Scott Gottlieb, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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Re: Request for Enforcement Discretion on the Vending Machine Labeling Rule // Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines

Dear Commissioner Gottlieb:

On behalf of the National Automatic Merchandising Association (NAMA), the Grocery Manufacturers Association (GMA) and the undersigned trade associations (the coalition), we are writing to request that the Food and Drug Administration (FDA or Agency) exercise enforcement discretion with respect to specific provisions of the Calorie Labeling of Articles of Food in Vending Machines final rule¹ until FDA makes the technical amendments to this rule to which it has committed. ² We are joined in this request by an industry coalition including American Beverage Association, National Confectioners Association, and SNAC International. We expect that once the technical amendments to the vending labeling rule are finalized, the agency would provide an appropriate compliance period to allow companies to make any necessary changes to labels or signage in, on, or adjacent to vending machines³.

The coalition thanks FDA for its continued work on vending labeling and appreciates the Agency's recognition of our industry's concerns. In August 2016, the Agency issued a limited extension in the compliance date for several specific provisions of the vending labeling rule⁴ to July 26, 2018, to align with the compliance date for the nutrition labeling regulations, with the expressed intention to issue a

¹ 79 Fed. Reg. 71259 (Jan. 01. 2014) Food Labeling; Calorie Labeling of Articles of Food in Vending Machines.

² In the proposed rule <u>Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size</u>, currently under EO 12866 review, FDA is proposing to amend regulations on the type size requirement for calorie declarations for certain foods sold from chain vending machines covered by statutory calorie disclosure requirements and changes to the type size requirements for Front of Pack (FOP) labeling in glass front vending machines.

³ In the case of the beverage industry's FOP labeling program (Clear on Calories), provided that FDA revises the final rule to provide for a minimum type size that is at least 150 percent of the size of the net quantity of contents, additional time to change labels would not be needed because that FOP labeling program already provides for the visible nutrition information to be in type size of at least 150 percent of the statement of net quantity of contents.

⁴ 81 Fed. Reg. 50303 (Aug. 01. 2016) Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date 81 Fed. Reg. 50303 (Aug. 01. 2016) Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date. The previous compliance date extension for 21 C.F.R. § 101.8(b)(2) was limited to food that is (1) sold from a glass-front vending machine that allows prospective purchasers to view packaged foods offered for sale; (2) not a covered vending machine food within § 101.8(b)(2); and (3) the label for such packaged foods provides front-of-package calorie disclosures that complies with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label. FDA also issued a compliance date extension for § 101.8(c)(2) limited to (1) gums, mints, and roll candy sold in packages that are too small to bear FOP labeling and where the gums, mints, and roll candy are located in a small space within a glass-front vending machine that allows prospective purchasers to view packaged foods offered for sale; where (2) the space within the glass-front vending machine holding the gum, mints, and roll candy is so small such that it is not practicable to provide calorie information under each gum, mint, or roll candy; and (3) the glass-front vending machine also does not or is not capable of providing calorie information electronically.

proposed rule to address stakeholder concerns about technical challenges for implementation. The Constituent Update was quite clear in its intentions regarding a proposed rule.

As noted in our July 2017 comments to the Agency⁵, the coalition identified these areas of concern in the vending labeling rule: (1) align the compliance date for the vending machine labeling rule with the forthcoming, and now final, extension in the compliance date for the Nutrition Facts Panel (NFP) revisions (which has now been finalized as January 1, 2020 for large manufacturers), so that companies only have to revise labels once to comply with both sets of requirements; and (2) require front-of-pack calorie information to be in a type size of at least 150% of the size required for the net quantity of contents, and (3) amend the final rule to allow the use of signage inside the vending machine or in close proximity to the article of food that could apply to the two bottom rows of gums, mints, and rolled candies that have 25 calories or less per serving, a reference amount of 5 grams or less, and that contain at least three servings per package.

The coalition notes that a proposed rule addressing these technical concerns was received by the Office of Management and Budget (OMB) on January 2, 2018, and remains under review. With the July 26, 2018, compliance date approaching, and the proposed rule on vending labeling not yet issued, the coalition's members continue to lack critical information for effective implementation of the vending labeling final rule by July 26, 2018, including information on the minimum type size that a front-of-pack calorie declaration would need to meet, and on the appropriate display of calories for gums, mints, and rolled candies.

Request for Enforcement Discretion

The coalition requests FDA exercise enforcement discretion with respect to specific provisions of the final rule that were covered by the agency's original August 2016, compliance date extension, until the completion of the technical amendments rulemaking process when a final rule is in place. We anticipate that FDA's proposed rule, and final rule when in place, would prevent the large cost associated with amendments to font size and reduce compliance costs to vending machine operators. With a rule pending, and if enforcement discretion is not granted, these benefits cannot be realized, as companies must invest in changes in absence of a final rule. Further, due to time needed to update FOP labeling, it would unduly burden vending machine operators with the need to apply signage on or adjacent to nearly every glass front vending machine until such time as the manufacturer makes label changes. Issuing enforcement discretion for these limited provisions until the final vending labeling rule is issued would allow for manufacturers to await additional information that may come from a proposed rule once published and then make labeling changes accordingly. It would be appropriate for the agency to provide a one year compliance period following the effective date of the technical amendments final rule to allow companies to make necessary changes to labels or vending machine signage.

This is an extremely important issue to our industries. Our collective members have made a significant investment in voluntary front-of-pack labeling, changes to the Nutrition Facts Panel and signage on or near vending machines to comply with the rule.-Furthermore, there will be significant market disruption

⁵ July 19, 2017 Coalition Request for Compliance Date Extension and Revisions to Vending Machine Labeling Rule (see attachment)).

and cost incurred if companies must proceed in labeling changes to meet the compliance date of July 26, 2018, while continuing to lack crucial information needed to comply with the rule. We respectfully a request a response from the agency by June 5, 2018, in order to ensure adequate time for stakeholder response.

Closing

The coalition is committed to giving consumers the information and tools they need to make informed choices. Enforcement discretion related to vending machine calorie labeling is urgently needed while the agency continues the rulemaking process. The coalition looks forward to partnering with the Agency to provide the clarity needed for effective industry implementation of the Calorie Labeling of Articles of Food in Vending Machines. We look forward to your response.

Attachments: July 19, 2017 Coalition Request for Compliance Date Extension and Revisions to Vending Machine Labeling Rule

Sincerely,

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for Scientific and Regulatory Affairs and Chief Science Officer

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