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MEMORANDUM

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BEFORE FEDERAL COURTS AND AGENCIES

August 25, 2010

BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: FDA Issues Guidance Documents on Menu Labeling

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The Food and Drug Administration (FDA) has issued two guidance documents regarding implementation of new nutrition labeling requirements for foods served in chain restaurants and similar retail food establishments. 75 Fed. Reg. 52426 and 52427 (Aug 25, 2010) (pre-publication copies attached):

- *Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act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* (available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm223266.htm>)
- *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* (available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm223408.htm>)

While FDA accepts comments on guidance documents at any time, comments on the draft guidance must be submitted no later than **October 12, 2010** in order to be considered in developing a final guidance.

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## **Background**

Section 4205 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require mandatory nutrition labeling of standard menu items sold in chain restaurants. Specifically, the new law requires that any restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name, regardless of type of ownership, and offering substantially the same menu items (“chain retail food establishments”) must provide the following disclosures: (1) calories on the menu or menu board (including drive-through menu boards); (2) a succinct statement about suggested daily caloric intake on the menu or menu board; (3) a clear and conspicuous statement on the menu or menu board notifying consumers of the availability of additional nutrition information; and (4) additional nutrition information (*i.e.*, calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein) available in writing on the premises.

Section 4205 also requires mandatory nutrition labeling of foods sold in vending machines operated by a person that owns or operates 20 or more vending machines (“chain vending machine operators”). Specifically, it requires a clear and conspicuous statement of the number of calories in each food presented in close proximity to the article of food or the selection button, unless the vending machine allows consumers to examine the Nutrition Facts panel of each food or otherwise provides visible nutrition information at the point of purchase.

The new law also provides that restaurants, similar food service establishments, and vending machine operators that are not covered by Section 4205 may elect to participate in a voluntary nutrition labeling program. By registering for the voluntary program, a restaurant, similar retail food establishment, or vending machine operator agrees to voluntarily provide the nutrition labeling required for chain retail food establishments or chain vending machine operators that are subject to Section 4205. FDA has published a *Federal Register* notice explaining how to register for the voluntary program (*see* our memorandum dated July 22, 2010).

Finally, Section 4205 provides that restaurants, similar retail food establishments, and vending machine operators that are subject to mandatory nutrition labeling or that elect to participate in the voluntary program are shielded from compliance with inconsistent State or local laws by federal preemption.

FDA is required to issue proposed regulations implementing the new law no later than March 23, 2011. FDA has opened a docket to receive comments and information regarding implementation of Section 4205 (*see* our memorandum dated July 7, 2010).

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### **Draft Guidance**

The draft guidance states that Section 4205 became effective immediately upon enactment of the Affordable Care Act on March 23, 2010. However, some provisions of Section 4205 require FDA rulemaking to implement.

According to FDA, the following requirements for chain restaurants and similar retail food establishments became effective immediately upon enactment:

1. The requirement to disclose calorie information for each standard menu item on menus and menu boards;
2. The requirement to make additional written nutrition information available to consumers upon request;
3. The requirement to provide a statement on menus and menu boards about the availability of such additional written nutrition information; and
4. The requirement to disclose calorie information (per serving or per food item) for most self-service food items on display by means of sign adjacent to the item.

In addition, the requirement that chain vending machine operators disclose, in a clear and conspicuous manner, calorie information for any article of food that does not permit prospective purchasers to examine the food's Nutrition Facts panel or otherwise does not provide visible nutrition information at the point of purchase also became effective immediately upon enactment.

The following requirements will not become effective until FDA issues a final rule implementing them:

1. The requirement to disclose calorie information for "variable menu items" (*i.e.*, menu items available in different forms or flavors, such as pizzas with different toppings, ice cream in different flavors, combination meals); and
2. The requirement to provide a succinct statement of suggested daily caloric intake on the menu or menu board.

The draft guidance also includes the following interpretations of Section 4205:<sup>1</sup>

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<sup>1</sup> Please note that FDA uses the word "should" frequently in the draft guidance. In guidance documents, the word "should" means that "something is suggested or recommended, but not required." We have tried in this memorandum to use the word "should" where FDA does.

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- Covered Establishments

Section 4205 applies to an establishment that meets the following three criteria: (1) it is a restaurant or similar retail food establishment; (2) it is part of a chain with 20 or more locations doing business under the same name (regardless of type of ownership); and (3) its locations offer for sale substantially the same menu items.

A “restaurant or similar retail food establishment” is any establishment that offers for sale directly to the consumer food that is intended for immediate consumption, regardless of whether the food is consumed on or off the premises. Generally, this would include table service restaurants, quick service restaurants, coffee shops, delicatessens, food takeout or delivery establishments (*e.g.*, pizza takeout and delivery establishments), convenience stores, movie theatres, cafeterias, bakeries, retail confectionery stores, food service vendors (*e.g.*, ice cream shops, mall cookie counters, lunch wagons), and transportation carriers (*e.g.*, airlines and trains). A grocery store that has a café, food court, or otherwise sells food for immediate consumption directly to consumers, it would also be considered a restaurant or similar retail food establishment. FDA is requesting comments on what facilities in grocery stores (beyond cafes, food courts, and in-store restaurants) should be covered by Section 4205. FDA is also seeking comments on what facilities in convenience stores should be covered.

“Doing business under the same name” means that the establishments share the same name and are owned, controlled, or operated by a single corporate entity. This includes establishments operated as franchised outlets of a parent company. The “same name” encompasses names that are the same in all relevant respects, including slight variations in a name (*e.g.*, “ABC” and “ABC Express” are the same name). FDA is requesting comments on how it should apply this to contractors, such as managed food services or other entities that own, control, or operate restaurants or similar retail food establishments offering substantially the same menu items but using names specific to a location.

“Offering for sale substantially the same menu items” means the locations are offering menu items (*i.e.*, foods included in the menu or menu board) that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies.

- Covered Foods

The foods covered by Section 4205 include “standard menu items,” “food on display,” and food sold at self-service facilities.

The term “food” includes meat and poultry products and alcoholic beverages, since they are included in the FD&C Act’s definition of “food.”

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A “standard menu item” is a food item routinely included in the primary writing of the restaurant or similar retail food establishment from which consumers make their selections. The term does not include: items not listed on the menu or menu board (*e.g.*, condiments and similar items on the table for general use), daily specials, temporary menu items on the menu for less than 60 days per calendar year, custom orders, and foods that are part of a customary market test and appearing on the menu for less than 90 days.

“Food on display” refers to food that is (a) intended for immediate consumption, whether on or off the premises; and (b) visible to the consumer, regardless of whether it is accessed by the consumer or an employee. This includes food packaged at a consumer’s request (*e.g.*, a slice of pizza sold at a counter, an entrée on a cafeteria line) or pre-wrapped by the establishment for direct customer selection (*e.g.*, a sandwich prepared on the premises and sold in a refrigerated display case). It should not include pre-packaged foods that bear complete nutrition labeling where the consumer is able to examine the Nutrition Facts panel prior to selection; such foods are not covered by Section 4205. FDA is seeking comments on whether and how Section 4205 should apply to foods on display that provide multiple servings (*e.g.*, a whole cake or loaf of bread).

“Food sold at a self-service facility” includes food in a covered establishment intended for immediate consumption and sold at a salad bar, buffet line, cafeteria line, or similar self-service facility (including self-service beverages).

- Calorie Disclosures

The calorie disclosure on the menu or menu board should be adjacent to the listing of the menu item, so that it is clear to the consumer that it is associated with the menu item. It should state the number of calories and may use either the word “Calories” or the abbreviation “Cal,” although FDA prefers the former. Both the number and the word “Calories” or “Cal” should appear in a type size at least as large as the name or price of the menu item, whichever is larger, with the same prominence (*i.e.*, the same color and contrasting background as the menu item). On menus and menu boards, calorie content may be listed in a single column under the heading “Calories” or “Cal.” Amounts should be rounded to the nearest 5-calorie increment up to an including 50 calories, and to the nearest 10-calorie increment above 50 calories. Amounts less than 5 calories may be expressed as zero.

Section 4205 defines “menu” and “menu board” as “the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.” FDA considers this to include all forms of such primary writing, such as dessert menus, beverage menus, and other specialty menus. The term “menu board” includes drive-through menu boards. An Internet or takeout menu can also be a “menu” if it is used as the primary writing from which

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consumers make order selections. During a conference call, FDA officials stated that a restaurant or similar retail food establishment that does not have a menu or menu board is not required to create one.

For a “food on display” or a “food offered for sale in a self-service facility,” the calorie disclosure must be clearly associated with the food item. It should use the term “Calories” or the abbreviation “Cal.” If the food item is labeled with a food tag (*e.g.*, a sign with the name and price of the item), the number of calories and the word “Calories” or “Cal” should be in a type size at least as large as the name or price of the food item, whichever is larger, and with the same prominence (*i.e.*, the same color and contrasting background).

- Additional Written Nutrition Information

The following nutrition information must be available in written form on the premises:

- Total number of calories
- Total number of calories from total fat
- Total fat
- Saturated fat
- Cholesterol
- Sodium
- Total carbohydrate
- Sugars
- Dietary fiber
- Total protein

In addition, this information should include *trans* fat.

This information may be provided by a variety of means including a counter card, sign, poster, handout, loose leaf binder, booklet, electronic device, or menu.

FDA is proposing a specific statement be used to inform consumers of the availability of additional written nutrition information. On menu boards, the statement “Additional nutrition information is available upon request” should appear in a type size at least as large as the name or price of a menu item and with the same prominence (*i.e.*, the same color and contrasting background as the calorie disclosures). On menus, the statement should appear on the bottom of the first page in the same type size and font as the calorie disclosure. If a menu has more than two pages, it may appear either (1) on every page, or (2) only on the first page, provided the first appearance of the word “Calories” on each succeeding page is followed by a symbol linking it to the statement.

- Enforcement

FDA “expects to refrain from initiating enforcement action until after a time period established in the final guidance.” Thus, the final guidance will set a date after which the agency will begin enforcement of Section 4205 requirements. FDA is requesting comments on the appropriate time period after issuance of the final guidance to begin enforcement. FDA anticipates issuing a final guidance in December 2010. As discussed below, while FDA may be exercising enforcement discretion for now, this does not obligate State and local governments with non-preempted menu labeling laws to do the same.

We believe FDA’s decision to implement Section 4205, at least in part, by guidance may be questionable. We note that a provision of the new menu labeling law states: “Not later than 1 year after the date of enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.” The statutory language does not authorize FDA to choose which provisions require rulemaking to implement. FDA’s draft guidance appears to be based on the contention that FDA is not required to promulgate regulations to implement certain menu labeling requirements, because those statutory provisions do not require interpretation. In contrast to that contention, there are at least 18 occasions in the draft guidance where FDA explains what statutory provisions “mean” or what FDA “considers” a provision to mean, or where FDA solicits comments on how to implement a provision.

### Guidance on Federal Preemption

This guidance document explains the preemptive effect of Section 4205 on inconsistent State and local laws. Section 4205, including its preemption provision, became effective immediately upon enactment of the Affordable Care Act on March 23, 2010. State and local government may not impose any nutrition labeling requirements on chain restaurants or similar retail food establishments that are not identical to Section 4205 and FDA’s implementing regulations. State and local laws that are identical to Federal requirements are not preempted.

The scope of federal preemption is limited in the following ways:

- State and local labeling laws that do not involve nutrition labeling (*e.g.*, State and local laws that require food safety warnings, consumer advisories, or allergen labeling) are not preempted.
- State and local governments may petition FDA for an exemption from preemption under 21 C.F.R. § 100.1.
- State and local menu labeling laws may impose non-identical menu labeling requirements on restaurants and similar retail food establishments that are not part of a chain with at least 20 locations, unless such establishments have registered for the voluntary program (*i.e.*, the program whereby restaurants and similar retail food

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establishments with fewer than 20 locations may voluntarily elect to comply with Section 4205 menu labeling requirements).

It should be noted that State and local governments have traditionally taken primary responsibility for enforcement of food labeling requirements in restaurants and similar retail food establishments. As discussed above, State and local governments may continue to enforce State and local menu labeling laws that are identical to Section 4205. During a conference call today, FDA officials stated that FDA has explained its enforcement policy to State and local governments, but State and local governments are free to make their own enforcement decisions.

\* \* \* \* \*

We trust this information is useful. If you have any questions, or would assistance in preparing comments, please contact Bob Hahn at (202) 518-6388 or [rhahn@ofwlaw.com](mailto:rhahn@ofwlaw.com).

Attachments  
RAH:mhh

**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](http://cspinet.org/new/pdf/comparison_of_ml_policies_6-9.pdf).

Dated: August 18, 2010.

Leslie Kux,  
Acting Assistant Commissioner for Policy.  
[FR Doc. 2010–21065 Filed 8–24–10; 8:45 am]  
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**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies 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 guidance at <http://www.fda.gov/FoodGuidances>.

Dated: August 18, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–21067 Filed 8–24–10; 8:45 am]

**BILLING CODE 4160–01–S**