July 5, 2011

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

Re: Docket No. FDA-2011-F-0171, Food Labeling; Calorie Labeling of Articles in Vending Machines

The Center for Science in the Public Interest (CSPI)<sup>1</sup> strongly supports calorie labeling of beverages and food items in vending machines. Vending labeling is a useful tool that will allow people to make informed choices for foods and beverages that currently do not provide nutrition information in a manner that people can access before purchasing. We applaud the Food and Drug Administration (FDA) for proposing regulations in a timely manner to implement vending labeling. We strongly support the FDA's conclusion that calories be posted per package (as offered for sale) and that ranges are not needed for labeling vended items.

We strongly disagree with the proposal to allow companies to post the calories for all vended items on a single sign next to a vending machine. Section 4205 of the Affordable Care Act requires that companies provide a sign with calorie information in close proximity to **each** article of food or its selection button. The FDA's proposal is inconsistent with the statute. In addition, we oppose the FDA's proposed exemption for bulk vending machines. The labeling requirement should not depend on whether the machine has a selection button or a crank mechanism. In addition, the FDA should require that the vending labeling be at least as large as the name or price associated with the item, whichever is larger (as opposed to the FDA proposal that the calories be as large as whichever is smaller). Finally, we disagree with the tentative conclusion that calorie information for electronic vending machines could be provided one item at a time, which would prevent consumers being able to compare options and make informed choices.

## Vending labeling is feasible

**Beverage companies have already agreed to vending labeling**. Providing calorie labeling for food items and beverages in vending machines is a new responsibility for some businesses, but not for many beverage vendors, which have already voluntarily agreed to provide calorie labeling on vending machines. Fifty percent of vending machines are for beverages. Most vend

<sup>&</sup>lt;sup>1</sup> CSPI, a nonprofit consumer organization supported by approximately 750,000 members and subscribers to its *Nutrition Action Healthletter* in the U.S., has worked since 1971 to improve health policies and conduct education programs in the areas of nutrition, food labeling, and food safety.

products from Coca-Cola, PepsiCo, and the Dr Pepper Snapple Group, which announced that they would provide calorie labeling for vended products on selection buttons by 2012.<sup>2</sup> The FDA should significantly reduce its cost analysis to reflect that fact.

**Vending labeling is not burdensome**. For those companies that are not already working toward vending labeling, posting calories for vended items could be as simple as adding a sticker for each item on the machine or editing the selection cards in the machine. Few items will need to be analyzed for calorie content, as the overwhelming majority of vended items already have Nutrition Facts labels. Those few items that do not can be analyzed using nutrition analysis software, which is inexpensive and even available for free online.

#### **Definitions**

We support most of the definitions in the proposed rule, including the definition for vending machines. That definition is comprehensive and covers the many different types of machines that consumers encounter. We agree that the requirement that businesses operating or owning 20 or more vending machines should apply just to machines that include foods or beverages, as calorie labeling applies only to those items. The FDA should make clear, however, that vending machines that contain a mix of food and nonfood items are included in that count. For example, if a vending machine in a bus station includes aspirin, mouthwash, and candy bars, the machine should be included in the number of food-vending machines owned or operated by the vendor.

## Requirements

We agree that the FDA should not apply an additional small business exemption. Congress provided an explicit small business exemption for vending operators -- those who operate fewer than 20 vending machines. That exemption in Section 4205 is the standard to be used in this rule, not the definitions of small businesses employed by the Small Business Administration (SBA) or the small business exemption provided under the Nutrition Labeling and Education Act (NLEA). As the FDA pointed out, using the SBA definition would exempt 97 percent of vending operators who would be covered by the proposed rule. Clearly Congress did not pass a law to apply to only 3 percent of the field. Also, Congress chose not to exempt blind vendors operating machines under the Randolph-Sheppard Act or similar state laws and programs, such as Commissions for the Blind. We agree with the FDA that those vendors are covered by the vending labeling requirements.

<sup>2</sup> American Beverage Association. *Beverage Industry Will Make Calories More Clear and Useable for Consumers*. February 9, 2010. Accessed at http://www.ameribev.org/news--media/news-releases--statements/more/180/.

Calorie labels must appear next to each vended item or its selection button. The FDA's proposal to allow companies to post the calories for all items on a single sign next to or on a vending machine does not comply with the requirements of the statute. The law requires that companies must "provide a sign [disclosing the calorie content] in close proximity to each article of food or the selection button" providing the calories separately for each vended item (emphasis added).

The FDA should therefore revise §101.8(c)(2)(ii)(A) in the final rule to read:

This calorie information mustay be placed on a sign in close proximity to the each article of food or its selection button, i.e., in, or on, or adjacent to the vending machine., but not necessarily attached to the vending machine, so long as the sign is visible at the same time as the food, its name, price, or selection button or selection number is visible.

The FDA should strike §101.8(c)(2)(ii)(C) in the final rule:

(C) When the calorie information is declared on a sign adjacent to the vending machine, the calorie declaration must be in type that is all black or one color printed on a white or other neutral background that contrasts with the type color.

The FDA has proposed in §101.8(c)(2)(ii)(A) that the sign posting calorie counts be "visible at the same time as the food, its name, price, or selection button or selection number is visible." Thus, the sign must be in a person's field of vision when they are looking at the name, price, or selection button. The only way to achieve that would be for the calories to be listed directly on the vending machine on the button or adjacent to the food item.

It is essential that the nutrition information be easy to see and easy to use. Just as the menu labeling proposed rule would require that signs be placed directly next to each food on display in restaurants, so calories for vended items should be directly next to the vended item or its selection button or device (such as a crank on a bulk vending machine). Consumers are not used to getting nutrition information for vended items. It is likely they would not see a sign posted next to a vending machine, even if the font size for the calories is large. There is ample space on or in vending machines for the calories to be posted in close proximity to each item or selection button, as Congress intended.

Also, it would be difficult to list the calorie information in the same order on the signs as they appear in the machines, given that products in vending machines are arranged in a grid of rows and columns and signs are more likely to present a single list of items. Having a different order or arrangement for the vended items and the nutrition information for those items would make it harder for consumers to find an item's nutrition information than if the information was

placed directly next to the item or its selection button. Signs also would not allow people readily see and easily use price and nutrition information together.

The vending labeling requirement does not depend on whether the machine has a selection button.

The FDA should strike  $\S101.8(c)$  (1)(i)(C) of the proposed rule:

(C) Is a vending machine with a selection button;

Congress was very specific about what exemptions it provided in Section 4205. Bulk vending machines were not included among the exemptions. We agree with the FDA's proposed definition of vending machines. But we strongly urge the FDA to require calorie labeling for all types of vending machines included in that definition. Congress' mention of selection buttons on vending machines referred to where the nutrition information should be placed. Congress was simply requiring that information be placed next to the food item itself *or* near the selection button. While most vending machines have selection buttons, the lack of a selection button is not a legitimate reason to exempt a vending machine from the calorie labeling requirement. In addition, for many such machines, a crank serves the purpose of a selection button. This modest difference in design seems a poor excuse for exempting the entire category of bulk vending machines from calorie labeling.

Indeed, posting calorie for bulk vending machines should be easier than for other vending machines, given the (1) limited number of vended items, (2) ready availability of calorie information for most of those items, and (3) ample space available to provide the calorie label.

According to the proposed rule, 20 percent of vending machines are bulk vending machines. While the revenue generated from those machines is a relatively small fraction of overall vending revenue, they represent a significant proportion of total vending. Also, bulk vending machines often contain foods of poor nutritional quality, such as candy, for which consumers especially need calorie information. Finally, adding bulk vending to the final rule would increase the cost of nationwide implementation (over what the proposed rule would cost) by only \$6 million, according to the FDA's cost estimates. Indeed, even that cost seems like an overestimate given that a sticker with the calorie content printed on it simply could be added to a bulk vending machine (see Figure 1 and 2 below). Looking at the FDA's more reasonable low estimate, the increase in cost would be just \$3 million.

Figure 1



Figure 2



It is vital that the calorie postings be clear and conspicuous. We urge the FDA to require that the calorie labeling be at least as large as the name or price associated with the vended item, whichever is larger (as opposed to the current proposal that the calories be as large as whichever is smaller). For the calorie information to be useful, the calories must be prominent and easy to read. We agree that the color and contrasting background must all be comparable to the name and price of the item, making it as easy to see and read as other ordering information.

The FDA should revise  $\S101.8(c)(2)(i)(C)$  of the proposed rule to read as follows:

For calorie declarations in or on the vending machine, the declaration of calories must be in a type size no smaller than as large as the name of the food on the machine, (not on the food label), selection number, or price of the food as displayed on the vending machine, whichever is largest smallest, with the same prominence, i.e., the same color, or in a color at least as conspicuous, as the color of the name, if applicable, or price of the food or selection number, and the same contrasting background, as the item it is in closest proximity to, i.e., name, selection number, or price of the food item as displayed on the machine.

We agree with the proposed rule that only if the full Nutrition Facts panel is readily visible without obstruction before purchase would the vendor have to provide a sign listing the

calories. We agree that it is important that not only the calorie information be visible, but also the serving size, given that many vended products include more than one serving. Possible obstructions include the coils of the vending machine, as well as folds in packaging. We agree that the Nutrition Facts label must be large enough to be read from the point of purchase for the exemption to take effect, and that smaller-format Nutrition Facts labels would not meet that requirement. Standing in front of a vending machine, a person usually would be too far away to read those small labels. It is not uncommon for candy bars to use small label formats and for the Nutrition Facts label to be under a fold in the packaging (see example in photo below).



We agree with the FDA that prominent front-of-pack labeling could be a way to provide visible nutrition information, as long as the calories are listed for the whole vended item and the font size, color, and contrasting background make the nutrition information readily visible and easily readable from the point of ordering. The final rule should clearly specify that to qualify for an exemption, such front-of-pack information must be provided for the entire vended item as offered per sale, and not per serving. The front-of-pack information must be clearly visible, unobscured by the coil or placement in the vending machine. We agree with the FDA that the exemption provided for items that "otherwise provide visible nutrition information" could only be for information on the package of the vended item.

**People must be readily able to make comparisons between items before making a purchase decision**. We disagree with the FDA's tentative conclusion that calorie information for electronic vending machines could be provided one item at a time and could be visible only once a consumer puts their money into the machine or presses a selection button. The calorie information for all the items in a vending machine must be available and readily visible to people **before** they make their purchase selection. It also must be available at the same time for all items in the machine to allow people to make comparisons between items. Making comparisons between items is a key way that people use nutrition information. People not only want to know that a Butterfinger candy bar has 270 calories, but also that it has 120 more calories than a bag of Pretzel M&M's (150 calories per bag).

The final rule should strike proposed §101.8(c)(2)(ii)(E):

(E) For electronic vending machines (e.g., machines with digital or electronic or liquid crystal display (LCD) displays), the calorie information may be displayed when the selection numbers are entered but before the selection is confirmed.

**Rounding calorie numbers is essential.** It is essential that calorie numbers be rounded as the FDA has proposed and as is required for Nutrition Facts labels. Unrounded calorie numbers would imply a precision that is misleading. Also, it is harder for consumers to make comparisons between unrounded numbers.

**Use of the term calorie or cal.** We agree that the word calorie or cal must be adjacent to the calorie number. People are not accustomed to having calorie labeling on vending machines. Without this identifier, it might be unclear what the number means.

Calories must be listed per item as offered for sale. We strongly support the FDA's conclusion that calories be posted per item as offered for sale. Section (H)(viii) of the statute explicitly requires the disclosure of calories contained in the whole vended item (even if the Nutrition Facts label on that item indicates it as more than one serving). The statute does not allow for exemptions for gum and mints as some vendor have requested.

Serving size information on packaged foods can be confusing. In one study, two-thirds of people could not correctly calculate the nutrition information in a 20-ounce bottle of soda that was labeled as 2.5 servings.<sup>3</sup> In addition, it would be deceptive to label a bag of chips as 160 calories (per one-ounce serving) on the vending machine, only to have people discover that the whole bag of chips contained 240 calories (in the whole 1.5-ounce bag) once they purchased it.

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<sup>3</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.

We disagree with the FDA's tentative conclusion that would allow vendors to also label items per Nutrition Facts serving, even voluntarily. That additional information would add clutter and confusion to vending labeling. It is rare that such items are eaten by more than one person or in more than one eating occasion. Vended items such as candy bars, snack cakes, bottles of soda, and chips usually are sold in sizes that are consumed by one person in a single eating occasion.

§101.8(c)(2)(E) should be revised as follows:

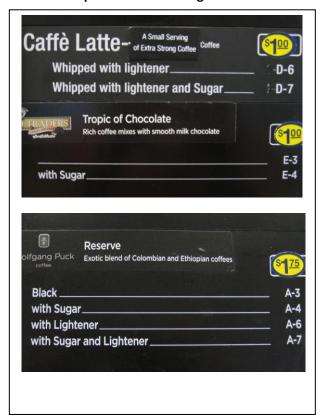
The number of calories for packaged foods that contain multiple servings must include the total calories present in the covered vending machine food. The vending machine operator may not voluntarily disclose calories per serving in addition to the total calories for the item food.

Ranges. We agree that ranges are not needed for labeling vending items. Items rarely are displayed in a manner in which two or more flavors or varieties of the item are listed together. There are generally unique items in each slot. For those exceptions, like hot coffee, we agree with the FDA that the selection buttons provide ample opportunity for labeling the different options available (see photos below).

#### **Coffee Vending Machine**



#### **Close up of Coffee Vending Machine**



Calorie analysis. We agree with the FDA that for calorie labeling companies should use the nutrition information provided on Nutrition Facts labels when such information is available. That would be easiest for vendors and provide accurate information for consumers. When such information is not available, vendors could demand calorie information from their suppliers or use databases, laboratory analyses, or other reasonable basis determinations. Companies need only provide calorie information or information about the methodology used to determine the calorie information to the FDA at the FDA's request -- for example, if there are enforcement concerns regarding the accuracy of the posted information.

# **Enforcement and implementation**

**Timeline.** We urge the FDA to enforce the final vending labeling regulations six months following publication of the final rule, not one year later as proposed. If six months is enough time for restaurants, it should be ample time for vending operators. As noted above, the major beverage companies have already agreed to implement vending labeling by 2012. Only a small fraction of vended items will require new nutrition analyses, and posting the calories on the vending machine can be as simple as adding a sticker next to each vended item or its selection mechanism.

The FDA can and should enforce vending labeling in a number of ways:

- a) Devise a reporting mechanism and regime of penalties for violation of the federal law. The FDA should set up a simple process for consumers, competitors, local health inspectors, and others to report potential violations of the federal requirements and develop a system for collecting and storing reports of violations in a database that would be accessible to the public and state and local authorities to aid enforcement efforts. The FDA should detail the penalties for violations of the law and direct any funds from fines or penalties to support the reporting system and inspection programs enforcing the federal menu labeling and vending labeling laws.
- b) Support state and local enforcement of the federal law. The FDA should provide training, guidance, and funding to states and localities to facilitate enforcement of the federal menu labeling and vending labeling regulations. The delegation of inspection authority to the states will need to be explicit. Although 21 U.S.C. §337 authorizes states to enforce the federal law in their own names, this option has proven to be of little or no utility to state authorities. Indeed, it is our understanding that this provision has rarely, if ever, been used in the decades that it has been in existence.
- c) The FDA should support state and local initiatives to enact "identical" vending labeling requirements (as it works with them to enact menu labeling requirements).

For reasons of familiarity, tradition, and established practice, local and state authorities are more likely to enforce their own laws than they are to enforce a federal law. Thus, the FDA should encourage and facilitate state and local enactment of new menu and vending labeling laws and amendment of existing menu labeling laws by providing technical assistance to jurisdictions that are working to enact "identical" disclosure requirements in their laws or amend their existing menu labeling law to make it "identical," including adding a vending labeling requirement. The FDA could provide this assistance in various ways, including (1) making staff available upon request to help assess proposed language for potential conflicts with the federal law and (2) providing model legislation, which could be made part of the Model Food Code. The FDA should reiterate in its technical assistance that the language of the state or local measure need not be the same as the federal law in order for the relevant labeling requirements to be considered "identical." The word "identical" does not mean verbatim in wording but rather in effect -- state or local requirements that are worded differently from the federal requirements may still be "identical" under Section 4205, unless they compel more than federal law requires. See 21 C.F.R. 100.1(c)(4).

As several court opinions have made clear, "identical" means that the language used is substantially the same as the parallel language found in the FDCA, and that differences between them do not result in "materially different requirements." In other words, a court should analyze the phrasing in terms of equivalence. "As long as Plaintiff's state law claims do not impose different requirements than the FFDCA or FDA regulations, these claims are not preempted."

State and local enforcement mechanisms need not be "identical." A significant benefit of local statutory regimes is that they allow states and municipal governments to make use of their existing inspection and enforcement apparatus. We recommend that language be added to the final rule that makes express an assumption that is implicit in the proposed rule: that enforcement provisions included in state or local menu and vending labeling laws—for example, the administrative processes or remedies used to bring about compliance—are not affected by Section 4205 and need not be "identical" to those of the federal regime. Such a statement would be fully consistent with a statute that explicitly contemplates the parallel existence and operation of state and local menu and vending labeling regimes.

<sup>4</sup> See Vermont Pure Holdings, Ltd. v. Nestle Waters N. Am., Inc., CIV.A.03-11465 DPW, 2006 WL 839486 (D. Mass. Mar. 28, 2006) (quoting H. Rep. No. 109-379 (Feb. 28, 2006).

<sup>5</sup> Pom Wonderful LLC v. Ocean Spray Cranberries, Inc., 642 F.Supp.2d 1112, 1121 (C.D.Cal.2009); See also Reyes v. Mcdonald's Corp., 06 C 1604, 2006 WL 3253579 (N.D. III. Nov. 8, 2006) (citing Bates v. Dow Agrosciences LLC, 544 U.S. 431, 454, 125 S. Ct. 1788, 1804, 161 L. Ed. 2d 687 (2005)).

## Preemption

The proposed rule adopts an appropriately circumscribed view of the extent of preemption of state and local authority with respect to nutrition labeling on vending machines. Unlike the Guidance issued August 25, 2010, the proposed rule takes into account the directives in the Affordable Care Act and the NLEA that Section 4205 preempts state and local law only where it does so expressly. In doing so, it applies the federalism principle of Executive Order 13132 that preemption in rulemaking be limited to instances where it is clearly required by legislation.

The proposed rule properly construes the preemptive effect of Section 4205 as limited to state and local laws mandating additional or different nutrition labeling requirements for food sold either (1) from vending machines that are operated by a person engaged in the business of owning or operating 20 or more vending machines subject to the requirements of 21 U.S.C. 343(q)(5)(H)(viii) or (2) from vending machines operated by a person not subject to the requirements of 21 U.S.C. 343(q)(5)(H)(viii) who voluntarily elects to be subject to those requirements by registering biannually under 21 U.S.C. 343(q)(5)(H)(ix).

This interpretation is, as the proposed rule notes, consistent with the fact that Congress included vending machine operators in the voluntary registration process. Plainly, there would have been no need to include vending machine operators in the provision that allows opting in to the voluntary system if states and localities could not otherwise require non-identical nutrition labeling for food and beverages sold from vending machines.

The alternative position -- that no state or locality may have a vending machine nutrition labeling requirement not identical to the Federal requirements, regardless of how many vending machines the operator owns or operates -- would create a regulatory vacuum inconsistent with the purposes and language of section 4205. It also would impose a restriction on states and localities inconsistent with the federalism principles expressed in Executive Order 13132. The petition process set out in 21 U.S.C. 343-1(b) and 21 CFR 100.1 would not fill that vacuum. In the decades that it has been available, there has not yet been a successful petition. The proposed rule properly construes the preemptive effect of section 4205.

"Identical" requirements. The final rule should explicitly state that, as provided by 21 CFR 100.1(c)(4), the word "identical" does not mean verbatim in wording but rather in effect --that is, state or local requirements that are worded differently from the federal requirements may still be "identical" under Section 4205. The rule might state, for example, "The specific words need not be the same. State or local requirements that are worded differently from the federal requirements and/or provide for different enforcement schemes may still be 'identical' under Section 4205."

<u>Warning statements.</u> The proposed rule correctly recognizes that state and local requirements for warning statements about the safety of food are explicitly *not* preempted by Section 4205.

The final rule could usefully clarify the scope of such exempted warnings. Given the flexibility necessary to meet new and emerging health threats, and to react swiftly to developments in scientific research, the exemption should be construed broadly enough to include at least consumer advisories, warnings in the form of symbols, allergen warnings, and similar alerts. The final rule should clarify that the exemption for statements providing a warning about the safety of a food or food component relates to the overall safety of the product, not just to microbiological contamination of food. Information about safety concerns regarding foods, unsafe food additives, or components of food that contribute to chronic disease also are not preempted. For example, a state or locality could require a warning notice about high levels of sodium in menu items that have the potential to contribute to high blood pressure and heart disease.

Rule of construction. The savings clause for warnings appears in a Section 4205(d) of the Affordable Care Act, designated "Rule of Construction," that is not codified. Because the absence of the Rule of Construction from the text of the United States Code may lead to confusion in properly interpreting the statute, we urge the FDA to set forth the Rule of Construction in the Code of Federal Regulation. The lack of a codified statement of a similar rule of construction in the NLEA (or an explicit restatement of the rule in the Code of Federal Regulations) has led to confusion and to court decisions that have not taken that rule into account -- presumably because litigants and courts were unaware of it. (*See, e.g., In re Farmed Raised Salmon Cases*, 142 Cal.App.4th 805 (Cal. Ct. App. 2006) (later overruled by California Supreme Court, which relied on the uncodified provision); *Cohen v. McDonald's Corp.*, 347 Ill.App.3d 627 (2004).) Ensuring that the "rule of construction" is explicitly set out in the CFR could help to avoid similar problems with the vending labeling law.

### **Conclusion**

We strongly support the FDA's conclusion that calories be posted for items as offered for sale (per package) and that ranges are not needed for labeling vended items.

However, we strongly oppose the proposal to allow companies to post the calories for all vended items on a single sign next to a vending machine and the proposed exemption for bulk vending machines. Those proposals are inconsistent with the statute and could be challenged in court if finalized. In addition, we urge the FDA to require that the calorie labeling be in print at least as large as the name or price associated with the item, whichever is largest (as opposed to the proposal that the calories be as large as whichever is smaller). Finally, we disagree with the tentative conclusion that calorie information for electronic vending machines could be provided one item at a time, which would prevent consumers from comparing options and making informed choices.

We thank the FDA for its work so far and respectfully urge that it correct these weaknesses in the final rule, issue the final rule in a timely manner, and provide companies with six, not twelve, months to implement the regulations following publication of the final rule.

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