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July 1, 2011

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

Docket No. FDA-2011-F-0171

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 calorie labeling of foods and beverages sold in vending machines.

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.

The Association is pleased that the agency has issued the proposed rule, and is supportive of many elements, such as requiring that calories be declared for a food as it is dispensed, and that calories be declared in 5- and 10-calorie increments. Below we offer suggestions on how the proposed rule for implementing the provisions of Section 4205 governing vending machines can be strengthened.

Vending Machines Without Selection Buttons

In the proposed rule, the agency tentatively concludes that vending machines such as bulk vending machines that do not have selection buttons are exempt from the requirements of the law. We disagree with this interpretation. The law states that a "...vending machine operator shall provide a sign in close proximity to each article of food **or** the selection button..." (emphasis added). The clear intent is to provide vending machine operators with flexibility in complying with the law, not to create an exemption for vending machines without selection buttons. Had Congress intended to exempt such machines, it would have included a clear exemption provision. Compliance with the law is not difficult for operators of such machines which, as the agency observes, generally dispense single types of unpacked articles of food: operators could simply apply a sticker to each machine reporting the number of calories of the item dispensed.

There is neither a public health nor a legal rationale for exempting operators of vending machines without selection buttons. It is important that they are required to comply with the law given that bulk vending machines often dispense candy that is high in calories. **In the final rule, the Association urges the FDA to remove any exemption for vending machines without selection buttons.**

Electronic Vending Machines

According to the proposed rule, electronic vending machines – i.e. machines with digital, electronic or liquid crystal displays – need only display calories once the customer has entered the selection numbers, but before the selection is confirmed, to be consistent with the law. AHA is concerned that this proposal undermines one of the main benefits of calorie labeling - to allow consumers to compare the calories in different foods before making a selection, thus empowering customers to choose options that limit their calorie intake. Under the FDA's proposal for electronic vending machines, customers will only see the calories once they've entered a selection number for an item, making it cumbersome for a customer to compare the calories in different food items. In the final rule, we request that the agency require calories to be displayed before a customer selects an item. Specifically, **the FDA should require electronic vending machines to follow the same requirements for non-electronic vending machines and post the calorie declaration next to each food item or next to the selection button for that food item.**

Proximity of Calorie Declarations

The FDA has concluded that it is permissible for vending machine operators to include the calorie declaration on a separate sign adjacent to the vending machine. We object to this proposal. The law specifies that a sign declaring the calories must be placed, "...in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories in the article..." The law is thus clear in requiring a separate sign for each food and that the sign be placed in close proximity to "each article of food", not in close proximity to the "vending machine". A sign merely placed near a vending machine is less likely to be noticed by a customer when they make their purchase. Just as the agency is requiring calories to be posted directly on menus or menu boards, (rather than requiring restaurants only to place a poster in a restaurant listing calorie information), so the agency should require that calories for each food be posted next to the food itself or the selection button used to purchase it. In each case, the rationale is the same, that the calorie information is displayed so that consumers will see it when they are deciding which foods to purchase. **We urge the FDA to craft a final rule that does not allow vending machine operators to post calorie declarations on posters placed in close proximity to machines rather than on the vending machine itself.**

Nutrition Facts Panels

Consistent with the statute, the agency clarifies in the proposed rule that no separate calorie declarations are required if the Nutrition Facts Panel (NFP) of a food can be read by a prospective purchaser. The Association cautions the FDA that, in general, it is unlikely that a prospective consumer will be able to read the NFP when the food item is in a vending machine. There are many reasons why the NFP may not be visible to the purchaser, such as the NFP being located on the back of the packaging or being covered by the dispensing coil. We therefore support the FDA's tentative conclusion that the NFP "...must be visible in full, without obstruction, before purchase..."

and urge the agency to retain this in the final rule. We further ask the agency when conducting inspections to ensure that NFPs are easily readable by prospective purchasers for **all** foods where calories are not separated declared.

Lastly, we are aware that the Center for Science in the Public Interest (CSPI) has submitted detailed comments to the FDA on this issue. We are supportive of CSPI's comments and encourage the agency to give them strong consideration.

The association appreciates the opportunity to comment on the proposed rule. 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,

A handwritten signature in blue ink, appearing to read 'G. Tomaselli', with a long horizontal flourish extending to the right.

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