



July 5, 2011

The Honorable Margaret A. Hamburg, M.D.  
Commissioner  
Division of Dockets Management (HFA305)  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**ATTN: Comment Docket No. FDA-2011-F-0172**

Dear Commissioner Hamburg:

Trust for America's Health (TFAH) is pleased to have the opportunity to comment in response to the Food and Drug Administration's (FDA) proposed regulations for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments. These provisions, enacted as part of the *Affordable Care Act* (ACA), are a fundamental step in improving the health of the nation and TFAH strongly supports menu labeling requirements.

TFAH is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. According to TFAH's 2011 report, *F as in Fat: How Obesity Threatens America's Future*, adult obesity rates are now greater than 30 percent in 12 states, and exceed 25 percent in more than two-thirds of states (38 states).<sup>1</sup> It is estimated that Americans currently consume one-third of their total calories outside of the home,<sup>2</sup> and often underestimate, or are unaware of, the calorie content of restaurant foods. A recent related survey of adults indicated that participants underestimated the calorie content of the foods prepared outside of their home and perceived to be "healthier food choices" by an average of 650 calories per item—nearly half of the calorie content.<sup>3</sup> Providing accurate, accessible, and easily

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<sup>1</sup> Trust for America's Health. *F as in Fat: How Obesity Threatens America's Future*. Washington, D.C.: Trust for America's Health, 2011.

<sup>2</sup> Lin, B-H., J. Guthrie and E. Frazzao. "Nutrient Contribution of Food Away From Home." In Chapter 12 of *America's Eating Habits: Changes and Consequences*, Elizabeth Frazzao (ed), USDA Agriculture Information Bulletin No. (AIB-750), pp. 213-242, May 1999.

<sup>3</sup> Burton, S. and E.H. Creyer. "What Consumers Don't Know Can Hurt Them: Consumer Evaluations And Disease Risk Perceptions Of Restaurant Menu Items." *Journal of Consumer Affairs*, 38:121-145, 2004.

understandable information on calorie content will promote personal responsibility by enabling consumers to make more informed decisions about menu items.

In response to the issues raised in FDA's request for comment, TFAH offers the following recommendations that we hope will augment the efficacy of these regulations.

### **Covered Establishments:**

**TFAH strongly urges the FDA to return to the definition of restaurants and similar retail food establishments that was provided in the draft menu labeling guidance issued last summer**, which specified "table service restaurants, quick service restaurants, coffee shops, delicatessens, food take out and/or delivery establishments (*e.g.*, pizza take out and delivery establishments), convenience stores, movie theatres, cafeterias, bakeries/retail confectionary stores, food service vendors (*e.g.*, lunch wagons, ice cream shops, mall cookie counters, and sidewalk carts), and transportation carriers (*e.g.*, airlines and trains)." Establishments covered by the law should include all chain restaurants as defined by a chain in the federal statute, and similar retail food establishments that sell directly to the consumer (food that is intended for immediate consumption and that is ordered through a menu, menu board, or other display that is for the purpose of ordering).

TFAH strongly opposes the language included in the current proposed rule, requiring that the sale of food be the retail establishment's "primary business activity" based on how the establishment uses its floor space or if it presents itself as a restaurant. Even when customers do not consume food at the establishment, or when the establishment offers services or entertainment beyond food-service, adequate nutritional information must be provided. Exempting these venues would reduce the number of venues providing nutritional information about food served, and therefore would limit the ability of individuals to make informed choices about their foods. Further, given that many of the establishments that the FDA has proposed exempting from menu labeling sell similar foods than those covered in restaurants, it would be unfair to exempt these competing venues from menu labeling regulations.

We agree with the definition of "offering for sale substantially the same menu items," and that the law should apply to establishments "doing business under the same name."

### **Prepared Foods at Chain Grocery and Convenience Stores**

TFAH agrees that prepared foods at chain grocery and convenience stores should be labeled, as well as superstores. These establishments sell many foods that are available for immediate consumption, and therefore should be required to provide calorie labeling that is easily accessible and readable. Even if food is for carry out or delivery, it is essential that the appropriate nutritional information be provided.

## **Food Covered:**

### **Standard Menu Item:**

TFAH strongly supports the FDA's defining of a "standard menu item" as being restaurant or restaurant-type food that is **routinely** included on a menu or menu board or that is routinely offered as a self-service food or food on display. Calories should be posted for full menu items rather than for a fraction of the menu item, which is confusing for consumers. This pertains to food sold in multiple servings, as well as standard menu items that come in different flavors, varieties, or combinations but are listed as a single menu item.

### **Multiple Servings:**

We agree with the FDA that foods sold in multiple servings should be considered standard menu items. Two-thirds of individuals could not accurately calculate the nutritional information for a 20-ounce bottle of soda that was labeled as having 2.5 servings, according to one study.<sup>4</sup> According to another study, 69 percent of individuals reported finishing their meal in a restaurant all or most of the time.<sup>5</sup>

Foods consumed by one person should not be listed as having multiple servings, but rather the total caloric intake should be provided. If the meal is intended to be shared by more than one person, or if the diner chooses to split the menu item, it would be less confusing to have the consumer divide the calories as opposed to providing caloric intake per serving size. For example, one food item may be intended to be two serving sizes, but if three people choose to share it, it may be more confusing to calculate the caloric intake based on that given per serving size, as opposed to if the full caloric intake was provided for the item. It is also misleading to allow the small portion sizes on packaged foods pertain to the often large restaurant portion sizes.

### **Combination Meals and Variable Menu Items:**

We urge the FDA to provide more guidance regarding menu items that come in multiple flavors and varieties and combination meals, so that establishments can provide meaningful calorie labeling. We do not recommend allowing averages for standard menu items that come in different flavors, varieties, or combinations, and urge the FDA to ensure that restaurants post calorie ranges as infrequently as possible. We strongly believe that for consumers to make an informed decision, they need to see the calorie content for each flavor, variety, or individual item in a combination meal regardless if it is listed as a single item or as individual components on the menu or menu board. We agree that custom orders, that deviate from standard menu items, should not be covered by the law.

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<sup>4</sup> Rothman R., Housam R., Weiss H., et al. "Patient Understanding of Food Labels: The Role of Literacy and Numeracy." *American Journal of Preventive Medicine* 2006, vol. 31 (5), pp. 391-398.

<sup>5</sup> American Institute for Cancer Research. *Awareness and Action: AICR Surveys on Portion Size, Nutrition, and Cancer Risk*. Washington, D.C.: AICR, 2003.

### **Alcoholic Beverages and Meats Should be Labeled:**

TFAH strongly opposes the exemption of alcoholic beverages from menu labeling. Calorie content of alcoholic beverages varies widely, and contributes to the total caloric intake of Americans. TFAH recommends that **all standard items listed on a menu or menu board**, including meat, poultry, and alcoholic beverages (such as wine, beer, or mixed drinks), be covered by the law.

### **Foods on Display in Food Establishments**

We recommend that the FDA clarify that this relates to foods in the open and behind glass, and foods that are self-serve or served by restaurant staff. We agree that foods on display, such as salad bars and buffets, should have easily accessible additional nutritional information. We recommend that the FDA provide more details about the format establishments can use to provide this information to ensure that it is readily available and easily readable. We also ask the FDA to provide additional guidance on serving sizes for calorie disclosures pertaining to foods on display in restaurants. Pre-packaged foods with Nutrition Facts on the individual label do not require additional calorie tags.

### **Disclosure of Calories/Additional Written Nutrition Information**

#### **Clear and Conspicuous Caloric Declarations**

It is necessary for caloric information to be as understandable as possible in order to increase the ability of consumers to make nutritious choices. TFAH strongly agrees that calorie declarations should be provided on each menu that lists the standard menu item. They should be located immediately adjacent to the menu item, and should not be located on a pamphlet or poster nearby menus, vending machines, or self-serve food-items. This includes all menu and menu boards in the establishment, as well as outside of the establishment (whether it be online or on a drive through menu board). For example, when customers are ordering food through a drive through, they have limited time, and field of vision from their car windows, and therefore should be able to view caloric information on the menu board itself.

We also agree that calorie content should be **clear and conspicuous**, and should have the same contrasting background, and be in the same color, or a color at least as conspicuous, as the color of the standard menu item on the menu board. We urge the FDA to modify its size requirement, and to require that caloric declarations be in a font size at least as large as that of the name or price of the standard menu item, whichever is *larger* (in contrast to the current proposal to require the font to be at least as large as whichever is smaller).

### **Putting Calorie Labeling in Context of a Day's Diet**

Evaluation data suggest that people do not clearly understand the daily recommendation for calories and other important information such as sodium and saturated fat content. Therefore, we strongly support the law requirement that the caloric statement must be **succinct and market-tested** to effectively increase consumers' knowledge about daily recommended values. We also support the FDA proposal regarding a "statement of availability" for additional written nutrition information, and the nutritional information required to be available upon request. We agree FDA's proposal for the wording, prominence, and placement of the statement, in order to ensure that it will adequately inform consumers of the availability of additional nutritional information. Suggested daily values should be displayed in a prominent manner to help increase consumer knowledge about daily recommended values for total fat, saturated fat, sodium, total carbohydrates, and dietary fiber. Furthermore, we recommend that the dietary statement be written with language easier to understand and that is appropriate for people with limited English proficiency. Once again, we strongly recommend that this be field tested before the statement is finalized.

### **Children's Statement**

The daily recommended values were originally developed for a typical adult. TFAH therefore agrees that the FDA should require the use of a different statement for children's menus. We recommend the following statement:

**"Most children 4-8 years old need about 1,500 calories a day, or less than 500 calories a meal."**

### **Rounding Calorie Numbers:**

TFAH strongly supports the FDA's proposal to round calorie numbers, which is also required for Nutrition Facts labels. Unrounded calorie numbers can falsely indicate that calorie numbers are more precise than reality, and can make comparing calorie content of food items more difficult.

### **Timing and Extent of Compliance and Enforcement:**

#### **Timeline**

TFAH strongly supports the FDA's proposal to implement menu labeling six months after issuance of final menu labeling guidance. This period is enough time for all affected establishments to analyze the law and available guidance and reach compliance. Many chain restaurants operate in state or local jurisdictions where menu labeling requirements are already in place and thus have previously analyzed the nutritional content of covered food items. California, Massachusetts, Maine, New Jersey, and Oregon all currently have laws that require the posting of nutrition information on menus and menu boards in restaurant chains with 20 or more in-state locations. Further, Seattle, Philadelphia, New York City, Nashville, San Francisco,

and Montgomery County, Maryland also have menu-labeling provisions.<sup>6</sup> For those chains that have not fully analyzed the calorie content of covered food items, this process should be underway given the FDA guidance issued last summer.

### **Support Development and Enforcement of State and Local Nutrition Labeling Requirements**

State and local authorities are more likely to enforce their own laws than the federal law, due to familiarity, tradition, and established practice. Therefore, we urge the FDA to support, through provision of technical assistance, state and local enactment of “identical” restaurant labeling requirements.

We strongly urge the FDA to swiftly establish an enforcement protocol, which involves supports of state and local initiatives to enforce the menu labeling law. Given that inspections are historically the responsibility of states and localities, we urge the FDA to provide training and guidance to facilitate state and local enforcement of the federal law. FDA support of state and local enforcement efforts is essential to ensure compliance with the final rule. Further, we urge the FDA to enforce fines or penalties for noncompliance, and to direct any resulting funds to inspection programs enforcing the law.

FDA should establish a pre-implementation program that provides adequate technical assistance to establishments required to comply with this new provision of the law. The program should also include outreach, preferably through a website, to help educate consumers about menu labeling requirements and to help them identify which establishments have already come into compliance.

### **Develop a Strong National Educational Campaign**

Menu labeling should be considered a necessary yet insufficient step in our efforts to combat obesity. While some studies have indicated that menu labeling reduced consumers’ caloric intake, other studies have indicated that menu labeling alone may not be enough to change consumer behavior.<sup>7</sup> Menu labeling should be implemented in conjunction with other interventions, such as consumer education, for the greatest impact. Therefore, we strongly urge the FDA to collaborate with state and local health departments, nutrition and public health organizations, and the National Restaurant Association and its affiliates, to launch a campaign to educate consumers on how menu labeling in restaurants can best be used to make nutritional choices. A comprehensive education campaign would increase awareness for the availability of nutrition information in restaurants, and would increase the efficacy of menu labeling.

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<sup>6</sup> Trust for America’s Health. *F as in Fat: How Obesity Threatens America’s Future*. Washington, D.C.: Trust for America’s Health, 2011.

<sup>7</sup> Trust for America’s Health. *F as in Fat: How Obesity Threatens America’s Future*. Washington, D.C.: Trust for America’s Health, 2011.

Thank you for your consideration of these views. We hope that our comments will assist the FDA in making nutritional information more accessible to the American public. If you have any questions, please do not hesitate to contact our Director of Government Relations, Becky Salay, at (202) 223-9870 ext. 15, or via email at [bsalay@tfah.org](mailto:bsalay@tfah.org).

Sincerely,

A handwritten signature in black ink that reads "Jeffrey Levi". The signature is written in a cursive style with a large initial "J" and "L".

Jeffrey Levi, Ph.D.  
Executive Director