American Heart Association | American Stroke Association

July 1, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Docket No. FDA–2011–F–0172

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to comment on the proposed regulations governing nutrition labeling in restaurants and similar retail food establishments.

AHA believes that, by providing consumers with nutrition information for the food they purchase, they are empowered to consume healthier diets. Overeating is a major cause of the obesity epidemic in the United States, and enabling the American public to practice calorie control is key for reversing the epidemic. Accordingly, the Association was a strong advocate of Section 4205 of the Affordable Care Act (ACA). To be effective, it is essential that the Food and Drug Administration (FDA) ensures that implementation of the law is robust and consistent with Congressional intent.

In response to the FDA's previous request for input (FDA–2010–N–0298), the Association submitted a letter on September 3, 2010, giving our perspective on the implementation of Section 4205. In a letter dated October 11, 2010, we also expressed our strong support for draft guidance for industry issued by the agency (FDA–2010–D–0370), which we observed to be reflective of the statute.

We are pleased that the agency has issued a proposed rule, as required by the ACA, and are strongly supportive of many of its elements such as the requirement that calorie information be posted on all menus from which a consumer can make an order selection; the inclusion of provisions to ensure that calorie declarations and the daily caloric intake statement are clear and conspicuous; and the requirement that additional nutritional information be made available upon request. We are, however, concerned with a few elements of the proposed rule, including the narrow proposed options for defining a restaurant and similar retail food establishment (R/SRFE); the use of unlimited, uninformative calorie ranges for variable menu items; and the proposed exemption for alcoholic beverages from this rule. We expand upon these points and offer additional comments below.

Scope of Establishments Covered

AHA was extremely pleased that the draft guidance to industry issued last year (FDA–2010–D–0370) contained broad criteria for defining types of establishments subject to the menu labeling requirements. According to that guidance, movie theaters, trains, airlines, supermarkets, grocery stores and convenience stores were all subject to the new law. We especially appreciated the FDA's stated intent "…to ensure that establishments that offer comparable food items for immediate consumption are treated comparably" since this is an appropriate public health standard and it mirrors the way R/SRFEs are defined under the Nutrition Labeling and Education Act.

The Association is therefore deeply disappointed that the agency has now rejected this definition of a R/SRFE and has chosen to base a definition on criteria unrelated to public health that creates inconsistency, and will be challenging to implement. Under the proposed rule, covered establishments would only include those where the sale of food is the primary business activity. This definition no longer ensures that establishments that offer comparable food items for immediate consumption such as movie theaters and airlines are treated comparably. Such establishments should be subject to the same regulation by the agency as restaurants. Whether a consumer eats at an establishment that is an upscale restaurant, a fast food chain franchise, a train dining car or a movie theater, the impact of over-eating and consumption of foods and beverages of low nutritional value on their cardiovascular – and overall health is the same.

We are also concerned with how the FDA and its enforcement partners will determine whether the sale of food is the primary business activity. The agency is considering two possible ways in determining whether the sale of food of a R/SRFE is its primary activity, either (1) measuring the percentage of floor space related to the sale of food, or (2) the percentage of the establishment's revenue that comes from the sale of food. Regardless of which method is used to determine whether a chain of R/SRFEs is subject to the rule, the FDA and state departments of health, which we understand will likely be called upon to help enforce the rule, will be required to first determine whether a chain has 20 or more locations in the United States – and in how many of those establishments across the country the sale of food is the primary activity. The only appropriate way to do this would be for inspectors to determine independently the status at each location.

For instance, there may be a R/SRFE chain with more than 20 locations nationwide where the floor space or revenue related to food sales varies at each site. Whether the chain is subject to the law is dependent upon how many of the locations meet the 'primary activity' definition. So, to determine whether the chain needs to comply with the law, the FDA would need to determine the percentage of floor space, or alternatively the revenue, for each establishment. Consumer trust would be compromised if agencies were to use industry data to make the determination, raising questions of how enforcement agencies know that chains are accurately representing their income or floor space.

By replacing the R/SRFE definition in the guidance to industry with a 'primary activity' definition that is dependent upon private data of establishments across the country, it will be challenging for state food safety inspectors to determine which chains in their jurisdiction are required to be in compliance. Similarly, it will be all but impossible for members of the public to identify violations so they can report them to their state department of health or the FDA.

In determining which facilities should be covered by the law, it is especially important that movie theater chains not be exempted. As indicated by the statement of Senator Harkin and Representative DeLauro – the two original authors of this provision of the Affordable Care Act – upon publication of the proposed rule[i], it was the intent of Congress that the FDA regulation include

movie theaters. The food sold at movie theaters is typically high calorie beverages and snacks of low nutritional value, often served in oversized portions. While food sales at movie theaters may not currently meet the proposed floor space or revenue requirements, food sales are a critical and large net source of revenue for the theater industry and increase the average purchase per customer.[ii] Meeting menu labeling requirements should not be burdensome for movie theater chains, especially where they are offering a limited number of standardized menu offerings and where packaged items with Nutrition Facts Panels would be exempt. We therefore urge the agency to follow Congressional intent and include movie theaters among the list of covered establishments.

In addition, it is paramount that facilities such as cafeterias in chain grocery stores and coffee shops within chain book stores be covered. Such facilities provide the same type of service as a restaurant, and the importance of providing consumers with nutritional information is the same. The Association concurs with the FDA that, where the facility itself is part of a chain that has 20 or more establishments, including some that are outside the larger retail establishments, it should be subject to the law. We urge the agency to retain this requirement within the final rule. We further urge the agency to extend this requirement in the final rule to chain stores of 20 or more establishments that house their own cafeterias or coffee shops, since the service these facilities provide is exactly. Similarly, we agree with the FDA that convenience store chains serving restaurant-type food should be covered, and urge them to keep that requirement in the final rule.

Finally, the FDA is also seeking comments on an alternative approach to determining which establishments should be subject to the law, based on whether the sale of restaurant or restaurant-type food – as opposed to food in general – is its primary business. As with the other approach, this standard is not one that makes sense from a public health perspective, and creates the same kinds of enforcement challenges. For the reasons stated above, we are greatly concerned that this approach further narrows the R/SRFE definition, excluding grocery stores and convenience stores, and we are strongly opposed to the adoption of the standard.

In summary, if the proposed 'primary activity' standard is implemented, it will lead to weak implementation of the law. We reject either a space- or revenue-based method for determining covered establishments. We instead concur with the previous FDA guidance which stated that establishments that offer food items for immediate consumption should be treated comparably. The value to the consumer of knowing the caloric value of a food or beverage is the same, irrespective of the venue. We urge the agency to reconsider its decision and declare that facilities such as movie theater chains, grocery stores and convenience stores are subject to the law. If the agency decides to use a floor space or revenue standard, we urge it to redefine the standard to include these types of facilities, such as including all establishments where at least 20% of the revenue comes from food.

Doing Business Under the Same Name - We concur with the FDA that a chain where establishments have similar but not identical names should be regarded as operating under the same name. This would prevent a chain from evading regulation by changing its name at each location, such as the "Joe's Burgers" and "ABC" examples provided in the preamble to the proposed rule. We further recommend the FDA require that, once a chain of establishments is covered by the regulation, it remains covered even if the parent company of the chain changes the name at some of its locations so that there are then fewer than 20 establishments doing business under the same name. The law should apply to facilities in grocery stores of a chain of 20 or more, even if the facility name varies from store to store, and also to movie theaters, convenience stores, and other such retail establishments.

Menu and menu board

AHA concurs that a menu or menu board should be the "…primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.", and that, accordingly, the labeling requirement should apply. We agree with the agency's interpretation that 'primary writing' should be interpreted from the consumer's perspective. Accordingly, when a restaurant or R/SRFE makes available the food choices through a variety of different menus and menu boards - such as a menu board, a paper menu, a children's paper mat menu, an online menu, and a drive through menu board - they should all be required to display the calorie and other information. Addressing the point raised by the FDA in the proposed rule, internet menus should still be subject to the requirement if the customer is not able to place an order on-line. Essentially, if restaurant materials or displays can be used for the purposes of selecting a meal, they should include calories and the other required information.

We would appreciate clarification from the FDA on what would be covered if advertising is exempt. The FDA 'tentatively concludes' that menus sent as a form of advertising 'fall outside of the scope of 4205', yet it then states that take-out and delivery menus are included. It is unclear whether the intent is to include or exclude take-out and delivery menus mailed or otherwise distributed (such as left on car windshields). We agree that it is not appropriate to require calorie labeling in advertising, such as a postcard announcing a new restaurant that has pictures of a few sample dishes. But when the advertising is the menu itself, and can be used as the 'primary writing' a customer uses to make an order, calorie labeling should be required. The test should be whether customers can use the menu as primary writing for making their selection, not the way in which the menu is presented or delivered to the customers by the restaurant or R/SRFE.

Food Covered

We concur with the FDA that labeling should be required for all standard menu items for all foods as defined by the FFDCA. However, we disagree with the agency with regard to the proposed exclusion of alcoholic beverages from any labeling requirements. The agency states that, "…it is not clear that Congress intended for the nutritional information disclosures…to apply to alcoholic beverages…" We strongly disagree. Section 4205 requires nutrient disclosure of standard menu items, and there is no explicit exclusion for alcoholic beverages. In contrast, as the agency is aware, Congress did craft specific exemptions for items such as condiments, daily specials and temporary items. Had Congress intended to exempt alcoholic beverages, they would have written an explicit exemption into the law. Consistent with this, the House sponsor of the law in referring to the exemption of alcoholic beverages (as well as the movie theater exemption) said, "…I am concerned that the scope of the proposed rule does not reflect the intent of the law."[ii] Therefore, the final rule should require that calorie information of all beverages listed on a menu or menu board be displayed, whether they contain alcohol or not.

There is also a strong public health argument why alcoholic beverages should not be exempt. The Dietary Guidelines for Americans recommend consuming alcohol in moderation and excess alcohol intake over time is associated with increased body weight.[iii] Alcoholic beverages are often calorie-dense and vary widely depending on the type of drink consumed. They also provide very few positive nutrients. It is important for consumers to understand their options with alcoholic beverages just as with any other menu item.

Lastly, Section 4205 of ACA states that one of the exemptions should be for 'items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use)'. The Association believes that it is in the interest of public health for this

exemption to be crafted narrowly, and would prefer it to include only those self-serve items on the table that meet FDA's definition for 'calorie free' or that have a Nutrition Facts Panel.

Restaurant food - We applaud the FDA for its definition of restaurant food. However, we recommend that the agency remove the term "walking away" from the definition. We think it would be clearer to state simply that foods served in R/SRFEs that are prepared for immediate human consumption are covered, whether customers choose to consume them on or off the premises. Whether foods are actually consumed on or off the premises should not be a determining factor as to whether a food or facility is covered by the law. In addition, we recommend that FDA clarify that facilities serving take-away food, if they otherwise meet the appropriate criteria of numbers of establishments, are covered by the law, as well as mobile facilities (i.e. food trucks) serving takeaway food.

Daily Specials - The FDA's definition of daily menu specials is appropriate and consistent with the law. The daily special exemption should be reserved for menu items served infrequently and should not be applicable to foods *routinely* sold. It is not burdensome for a restaurant to calculate the nutritional information for a menu item that they routinely serve, even if it is not offered for sale every day. We therefore support the FDA's example that a menu item sold every Monday should not constitute a daily special since it is being routinely sold. Nor should regular menu items be regarded as daily specials if the "special" simply refers to a price change rather than a change to the content of the menu item.

Temporary menu items – The law provides an exemption for menu items on the calendar for 'less than 60 days per calendar year'. We agree that there is no explicit requirement for the 60 days to be consecutive. However, just as a menu item only sold one day a week should not count as a daily special, it also should not count as a temporary menu item, even though it would only be sold 52 days a year. Further, we do not think seasonal menu items such as the pumpkin-flavored latte example described by the FDA should be exempt if the same menu item is offered each year for a set period of time. The purpose of the temporary menu item provision in the law is to allow restaurants to sell menu items for a short period without the burden of generating the nutritional information. There is no need for such concern when the same seasonal menu items are routinely offered each year.

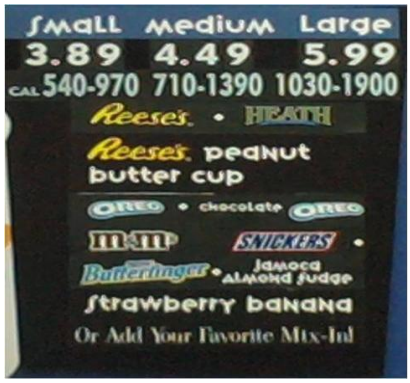
<u>Information that must be declared by Covered Establishments</u>

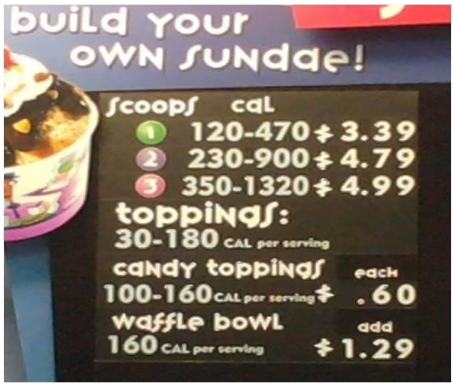
The agency proposes that calories be displayed in increments of 5 or 10 calories for standard menu items. We support this proposal and recommend that FDA retain this requirement in the final rule.

For variable menu items that come in different flavors, varieties, or combinations, the agency proposes a number of options. We support option 2 suggested by the agency, where the calorie information be presented as a range, but only if the agency limits the calorie range allowed. We think that reporting a range is a reasonable approach, but unlimited ranges that result in large differences between the lower and upper values (ex. 150-750 calories), are of little, if any use to consumers.

To illustrate the problem with large ranges, we recommend that the agency consider the experience of consumers in Montgomery County, Maryland, where new menu and menu board calorie labeling requirements were recently implemented. The first two photos are from an ice cream parlor chain. The calorie range for a large cup of vanilla soft serve ice cream (picture on left) with optional candies, cookies and toppings is declared as 1030-1900 calories, a difference of 870 calories. The calorie range for a three scoop sundae (picture on right) is 350 – 1320 calories, a 377% difference

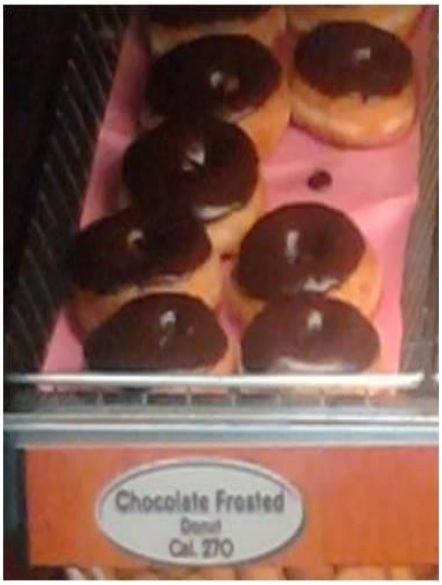
between the greater and the lower value. When ranges are so broad, the customer has no way of knowing the calorie content of the food item they buy. Since consuming an additional 100 kcal/day beyond energy expenditure can account for significant weight gain over time, these broad ranges are essentially meaningless for the consumer who is trying to maintain or lose weight or simply make a healthier selection.[iv, v]



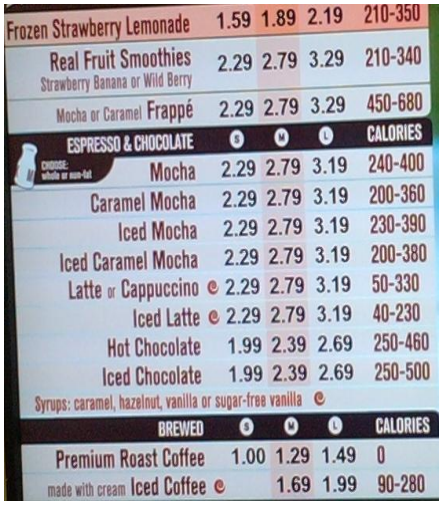


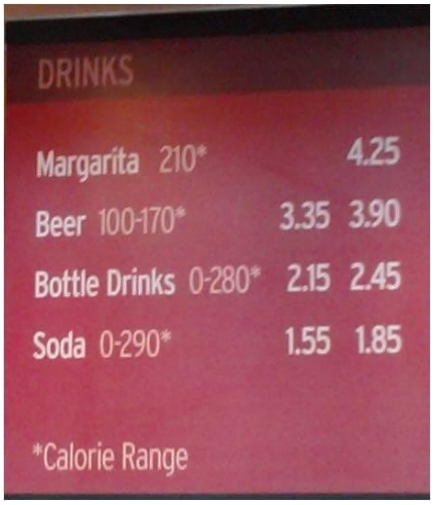
Another menu board of a national fast food chain specializing in doughnuts displays wide ranges on its menu boards. The range of a single doughnut is 200-550 calories (275% difference), which again does little to empower a consumer to make health choices.

However, the same establishment does separately label the calorie content of the individual doughnuts that are on display (see picture below), enabling the customer to learn of the calorie value of each doughnut before making a choice. We think it is acceptable for establishments to display ranges only when they also provide individual calorie declarations for every food item on display.



Where a menu item comes in different sizes, establishments should only be able to display a single calorie range for all sizes if the difference in the lower and upper limits is less than five percent. In the picture below, a national fast food chain displays the calories for a Latte or Cappuccino as 50-330, a 660% difference from the lower to the upper limit. The range is so large because it represents the calories of three different sizes. Similarly, another chain lists the calories in all bottle drinks as 0-280 calories.





In our previous comments to the agency, we recommended that there be a five percent limit in the difference between the lower and upper values. We repeat our recommendation – the agency should establish a limit on calorie ranges. Calorie ranges will only be of use if the FDA imposes realistic limits between the lower and upper values. For items such as pizzas or sundaes, we think it is acceptable for menus and menu boards to display the calories for the standard preparation of the menu items, so long as they also display the added calories in each of the optional toppings or options.

Succinct Statement Concerning Suggested Daily Caloric Intake Required on Menus and Menu Boards

AHA supports the steps the agency is taking to ensure that the proposed statement is conspicuous. We concur that the statement text should be at least as large as any other text, such as the listing of menu items and calorie declarations, and with a contrasting background that allows it to be read easily. We support the requirement that the statement be displayed at the bottom of each page as a reminder to the customer as they make their selections.

The agency requested input on the succinct statement itself. We agree with the agency that it is not an easy task to develop such a statement that takes into account the differing needs of individuals based on their size and activity levels. However, we recommend the statement below, a variation on some of the suggestions listed by the agency in the proposed rule, since it not only captures the typical person's daily needs but succinctly helps consumers understand how individual needs vary:

"A 2,000 calorie daily diet is recommended for most adults; however, individual needs vary depending on age, gender, and physical activity."

For children's menus and menu boards dedicated to children's meals, the FDA should consider requiring a separate statement such as:

"Calorie needs for young children range from 1,000 to 2,000 calories per day and vary based on age and physical activity levels."

We applaud the agency for conducting consumer research to determine which statement best conveys information to individuals regarding their dietary needs in a way that empowers them to make healthy choices.

Nutritional Information That Must Be Made Available in a Written Form

The availability of additional nutritional information is a key provision of the law. It is especially important for consumers wishing to limit specific nutrients in order to maintain or improve their health, such as a person with hypertension pursuing a low sodium diet. To empower consumers, the information needs to be easily obtainable and provided in a format that can be easily read and interpreted by the average consumer.

As stated in previous comments, AHA concurs with the FDA that the additional information should include the amount of *trans* fats in menu items, and applauds the agency for proposing this addition to the nutrition information available. AHA has recognized for over a decade that the consumption of partially-hydrogenated fats is a health risk to the American people. The law clearly provides the Secretary the flexibility to require R/SRFEs to provide this additional information.

For variable menu items, the Association endorses the FDA in its support for option 2 of the three options it proposes, where the nutrition information for each component in the variable menu item is listed. This is the only option of the three that provides consumers with detailed information on how their total nutrient consumption can vary dependent upon their food and beverage selections.

We also support the FDA's assertion that restaurants should be allowed some flexibility in how they provide the information to consumers. We do question, however, the proposal to allow R/SRFEs to print nutrition information on food wrappers. It seems unlikely that there is sufficient room on wrappers to capture all of the nutrition information for all of the food products the establishment

offers on a food wrapper, and to include that information in a format that is easily readable. While restaurants and R/SRFEs may employ a variety of means to make the nutritional information available, the information should be easy to read and interpret, as well as being readily available at point of purchase.

Lastly, as the agency makes future changes to the information provided on the Nutrition Facts Panel, we encourage you to ensure that consistency is maintained between the Nutrition Facts Panel and information provided by restaurants and SRFEs.

Requirements for Self-Service and Food on Display

In general, AHA strongly supports the proposed regulations pertaining to self-service food and food on display. For instance, we agree it is appropriate that the calories be listed on the same sign as the name, price, or both.

The agency requests input on self-serve beverages. We share the agency's concern that the terms 'small' or 'tall' refer to different sized beverages in different establishments, and could be confusing to consumers. We prefer declarations of the calories to be coupled with a declaration of the size of the beverages as measured in ounces. We further believe that the calories should be declared without ice, since to do otherwise could lead consumers to under-estimate the calories in their beverages.

Determination of Nutrient Content

As observed in previous comments to the FDA, the Association recognizes that the statute gives R/SRFEs great flexibility in how they calculate the nutrition content of menu items such as using a nutrient database, cookbook, laboratory analysis, or some other reasonable means. We think this is reasonable and appropriate. That said, we think it important that, whichever method an establishment uses, the FDA must ensure that it is scientifically-based.

We previously recommended that the FDA require, upon request, that covered establishments send evidence explaining how they have determined the calorie and nutrition information provided to the consumer. We are very pleased that the agency intends to require establishments to provide that information upon request. As resources allow, we further recommend that the FDA undertake random testing to ensure compliance.

The agency proposes that there be a limit of 20 percent variance between the declared nutrient value and actual nutrient value. AHA supports this limit, recognizing that this proposal is consistent with the accuracy requirements of the nutrition facts panel. Even relatively small variances can be significant in influencing cardiovascular health.

Federalism

The FDA has requested input on how the statute preempts state or local action to impose menu and menu board labeling requirements that are not identical to those required by the FDA. We concur with the agency that the preemption only covers those R/SRFEs that are required to comply with the law, as well as those establishments that voluntarily register as a covered establishment. It imposes no restrictions on state or local menu or menu board requirements for establishments not subject to the law, such as restaurant chains with fewer than twenty establishments. The rule of construction – ACA Section 4205 (d)(3) - explicitly states that the law does not apply to any R/SRFE other than those defined by the Section 403(q)(5)(H) parts (i) and (ix) of the Federal Food, Drugs

and Cosmetic Act. Thus, we reject the alternative proposal that would prohibit states and localities from imposing menu labeling requirements on establishments that are not covered by the proposed rule.

It is in the interests of public health that a state or locality is able to impose nutrition labeling requirements on establishments not covered by the federal law. The health impact of overconsumption is the same whether the food is consumed in a fast food chain restaurant or a one-of-a-kind local diner. Ultimately, it will be in the best interests of consumers for nutritional information to be provided by all restaurants and establishments providing similar services.

Conclusion

In closing, we appreciate the FDA's efforts to establish regulations to implement Section 4205 of ACA. A key component of reversing the obesity epidemic is enabling consumers to practice calorie control when eating out, especially when eating outside the home is so common in modern society. Consumers therefore need to know how many calories are in all foods and beverages they eat away from home so that their consumption does not exceed their energy needs. The proposed regulation is an important step forward in this direction and we are supportive of many aspects of the proposed rule; however, as discussed above, we also have a number of concerns.

The effectiveness of the law will be limited if the R/SRFE definition exempts many facilities providing a service similar to that of a restaurant. Indeed, the rationale for including SRFEs in the law was to ensure that the statute covered not only restaurants, but other establishments that provide a similar service, and thereby ensure that consumers have the benefit of calorie information irrespective of where they choose to dine. **In the final rule, the FDA should expand the R/SRFE definition to include facilities such as movie theaters, grocery stores and convenience stores.** By excluding these facilities from the menu labeling requirements, the FDA may unintentionally send the message to the public that calories consumed at these facilities 'don't count'.

Similarly, consumers' ability to monitor their calorie intake will be limited if R/SRFEs are not required to provide calorie information for all menu items, or if they are permitted to display large calorie ranges or averages for individual menu items. We therefore urge the agency in the final rule to **remove the exemption for alcoholic drinks**, and to **clarify that calorie ranges may only be utilized if the difference between the lower and upper calorie values is five percent or less.**

If you have any questions or need any additional information, please do not hesitate to contact Sue Nelson, Vice President of Federal Advocacy, at 202-785-7912 or via email at sue.nelson@heart.org.

Sincerely,

Gordon F. Tomaselli, MD, FAHA
President
American Heart Association

[i] http://harkin.senate.gov/press/release.cfm?i=332329 (Accessed 5/24/11)
[ii] Hoover's. An Industry Overview. 2011. http://www.hoovers.com/movie-theatres/--ID__286--/freeuk-ind-fr-profile-basic.xhtml. (Accessed 6/22/11)
[iii] U.S. Department of Agriculture, US Department of Health and Human Services. Dietary Guidelines for Americans 2010. Washington, DC. http://www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf
[iv] Hill JO. Can a Small Changes Approach Help Address the Obesity Epidemic? A Report of the Joint Taskforce of the America Society for Nutrition (ASN), Institute of Food Technologists (IFT), and the International Food Information Council (IFIC). American Journal of Clinical Nutrition 89:477-484, 2009.
[v] Stroebele N, de Castro J, Stuht J, Catenacci V, Wyatt HR and Hill, JO. A Small-Changes Approach Reduces Energy Intake in Free-Living Humans. Journal of the American College of Nutrition 28: 63-68, 2009.