber.* The nutrient content of the appropriate composite is at least equal to 80 percent of the value for that nutrient declared in the nutrition information in written form. Provided, that no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(4) A standard menu item with a nutrient declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act if the nutrient content of the appropriate composite is greater than 20 percent in excess of the value for that nutrient declared on the menu, menu board or in the nutrition information in written form for calories or in the nutrition information in written form for all other nutrients. Provided, that no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) Reasonable excesses of protein, total carbohydrate, dietary fiber, over the declared amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under declared amounts are acceptable within current good manufacturing practice.

(6) A restaurant or similar retail food establishment must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient levels. This information must include the following:

(i) For nutrient databases:

(A) The identity of the database used.

(B) The recipe or formula used as a basis for the nutrient declarations. The recipe posted on the database must be identical to that used by the restaurant or similar retail food establishment to prepare the menu item.

(C) For the specified amounts of each ingredient identified in the recipe, a detailed listing (*e.g.,* printout) of the amount of each nutrient that that ingredient contributes to the menu item.

(D) If this information is not available because the nutrition information was derived from a computer program, which is designed to provide only a final list of nutrient values for the recipe, a certificate of validation attesting to the accuracy of the computer program.

(E) A detailed listing (*e.g.,* printout) of the nutrient values determined for each menu item.

(F) If this information is not derived through the aid of a computer program

which provides a final nutrient analysis for the menu item, worksheets used to determine the nutrient values for each of these menu items.

(G) Any other information pertinent to the final nutrient levels of the menu item *(e.g.,* information about what might cause slight variations in the nutrient profile such as moisture variations).

(H) A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.

(ii) For published cookbooks that contain nutritional information for recipes in the cookbook:

(A) The name, author and publisher of the cookbook used.

(B) If available, information provided by the cookbook about how the nutrition information for the recipes was obtained.

(C) A copy of the recipe used to prepare the menu item and a copy of the nutrition information for that menu item as provided by the cookbook.

(D) A statement signed by a responsible individual employed by the covered establishment certifying that the recipe used to prepare the menu item by the restaurant or similar retail food establishment is the same recipe provided in the cookbook. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the menu item but no changes may be made to the proportion of ingredients used.)

(iii) For analyses:

(A) A copy of the recipe for the menu item used for the nutrient analysis.

(B) The identity of the laboratory performing the analysis.

(C) Copies of analytical worksheets used to determine and verify nutrition information.

(D) A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and an additional signed statement certifying that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.

(iv) For nutrition information provided by other reasonable means:

(A) A detailed description of the method used to determine the nutrition information.

(B) Documentation of the validity of that method.

(C) A recipe or formula used as a basis for the nutrient determination. The recipe used in determining these nutrient values must be the same recipe used by the restaurant and similar retail food establishment to prepare the item.

(D) Any data derived in determining the nutrient values for the menu item.

(E) A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.

(d) *Voluntary registration to be subject to the menu labeling requirements.* (1) *Applicability.* A restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items may voluntarily register to be subject to the requirements established in this section. Restaurants and similar retail food establishments that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.

(2) *Who may register?* The authorized official of a restaurant or similar retail food establishment as defined in paragraph (a) of this section, which is not otherwise subject to paragraph (b) of this section, may register with FDA.

(3) *What information is required?* Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information on Form FDA 3757 (7/10).

(i) The contact information (including name, address, phone number, and e-mail address for the authorized official);

(ii) The contact information (including name, address, phone number, and e-mail address) of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;

(iii) All trade names the restaurant or similar retail food establishment uses;

(iv) Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and

(v) Certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug and Cosmetic Act and this section.

(vi) Information should be submitted by e-mail by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by e-mail to *menulawregistration@fda.hhs*.

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

(4) *How to register?* Authorized officials of restaurants and similar retail food establishments who elect to be subject to requirements in section 403(q)(5)(H) of the Federal Food, Drug and Cosmetic Act can register by visiting *http://www.fda.gov/menulabeling*. FDA has created a form that contains fields requesting the information in § 101.11(c)(3) and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

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

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

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

Dated: March 28, 2011.

Margaret A. Hamburg,

Commissioner of Food and Drugs.

Kathleen Sebelius,

Secretary of Health and Human Services.

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