

ANDA that does not refer to a listed drug.

Lachman Consultant Services submitted a petition dated January 12, 2010 (FDA-2010-P-0027), requesting a determination that ACTONEL (risendronate sodium) Tablets, 75 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. ACTONEL (risendronate sodium) Tablets, 75 mg, is the subject of NDA 20-835, held by Warner Chilcott and initially approved on April 16, 2004. ACTONEL (risendronate sodium) Tablets, 75 mg, is indicated for the treatment of postmenopausal osteoporosis in men, and Paget's disease in men and women.

In a separate citizen petition dated January 20, 2010 (FDA-2010-P-0051), Lachman Consultant Services requested a determination that ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, was not withdrawn from sale for reasons of safety or effectiveness. In another separate petition dated January 21, 2010, EAS Consulting Group, LLC, requested the same determination on behalf of Aurobindo Pharmaceuticals. ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, is the subject of NDA 21-823, held by Procter & Gamble and initially approved on August 12, 2005. ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, is indicated for the treatment of postmenopausal osteoporosis.

FDA has reviewed its records and, under § 314.161, has determined that neither ACTONEL (risendronate sodium) Tablets, 75 mg, nor ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, was withdrawn from sale for reasons of safety or effectiveness. None of the petitions identified any data or other information suggesting that either of the products named in the petitions was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that either product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ACTONEL (risendronate sodium) Tablets, 75 mg, and ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List"

delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

ANDAs that refer to ACTONEL (risendronate sodium) Tablets, 75 mg, or ACTONEL WITH CALCIUM (risendronate sodium and calcium carbonate (copackaged)) Tablets, 35/500 mg, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for either or both of these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: June 30, 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-N-0298]

Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments, data, and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to solicit comments, data, and other information helpful to the implementation of section 4205 of the Patient Protection and Affordable Care Act of 2010, which was enacted on March 23, 2010. That section, principally amending sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (the act), 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 nutrient content information for standard menu items appearing on restaurant menus and menu boards, and requires vending machine operators that own or operate 20 or more vending machines to disclose nutrient content information for certain articles of food sold from vending machines. Section 4205 also amended the act to allow

restaurants or similar retail food establishments and operators of vending machines not subject to the requirements of section 4205 to elect to be subject to the requirements through biannual registration. FDA is establishing this docket to provide an opportunity for interested parties to submit data and other information relevant to the implementation of section 4205.

DATES: Submit either electronic or written comments by September 7, 2010.

ADDRESSES: Submit electronic comments 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.

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

The availability of nutritional information through menu labeling would provide Americans the opportunity to exercise personal responsibility and make informed choices about their diets. Studies show that providing nutrition information at restaurants can help people make healthier choices (e.g., Refs. 1 and 2). Responding to this demand for information, several states and localities have initiated legislative or regulatory efforts on restaurant menu labeling, creating a patchwork of ideas and logistical challenges for many restaurant chains (Ref. 3). While various approaches to menu labeling in chain restaurants have been tried, several stakeholders ultimately sought a national approach that would ensure nationwide uniformity, better protections, and flexibility in how additional nutrition information is provided.

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (Affordable Care Act) (Public Law 111-148). 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 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 (hereinafter “chain retail food establishments”) to disclose specific nutrition information on certain food items offered for sale. The new provision also requires vending machine operators that own or operate 20 or more vending machines (hereinafter “chain vending machine operators”) to disclose nutrient content information for certain food articles sold from vending machines.

A. Chain Restaurants or Similar Retail Establishments

Specifically, section 4205 provides that chain retail food establishments must:

- Display on menus and menu boards, including drive-through menu boards, the number of calories next to the listing for each “standard menu item, as usually prepared and offered for sale.”
- Include on the menu or menu board, “posted prominently,” “a succinct statement concerning suggested daily caloric intake.” This statement, which is to be specified by the Secretary of the Department of Health and Human Services (the Secretary) by regulation, must be “designed to enable the public to understand, in the context of a total daily diet, the significance” of the required information.
- Provide in a written form, available to the customer upon request, the nutrition information required under section 403(q)(1)(C) and (D) of the act (i.e., per-serving information with respect to the amount of calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, fiber, and total protein).
- Make a “prominent, clear, and conspicuous statement” on the menu or menu board about the availability of the written nutrition information under section 403(q)(1)(C) and (D).
- In the case of self-service food and food on display (e.g., food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility), include a sign adjacent to each food item that lists the calories per displayed food item or per serving.
- Base its nutrient content disclosures on sources described in 21 CFR 101.10 or related FDA guidance.

Under section 4205, the Secretary must 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.

Certain food items sold in chain retail food establishments are not subject to the nutrition content disclosure requirements. These items include:

- Items not listed on a menu or menu board (such as condiments or items placed on the table or counter for general use).
- Daily specials, temporary menu items appearing on the menu for fewer than 60 days per calendar year, or custom orders.
- Food that is part of a customary market test and appearing on the menu for fewer than 90 days, under terms and conditions established by the Secretary.

B. Vending Machines

Section 4205 provides that chain vending machine operators must provide a sign “in close proximity to” each article of food or to the selection button that includes “a clear and conspicuous statement disclosing the number of calories contained in the article,” unless the vending machine permits a prospective purchaser to examine the Nutrition Facts panel before buying the food article, or otherwise provides “visible nutrition information at the point of purchase.”

C. Proposed Rule

Section 4205 requires FDA to issue proposed regulations to carry out the provisions of section 4205 no later than March 23, 2011. In issuing these regulations, FDA must: (1) Consider “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” and (2) “specify the format and manner of the nutrient content disclosure requirements” under section 4205.

D. Voluntary Provision of Nutrition Information

Under the Affordable Care Act, persons or firms not subject to the disclosure of nutrition information required by section 4205, such as retail food establishments with fewer than 20 locations or vending machine operators with fewer than 20 vending machines, may elect to be subject to the requirements by registering biannually with FDA. FDA must publish a notice in the **Federal Register** within 120 days of the date of enactment of the Affordable Care Act (i.e., by July 21, 2010), specifying the terms and

conditions for implementation” of the voluntary registration provision.

II. Request for Data and Other Information

FDA is establishing a docket to provide an opportunity for interested parties to submit data and other information and share views that will inform us in the implementation of the new legislative requirements for mandatory or voluntary menu, menu board, and vending machine labeling. In particular, we welcome input on any of the matters listed below:

A. Chain Retail Food Establishments

- The types of restaurants or similar retail food establishments and the nature of their food service activities.
- Current practices within the restaurant or similar retail food establishment industry with respect to standard and non-standard menu items and the use of menus or menu boards.
- Current practices with respect to the format and manner of nutrient content disclosures concerning food items that appear on retail food service menus or menu boards.
- Considerations in the disclosure of calorie content information for food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display.
- Issues to be considered in developing a succinct statement about a suggested daily caloric intake that is required to appear on menus and menu boards.

- Methods related to presentation of nutrient content (ranges, averages, or other methods) for standard menu items that come in different flavors, varieties, or combinations but which are listed as a single menu item, such as soft drinks, ice cream, pizza, etc., or combination meals such as children’s combination meals.
- Factors to consider with respect to determining what foods or categories of foods might be exempt from the menu labeling requirements because, e.g., they are condiments and other items placed on tables or counters for general use; daily specials, temporary menu items, or custom orders; or other food that is part of a customary market test.

- Information about the size of chain retail food establishments (e.g., based on annual revenue or on number of locations).
- Information about the number of chain retail food establishments that are or could be affected by section 4205.
- Information about the number of retail food establishments that may

choose voluntarily to be subject to section 4205.

- Factors to consider with respect to availability and use of space on menus and menu boards.

B. Determination of Calorie Content of Foods Offered by Chain Retail Food Establishments

- Information about standardization of recipes and methods of preparation.
- Information about variation in serving size and formulation of menu items.
- The role of inadvertent human error.
- Information about training of food service workers.
- Information about variations in ingredients.
- Any other relevant factors.

C. Vending Machine Operations

- Current practices within the vending machine industry with respect to the availability to prospective purchasers of Nutrition Facts panel information or otherwise providing visible nutrition information at the point of purchase.
- Possible mechanisms for displaying products' Nutrition Facts panels or otherwise providing visible nutrition information at the point of purchase.
- Factors to consider with respect to availability and use of space on vending machines.
- Considerations in requiring caloric content disclosure about food items sold from vending machines.
- Information about the size of chain vending machine operators (e.g., based on annual revenue or on number of locations).
- Information about the number of chain vending machine operators that are or could be affected by section 4205.
- Information about vending machine operators not covered by section 4205 of the Affordable Care Act that might elect to be subject to the requirements of section 4205.

D. Implementation and Enforcement

- Information about implementation, including information about options for inspection and enforcement.
- Information about inspection and enforcement mechanisms in state and local nutrition labeling programs.

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. References

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," Available at <http://www.journals.uchicago.edu/doi/pdf/10.1086/598799> *Journal of Consumer Research*36(3): 494–503, 2009.
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: June 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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Health, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Matters to be Discussed: The agenda will include agency updates from the CDC, the Centers for Medicare & Medicaid Services, and the Food and Drug Administration. Reports and Committee discussion will address issues pertaining to cytology testing and workload recording; the electronic exchange of laboratory information; and consideration of proposals from the CLIAC proficiency testing workgroup. Agenda items are subject to change as priorities dictate.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments whenever possible.

Oral Comments: In general, each individual or group requesting to make an oral presentation will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, individuals or groups planning to make an oral presentation should, when possible, notify the contact person below at least one week prior to the meeting date.

Written Comments: For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, the comments should be received at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person below. Written comments will be included in the meeting's Summary Report.

Contact Person for Additional Information: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Science and Standards (proposed), Laboratory Science, Policy and Practice Program Office (LSPPO) (proposed), Office of Surveillance, Epidemiology and Laboratory Services (proposed), Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop F-11, Atlanta, Georgia 30333; telephone (404) 498-2741; fax (404) 498-2219; or via e-mail at Nancy.Anderson@cdc.hhs.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 28, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-16387 Filed 7-6-10; 8:45 am]

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