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November 2, 2015

Stephen Ostroff, MD
Acting Commissioner
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2011–F–0172; A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11); Draft Guidance for Industry

Dear Dr. Ostroff:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to provide input on the Food and Drug Administration's (FDA) Draft Guidance for Industry, *A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II*. ACS CAN is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society dedicated to eliminating cancer as a major health problem. ACS CAN supports legislative, regulatory, and policy efforts that will make cancer a top national priority.

Poor nutrition, physical inactivity, and excess weight are major risk factors for several common types of cancer, second only to tobacco use. One fourth to one third of the 1,658,000 cancer cases expected to occur in the U.S. this year¹ can be attributed to these three factors. Excess weight is clearly associated with an increased risk of developing cancers of the breast in postmenopausal women, colon and rectum, endometrium, kidney, esophagus, pancreas, and probably gallbladder, and may also be associated with an increased risk of cancer of the liver, non-Hodgkin lymphoma, multiple myeloma, cancer of the cervix, cancer of the ovary, and aggressive prostate cancer.² As a result of the clear relationship diet and body weight have with many types of cancer, ACS CAN supports multi-faceted, population-based policy approaches to improving nutrition and physical activity by removing barriers to healthy lifestyles,

1 American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures, 2015-2016*. Atlanta, GA: American Cancer Society, 2015.

2 Kushi LH, Doyle C, McCullough M, et al. American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention: Reducing the Risk of Cancer With Healthy Food Choices and Physical Activity. *Ca Cancer J Clin* 2012; 62: 30-67.

changing social norms, and increasing education and awareness of healthy choices. Providing consumers with access to accurate, science-based information about the nutritional content of food and beverage products available for sale will facilitate their making healthier diet and lifestyle choices.

Overall, ACS CAN supports the final regulations for nutrition labeling of standard menu items in restaurants and similar retail food establishments issued by FDA in December 2014 and this draft guidance to implement the menu labeling requirements. We encourage the FDA to finalize the guidance as soon as possible to allow restaurants and other food establishments to move forward with posting calories on menus and menu boards and for foods on display. We also encourage the FDA to include as many examples as possible throughout the guidance to reduce the likelihood that covered retailers and consumers will be confused about the calorie information that must be provided and what the information means. Menu labeling is an important tool to help people make informed choices when they eat meals and snacks prepared away from home.

We suggest a few clarifications to the guidance to make it easier to understand and to allow consumers to more easily use the nutrition information provided to make informed food and beverage choices that will improve their long-term health:

List of Covered Venues: In Sections 3.9 and 5.1, concession stands should be added to the list of covered establishments. Concession stands are mentioned a number of times in the preamble to the final rule and should be explicitly included in the guidance.

Definition of Menu and Menu Board: In Sections 3.23 and 5.12, the guidance should clarify that all menus in an establishment must include calorie information if they may be the “primary writing” from which a customer makes an order selection. The guidance should clarify that this may mean that multiple forms of menus in a single establishment may be required to include calorie information. For example, a fast casual restaurant with paper menus and menu boards in the store and an Internet menu used for ordering online would be required to provide calorie information on all three of these types of menus.

Internet Menus: In Section 5.12, the guidance should make clearer how calories should be provided on Internet menus. To meet the requirement that calories be provided on any writing from which customers make an order selection, calories should be provided directly on Internet menus, rather than on a separate page or table, as restaurants often do. Customers should not have to click through several pages to get to the calorie information.

A sentence could be added to the end of second paragraph of the section to read:

Calories should be listed directly on Internet menus, rather than on a separate page or table.
Customers should not have to click through to a separate page to get to calorie information.

Labeling of Combination Meals: In Sections 5.14 and 5.38, the guidance should be amended to require food establishments to list calories next to pictures of combination meals or combination offers on

menus and menu boards. Many people order combination meals rather than individual items a la carte, and do so directly from the photos or listing of the combination meals. Combination meals constitute menu items and the law requires that calories be posted for all standard menu items listed on the menu or menu board.

Menu Items that Come in Different Flavors or Varieties: Posting wide ranges of calories for a single menu item is not as informative to customers as a single number and makes it harder for people to make informed choices. The FDA should give additional guidance to encourage food service establishments to post calorie ranges as infrequently as possible, to keep those ranges as narrow as possible, and to disclose on the menu or menu board the calories for each menu choice that is responsible for the calorie range to the greatest extent possible. That could be accomplished in a number of ways. For example, when menu items include a main dish with a choice of sides or toppings, and those sides and toppings are described on the menu, the description could include calorie information for each side or topping. The FDA should clarify that variable menu items do not include a food item that is listed on the menu in different sizes. Each size of a menu item listed on the menu, menu board, or display tag must be accompanied by a calorie posting. For example, calorie information should be provided for all serving sizes of soft drinks or French fries.

We agree with the guidance in Section 5.31 that calories should be posted for each pizza topping, sandwich component, omelet selection, sundae topping, or salad ingredient or dressing that is listed on the menu or that is on display.

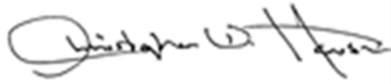
Multiple-Serving Items: In Section 5.17, the FDA should provide more guidance about what does and does not constitute a discrete unit of a multiple-serving item. The guidance should clarify that the discrete unit should be easily identifiable by customers as a unit, is distinctly separate from other units, and that each discrete unit has the same number of calories. More examples should be given. The guidance should be clear that discrete units include slices of pizza, cake, bread, or pie. Items that are not discrete units include appetizers, side dishes, desserts, or other menu items that are not clearly divided into units, items where part of the menu item is in discrete units and part is not, or half a sandwich or muffin, for example, if the whole sandwich or muffin comes in an order.

Kiosks: We agree with the FDA guidance in Section 5.66 that kiosks that customers can use to place orders, such as made-to-order sandwiches, constitute a menu. As such, calories should be provided for each item as it is displayed on the kiosk, so people can make informed decisions. The FDA should clarify in Section 5.66 that this guidance also applies to interactive Internet menus.

Additional Clarification: Example 1 and 2 in Section 5.34 should read “Green Peppers, Red Peppers, or Onions”, rather than “and”. The calorie posting applies to one of the toppings, not all three.

Thank you again for the opportunity to provide input. We encourage the FDA to incorporate these suggestions and finalize the guidance far in advance of the December 1, 2016 implementation date. If we can provide additional information, please contact Melissa Maitin-Shepard, MPP, Senior Analyst, Policy Analysis & Legislative Support, at melissa.maitin-shepard@cancer.org or 202-585-3205.

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher W. Hansen". The signature is fluid and cursive, with a large initial "C" and a distinct "H" at the end.

Christopher W. Hansen
President
American Cancer Society Cancer Action Network