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Part III

Department of Health and Human Services

Food and Drug Administration

**Guidance for Industry; Section 4205 of
the Patient Protection and Affordable
Care Act of 2010; Availability; Notices**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0370]

Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010." Section 4205 of the Patient Protection and Affordable Care Act (Affordable Care Act) requires certain chain restaurants and similar retail food establishments with 20 or more locations (hereinafter "chain retail food establishments") to provide calorie information, and other nutrition information, for standard menu items, food on display, and self-service food. Section 4205 also requires vending machine operators who own or operate 20 or more machines (hereinafter "chain vending machine operators") to disclose calories for articles of food. Restaurants and similar retail food establishments with fewer than 20 locations and vending machine operators with fewer than 20 machines may elect to be subject to these Federal requirements by registering every other year with the FDA.

Section 4205 of the Affordable Care Act became effective on the date the law was signed, March 23, 2010; however, some provisions specifically require FDA to issue rules before FDA implements them. Other provisions became requirements immediately upon enactment of the law. The draft guidance, when finalized, will explain how those provisions should be implemented.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by October 12, 2010.

ADDRESSES: Submit electronic comments on the draft guidance to

<http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 draft 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 draft guidance.

FOR FURTHER INFORMATION CONTACT:

Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "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 availability of nutrition information through menu and vending machine labeling would provide Americans with additional information to make informed choices about their diets. Studies show that providing nutrition information at restaurants can help people make healthier choices (Refs. 1 and 2). Responding to this demand for information, several States and localities have initiated a variety of legislative or regulatory efforts for menu labeling, which has resulted in differing requirements across jurisdictions. These differing requirements have created logistical challenges for restaurant chains that have locations in more than one jurisdiction (Ref. 3).

On March 23, 2010, the President signed into law the Affordable Care Act (Public Law 111-148), which sets up a uniform nationwide approach to menu and vending machine labeling. Section 4205 of the Affordable Care Act (hereinafter "section 4205") creates a new subparagraph (H) within section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (the act), to be codified at 21 U.S.C. 343(q)(5)(H), which requires certain chain retail food establishments to provide calorie information and other nutrition information for menu items, food on display, and self-service food. Section 4205 also requires chain

vending machine operators to disclose calories for articles of food. Chain retail food establishments with fewer than 20 locations (or other restaurants or similar retail food establishments not covered by section 4205) and vending machine operators with fewer than 20 machines may elect to be subject to these Federal requirements by registering every other year with the FDA.

Section 4205 became effective on the date the law was signed, March 23, 2010; however, some provisions require FDA to issue rules before FDA implements them. Other provisions must be implemented immediately upon enactment of the law. FDA is required to issue a proposed rule implementing section 4205 by March 23, 2011.

For chain retail food establishments, the provisions that became requirements immediately upon enactment of the law include:

(1) Disclosing the number of calories in each standard menu item on menus and menu boards,

(2) Making additional written nutrition information available to consumers upon request,

(3) Providing a statement on menus and menu boards about the availability of the additional nutrition information, and

(4) Providing calorie information (per serving or per food item) for most self-service items and food on display, on a sign adjacent to each food item.

In addition, the provision requiring chain vending machine operators to disclose, in a clear and conspicuous manner, calories of any article of food that does not permit a prospective purchaser to examine its Nutrition Facts panel before purchasing, or does not otherwise provide visible nutrition information at the point of purchase, became an immediate requirement upon enactment of the law.

FDA is issuing this draft guidance as Level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the provisions in section 4205 related to chain retail food establishments that became requirements immediately upon enactment of the law. 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. FDA is soliciting comments from interested parties on the entire document to better inform the agency as it develops further guidance.

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.

Dated: August 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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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.