

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in section 4205 of the Affordable Care Act have been approved under OMB Control No. 0910–0665 (menu labeling third party disclosures and recordkeeping) and OMB Control No. 0910–0664 (voluntary registration program).

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the draft guidance. It is only necessary to send one set of comments. It is no longer necessary to send two sets 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/FoodGuidances>.

## V. References

FDA has placed the following references on display in the Division of Dockets Management (see **ADDRESSES**), and they 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. Howlett, E.A., S. Burton, K. Bates, and K. Huggins, "Coming to a Restaurant Near You? Potential Consumer Responses to Nutrition Information Disclosure on Menus," *Journal of Consumer Research* 36(3): 494–503, 2009. Available at <http://www.journals.uchicago.edu/doi/pdf/10.1086/598799>.

2. Tandon, P.S., J. Wright, C. Zhou, C.B. Rogers, D.A. Christakis, "Nutrition Menu Labeling May Lead to Lower-Calorie Restaurant Meal Choices for Children," *Pediatrics* 125(2): 244–248, 2010.

3. Center for Science in the Public Interest, "Comparison of Menu Labeling Policies," Available at [http://cspinet.org/new/pdf/comparison\\_of\\_ml\\_policies\\_6-9.pdf](http://cspinet.org/new/pdf/comparison_of_ml_policies_6-9.pdf).

Dated: August 18, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–D–0354]

#### **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; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a 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." Section 4205 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) establishes requirements for nutrition labeling of standard menu items for chain retail food establishments and chain vending machine operators. FDA is issuing this guidance 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.

**DATES:** Submit either electronic or written comments on the guidance at any time.

**ADDRESSES:** Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Felicia B. Billingslea, Center for Food

Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2373.

#### **SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a 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." FDA is issuing this guidance in a Questions and Answers format as an informational guide to industry and State and local governments affected by the enactment of section 4205 of the Affordable Care Act (Public Law 111–148), which became effective on March 23, 2010. Section 4205 of the Affordable Care Act requires 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 ("chain retail food establishments") to disclose specific nutrition information about certain food items offered for sale. Section 4205 also requires vending machines operated by persons who own or operate 20 or more vending machines ("chain vending machine operators") to disclose calorie information for certain food articles sold in vending machines. FDA is issuing this guidance 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 is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the mandates in section 4205 of the Affordable Care Act, which was effective on March 23, 2010. The guidance represents the agency's current thinking on section 4205's effective date, and effect on State and local menu and vending machine labeling laws. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in the Federal Food, Drug, and Cosmetic Act and established by section 4205 of the Affordable Care Act. These collections of information 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 collections of information in section 4205 of the Affordable Care Act

have been approved under OMB control no. 0910–0665.

## III. Comments

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Dated: August 18, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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