

Report to Congress

**Quarterly Report on Progress Toward Promulgating Final Regulations
for the Menu and Vending Machine Labeling Provisions of the Patient
Protection and Affordable Care Act of 2010**

Submitted pursuant to Section 4205 P. L. 111-148

U.S. Department of Health and Human Services

Food and Drug Administration

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Introduction

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (Public Law 111-148; hereinafter “the Affordable Care Act”). Section 4205 of the Affordable Care Act (hereinafter “section 4205”) amends section 403(q) of the Federal Food, Drug, and Cosmetic Act to provide requirements for nutrition labeling for foods offered for sale in certain restaurants and similar retail food establishments, and for food items sold from certain vending machines. Section 4205 requires that the Secretary of Health and Human Services (“the Secretary”) promulgate regulations to implement certain provisions of section 4205. Section 4205 also requires the Secretary to submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a quarterly report that describes the Secretary’s progress toward promulgating final regulations to implement section 4205.

The following report, prepared by the Food and Drug Administration (FDA), Department of Health and Human Services, is the second quarterly report in response to this mandate.

Background

Section 4205 requires chain restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items to disclose specific nutrition information on certain food items offered for sale. The provision also requires vending machine operators that own or operate 20 or more vending machines to disclose the number of calories contained in certain food items sold from vending machines.

Section 4205 requires that the Secretary promulgate regulations to carry out certain provisions of section 4205, including:

- Specifying the format and manner of the nutrient disclosure requirements of section 4205, which requires on the menu or menu board, “posted prominently,” “a succinct statement concerning suggested daily caloric intake” that must be “designed to enable the public to understand, in the context of a total daily diet, the significance” of the required information.
- Establishing standards, by regulation, for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but that are listed as a single menu item (e.g., soft drinks, ice cream, pizza, doughnuts, and children’s combination meals), through means including ranges, averages, or other methods.
- Considering standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines.

FDA Actions

First Quarter – March 23, 2010 through October 15, 2010

FDA's progress towards promulgating final regulations pursuant to section 4205 includes the following activities:

- (1) FDA published on July 7, 2010, a *Federal Register* notice (75 FR 39026) opening a docket to solicit comments, data, and other information helpful to the implementation of section 4205. The information submitted to the docket will be considered by FDA in the implementation of the new legislative requirements and in the development of the proposed rule.
- (2) FDA published on July 23, 2010, a *Federal Register* notice (75 FR 43182) to specify the terms and conditions for implementation of voluntary registration, pending promulgation of regulations.
- (3) FDA issued on August 25, 2010, a final guidance, to clarify the effect of section 4205 on state and local menu and vending machine labeling laws, and to ensure that industry and state and local governments understand the immediate effects of the law. FDA published on August 25, 2010, a *Federal Register* notice (75 FR 52427) announcing the availability of this final guidance.
- (4) FDA issued on August 25, 2010, draft guidance to industry to provide further clarification of the self-executing requirements of section 4205 for standard menu items that are sold in certain restaurants and similar retail food establishments. FDA published on August 25, 2010, a *Federal Register* notice (75 FR 52426) announcing the availability of this draft guidance. Comments submitted to the docket concerning this draft guidance will be evaluated in the development of the proposed rule.

Second Quarter – October 15, 2010 through January 15, 2011

- (1) FDA received the following number of responses to the notices and guidances that issued: (1) approximately 875 to the docket notice; (2) seven to the registration notice; (3) three to the preemption guidance and (4) approximately 80 to the draft implementation guidance. Each response contained one or more comments.
- (2) FDA has reviewed all of the comments and, as directed by section 4205, intends to issue proposed rules to require nutrition labeling for foods sold in certain restaurants and similar retail food establishments, and in vending machines.
- (3) FDA withdrew on January 21, 2011, the draft guidance to industry that provided clarification of the self-executing requirements on section 4205 for standard menu items that are sold in certain restaurants and similar retail food establishments

(issued on August 25, 2010). FDA instead will focus its efforts on completion of the notice and comment rulemaking process for section 4205 before initiating enforcement activities.

FDA intends to publish its proposals by the week of March 23, 2011, with a minimum 60-day comment period. After the comment period, FDA will review the comments and develop the final rules.