

Report to Congress

**Quarterly Report on Progress toward Promulgating Final Regulations
for Nutrition Labeling of Food Offered for Sale in Restaurants and
Vending Machines as Directed by 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 (FFDCA) to provide requirements for nutrition labeling for foods offered for sale in certain restaurants and similar retail food establishments, and for food articles sold from certain vending machines.

Section 4205 requires that the Secretary of Health and Human Services (“the Secretary”) promulgate rulemaking to implement certain provisions of 4205. Sections 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 first quarterly report in response to this request.

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 nutrient content for certain food articles 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.
- Establish 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, 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

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

- (1) FDA published a notice in the *Federal Register* on July 7, 2010 (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 a final guidance on August 25, 2010 to clarify section 4205's effect on state and local menu and vending machine labeling laws, and to ensure that industry and state and local government understand the immediate effects of the law. FDA published a notice in the *Federal Register* announcing the availability of this guidance (75 FR 52427).
- (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 covered restaurants and similar retail food establishments. . FDA published a notice in the *Federal Register* announcing the availability of this draft guidance (75 FR 52426). Comments submitted to the docket concerning this draft guidance will be evaluated in the development of the proposed rule.

FDA intends to publish the proposed rule by March 23, 2011 with a 90 day comment period. After the comment period, FDA will review the comments and develop the final rule.