

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

Contains Nonbinding Recommendations
August 2010

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
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Guidance for Industry¹

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 represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you wish to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) is issuing these Questions and Answers as a guide for industry and State and local governments affected by the enactment of section 4205 of the Patient Protection and Affordable Care Act of 2010 ("Affordable Care Act"), which was signed into law on March 23, 2010. Section 4205 establishes requirements for nutrition labeling of standard menu items for chain restaurants, similar retail food establishments, and chain vending machine operators.

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

FDA is issuing this guidance to: (1) ensure that industry and State and local governments understand the immediate effects of the law; and (2) clarify section 4205's effect on State and local menu and vending machine labeling laws. Additional Questions and Answers regarding the implementation of section 4205 are given in the draft guidance entitled "Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordability Care Act of 2010" and in the Federal Register notice entitled "Voluntary Registration by Authorized Officials of Non-Covered Retail Food Establishments and Vending Machine Operators Electing To Be Subject to the Menu and Vending Machine Labeling Requirements Established by the Patient Protection and Affordable Care Act of 2010," 75 *Federal Register* 43182 (July 23, 2010).

II. Questions and Answers

A. General

1. What is the effect of section 4205 of the Affordable Care Act?

Section 4205 of the Affordable Care Act amends section 403(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which governs nutrition labeling requirements, and section 403A of the FFDCA, which governs federal preemption of State and local food labeling requirements.

2. What are the basic requirements of section 4205 of the Affordable Care Act for foods that are standard menu items sold in restaurants or similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items (hereinafter "chain retail food establishments")?

The following information must be provided for standard menu items that are sold in chain retail food establishments:

- The number of calories in each standard menu item on a menu or menu board (the calorie disclosure must be "clearly associated with" and "adjacent to" the name of the standard menu item),
- A statement on the menu or menu board that puts the calorie information in the context of a recommended total daily caloric intake,
- Additional nutrition information for standard menu items in written form ("written nutrition information"), 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) adjacent to self-service food and food on display. These foods include 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.

3. What are the basic requirements of section 4205 of the Affordable Care Act for food sold from vending machines operated by persons who own or operate 20 or more vending machines (hereinafter “chain vending machine operators”)?

For food sold from a vending machine by a chain vending machine operator, where the purchaser cannot examine the Nutrition Facts Panel of the food before buying, or where the nutrition information is not otherwise visible at the point of purchase, the operator must put a sign close to each article of food or selection button disclosing the amount of calories in a clear and conspicuous manner.

B. Effective Date and Compliance

4. When does section 4205 of the Affordable Care Act go into effect?

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.

5. Which menu and vending machine labeling provisions of section 4205 became requirements immediately upon enactment of the law?

For chain retail food establishments:

- Disclosing the number of calories in each standard menu item 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.

For chain vending machine operators:

- Providing a sign in close proximity to each article of food (or the selection button) that discloses the number of calories contained in the article, unless a prospective purchaser is able to examine the Nutrition Facts Panel before purchasing the article, or visible nutrition information is otherwise provided at the point of purchase.

6. Which provisions of section 4205 cannot be required until the regulations are final? The law specifies that FDA must establish:

- Requirements for a statement on the menu or menu board that puts the calorie information in the context of a total daily caloric intake.
- 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.

The law also allows FDA to issue regulations requiring chain retail food establishments to include additional nutrients, which were not initially required by the statute, in the written nutrition information, if FDA determines that such nutrients should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices.

C. Effect of Section 4205 on State and Local Nutrition Labeling Requirements for Restaurants, Similar Retail Food Establishments, and Vending Machine Operators

7. What if my State or local government already has a law in effect on menu labeling?

Under section 4205, State and local governments cannot directly or indirectly impose any nutrition labeling requirements on chain retail food establishments that are not “identical to” requirements imposed by section 4205. In other words, State and local governments cannot directly or indirectly impose any nutrition labeling requirements that are different from, or not imposed by (or contained in) section 4205, or the related implementing regulations. State and local laws that are "identical to" the federal requirements are not preempted by section 4205.

Nutrition labeling for restaurants or similar retail food establishments that are not “chain retail food establishments,” as the term is used in this guidance, will continue to be governed by State and local regulation, if applicable, unless those establishments elect to participate exclusively in the federal regulatory program (as explained in the answer to Question 9, below).

8. What effect does section 4205 have on any State and local food labeling requirements other than nutrition labeling, such as consumer advisories and allergen labeling?

None. Any State or local labeling requirements that do not involve nutrition labeling, such as any warning statements, consumer advisories, or allergen labeling concerning the safety of the food or component of the food are not affected by section 4205.

9. What if the law in effect in my State or locality regulates restaurants or similar retail food establishments with fewer than 20 locations, or vending machines operated by a person who owns or operates fewer than 20 vending machines?

Restaurants and similar retail establishments that are not chain retail food establishments as that term is used in this guidance could still be regulated under State and local nutrition labeling laws. However, these establishments will be able to elect to participate in the federal program by voluntarily registering every other year with FDA. Those restaurants and similar retail establishments that elect to participate in the federal program will not be subject to State or local nutrition labeling requirements unless these State or local requirements are identical to federal requirements. As required by the statute, FDA published a notice in the *Federal Register* specifying the terms of the voluntary registration process. See 75 *Federal Register* 43182 (July 23, 2010).

With respect to vending machines no State or locality may have a requirement that is not identical to the federal requirements. This is true regardless of how many vending machines the operator owns or operates.

10. Can States and localities that had their own nutrition labeling requirements prior to the enactment of the Affordable Care Act apply to be exempt from preemption?

Yes. FDA's regulations, at 21 C.F.R. 100.1, allow any State or locality to petition FDA for an exemption from preemption, and they describe the procedure for submitting a petition.

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

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1. <http://www.regulations.gov/>

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