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Mr. Erik Mettler  
Office of Policy  
Food and Drug Administration  
10903 New Hampshire Avenue, W01  
Room 4300  
Silver Spring, MD 20993

**Re:** Docket No. FDA-2009-N-0294

Dear Mr. Mettler:

On behalf of the National Association of Convenience Stores (“NACS”), we welcome this opportunity to provide our views in response to the Food and Drug Administration (“FDA”)’s request for comments concerning implementation of the Family Smoking Prevention and Tobacco Control Act (the “Act”), Pub. Law 111-31, which vests the FDA with the authority to regulate sales of cigarettes and other tobacco products.<sup>1</sup> NACS is an international trade association representing more than 2,200 retail convenience stores and 1,800 supplier company members. The U.S. convenience store industry has nearly 145,000 stores across the nation. While 49 of the largest 50 convenience store chains in the United States are members of NACS, the majority of NACS members are small, independent convenience store operators.

The Notice solicits comments on implementation and enforcement of rules governing the sale and marketing of tobacco, among other matters. The Notice further indicates that FDA is particularly interested in approaches and actions that will reduce the incidence of tobacco use. NACS accordingly provides its comments with these issues in mind.

Generally, the matters of greatest concern for convenience stores relate to the regulations that will govern the sale and marketing of tobacco products, as regulation in this area will directly impact retailers’ activities and responsibilities. Of particular importance will be how compliance with these restrictions will be enforced with respect to retailers. And along with these substantive issues are concerns related to parity in treatment of convenience stores versus other retail sectors. Comments and concerns in each of these areas are discussed in detail below.

## **1. Compliance/Enforcement**

### **a. Retailer Training Programs**

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<sup>1</sup> Regulation of Tobacco Products; Request for Comments, Food and Drug Administration, Department of Health and Human Services, Docket No. FDA-2009-N-0294, 74 Fed. Reg. 31457 (July 1, 2009) (“Notice”).

From a retailer’s perspective, the Act’s incentives designed to encourage formal training of retail employees concerning tobacco sales restrictions are among the most noteworthy aspects of the law. We note, for example, that the penalties for violating sales and distribution restrictions (such as the federal age verification rule that will require an identification check for any in-person tobacco purchaser under age 26) can be reduced, or avoided altogether in some cases, if the retailer has an “approved training program” in place.<sup>2</sup> And the Act directs HHS to implement other forbearance measures for retailers who are taking “effective steps” to prevent sales to minors, and describes “effective steps” as including employee education concerning applicable laws.<sup>3</sup> Employee training is very important to ensure that retailers comply with the law and to help achieve FDA’s goals of reducing youth access to tobacco. There is no better way to facilitate widespread, voluntary compliance with the law than to provide meaningful guidance and help get training that is effective and usable to retailers.

The Act directs FDA to develop standards for “approved training programs.”<sup>4</sup> NACS members have experience with and currently utilize the “We Card” program, run by the Coalition for Responsible Tobacco Retailing, Inc. (of which NACS is a member). We Card is an award winning program that has trained hundreds of thousands of retailers since 1996 both in classroom and in online settings. To date, We Card has held more than 2,100 classroom training sessions in all 50 states and in the U.S. territories; 237 regional, state, and local trade associations support the We Card program; state government agencies in 25 states have supported the We Card program; and more than 1 million We Card kits have been distributed to retailers nationwide.

We Card includes formal training for store employees on matters such as identifying underage customers, calculating a customer’s age properly, handling difficult situations, and denying tobacco sales to minors. We Card also provides retailers with a wealth of resources such as information and updates on various state and federal laws governing tobacco sales, as well as best practices and tools for assessing the effectiveness of stores’ compliance efforts (for more information, see [http://www.wecard.org/index.php?option=com\\_frontpage&Itemid=1](http://www.wecard.org/index.php?option=com_frontpage&Itemid=1)). These training programs include hands-on exercises and help individuals not just understand the laws that are in place, but understand how they can comply within the context of the pressures they face on the job. In contrast, most training programs that have been used by the various states simply provide the text of legal requirements but are not designed to ensure that people apply the knowledge and learn how to comply with the law.

NACS urges FDA to designate We Card as an approved training program under the Act. Because We Card is already an established program and is in use by thousands of retailers nationwide, approval of We Card would have the advantage of rapid implementation and higher compliance rates among retailers, characteristics the Act also seeks to promote. Finally, retailers

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<sup>2</sup> See Act, Section 103(q)(2)(A)(i).

<sup>3</sup> *Id.* § 103(q)(1)(F).

<sup>4</sup> *Id.* § 103(q)(2)(B).

would benefit from having less disruption and lower compliance costs, points especially important for the scores of small, independent convenience stores across the nation.

b. Other Enforcement Issues

The Act instructs FDA to promulgate the Final Rule on tobacco regulation that FDA originally adopted in 1996.<sup>5</sup> As part of the 1996 Final Rule, the FDA would require retailers to check photographic identification of any purchaser who appeared to be age 26 or younger.<sup>6</sup> NACS does not disagree with the approach of using a high age threshold to increase the likelihood that sales to minors will not occur. In fact, many training programs (including We Card's) take this approach to more effectively ensure compliance. The FDA should, however, bear in mind that the Act outlaws sales to persons younger than 18. The Act does not outlaw failure to check identification of persons who appear 26 or younger.

It follows that the agency should ascribe penalties to the act of selling tobacco products to those under 18, and not a failure to check identification of someone who appears younger than 26. Such an approach is reasonable given the realities of tobacco retailing. For example, many convenience stores have customers who come in regularly – sometimes daily – to purchase tobacco products. After a clerk has checked the identification of the same person multiple times and observed that the person is 18 or older, that clerk and store should not face a penalty if the clerk, thereafter, does not check that customer's identification. While penalties should, consistent with the Act, only be imposed when sales are made to underage persons, FDA could still strongly incentivize checking identification for everyone 26 or younger through its process of approving training programs.

c. Procedural Due Process Protections for Retailers

A number of procedural protections for retailers were adopted in the Act, such as the requirement of timely and effective violation notices to retailers before a follow-up compliance check is conducted,<sup>7</sup> and a requirement that no civil fines or no-sale orders may be imposed upon a retailer without first providing the retailer with an opportunity for a hearing.<sup>8</sup>

The FDA is directed to establish rules to implement these due process protections, and should keep in mind that these procedural due process protections are critically important to all retailers, but especially small ones whose livelihood depends on their ability to offer the full range of products consumers expect to find available at their local convenience store.

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<sup>5</sup> Act § 102(a)(2) (referencing “Restrictions Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,” Final Rule, 61 Fed. Reg. 44615 (Aug. 28, 1996)).

<sup>6</sup> See 1996 Final Rule, 61 Fed. Reg. at 44439.

<sup>7</sup> *Id.* § 103(q)(1)(B).

<sup>8</sup> *Id.* § 103 (c).

NACS also emphasizes the need for these rules to afford small store owners a full and fair opportunity to be heard if a hearing becomes necessary. For example, the Act notes that telephonic hearings should be available at a retailer's request.<sup>9</sup> The FDA's rules must, therefore, provide for telephonic hearings. The agency should also make use of the closest appropriate federal, local or state facility for in-person hearings (as appropriate to the type of hearing) in addition to using FDA field offices as specified in the Act.<sup>10</sup>

d. Offsetting State and Federal Fines

In assessing federal civil penalties for violations by retailers, the Act directs FDA to consider any state penalties paid by the retailer for the same violation.<sup>11</sup> The report language makes clear that this means federal fines must be reduced by the amount of any state fines paid for the same violation.<sup>12</sup> Therefore, the rules must be structured to fulfill this explicit Congressional intent that retailers not face duplicative state and federal fines for the same violation.

2. Parity Among Retailers

The Act contains a number of directives aimed at ensuring parity in application and enforcement of the tobacco regulations among various types of retailers. For example, the Act explicitly requires that the restrictions applicable to retail sales be enforced against retailers on Indian reservations,<sup>13</sup> and that sales, marketing and advertising restrictions be developed for remote (i.e., mail order and Internet) sellers of tobacco products.<sup>14</sup>

We note, however, that because of separate rulemaking timelines incorporated into the Act, remote retailers could have more time than face-to-face retailers to come into compliance with age verification and marketing rules.<sup>15</sup>

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<sup>9</sup> *Id.* § 103 (q)(1)(C).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.* § 103 (q)(2)(C).

<sup>12</sup> “Section 103(q)(2)(C) is designed to protect retailers against the imposition of double penalties based on a single violation of any restriction under section 906(d) by directing the Secretary to consider the amount of penalties paid to a state by a retailer for the same violation.” H.R. Rep. 111-58, Part 1 (2009) at 48.

<sup>13</sup> Act § 102(a)(5).

<sup>14</sup> *Id.* § 101(a) (which created new Section 906(d)(4) in the Federal Food, Drug, and Cosmetic Act).

<sup>15</sup> This is so because Section 102(a) of the Act directs the FDA to make age verification and certain marketing rules effective one year from the date the Act became law (i.e., June 22,

Parity is not promoted by giving Internet and mail order retailers more time to comply with restrictions designed to discourage sales to minors. Indeed, more minors may be driven to remote purchasing channels if those channels are not subject to similar restrictions at the same time as face-to-face retailers. There is no need to delay – given that there are already a number of ways to restrict remote sales to minors. The FDA can, and should, implement age verification and marketing restrictions for Internet and mail order simultaneously with those for face-to-face retailers. These rules should require an actual check of an ID at the point when the product is delivered to the consumer. Delivery companies already have services to do this and remote sellers of tobacco should be required to use them. These services should also be subject to enforcement efforts to ensure they are checking IDs.

In addition, the FDA should include concrete provisions for enforcement on Indian reservations as part of its overall enforcement plan.<sup>16</sup> Often, tribes themselves are involved in the sale of tobacco on reservations. With that in mind, FDA should implement a plan such that the agency directly enforces the law on reservations. Contracting that important function to an entity that acts as a retailer of tobacco products is unrealistic and unlikely to lead to compliance.

Finally, Congress has emphasized the importance of having FDA inform manufacturers, retailers, and others, that there are no restrictions on the types or locations of retailers that can sell smoking cessation products so long as the retailers verify purchasers' age.<sup>17</sup> Given the obvious importance of having such products readily available to consumers to help reduce the incidence of smoking, the FDA should facilitate broad and thorough dissemination of information about the availability of smoking cessation products. For example, the information should be included in any materials the agency disseminates to manufacturers and retailers (e.g., training materials or registration forms) that relates to the Act. Given the breadth and complexity of the Act, the FDA's rules should help avoid situations where the Act's restrictions are misread to limit the availability of smoking cessation products.

### **3. Other Sales and Marketing Restrictions**

#### **a. Labeling**

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2010), but Section 101(a) gives the agency 18 months from the Act's enactment (until December 22, 2010) to develop age verification requirements for Internet and mail order sales, and two years (until June 22, 2011) to develop marketing regulations restricting sales to minors.

<sup>16</sup> *See id.* § 103(g).

<sup>17</sup> *See* H.R. Rep. 111-58, Part 1, at 46 (“The Committee has found that public health officials and other interested parties are not widely aware that FDA does not currently prohibit the sales of over-the-counter smoking cessation products—such as certain nicotine replacement products—in retail settings where age verification takes place. The Committee urges FDA to communicate its policy on such sales to the regulated community and public health officials through simple and effective means, such as through posting a statement of policy on the FDA’s web site.”).

While the Act directs FDA to implement a plethora of other restrictions on distribution and marketing, the labeling rules will be important to NACS members because our retailers want to avoid any practices that would inadvertently run afoul of the new labeling restrictions.

More specifically, the Act provides that retailers will be absolved from liability for violations concerning warning labels if retailers avoid doing certain things, such as altering labels, and selling product with non-compliant labels.<sup>18</sup> Accordingly, it is critical that the FDA's rules establish clear, "bright lines" about what retailers can and cannot do in this regard, since the potential for liability hangs in the balance. And before the text of any such rules becomes effective, FDA should also give retailers (as well as the general public) a chance to review and comment on them, so that any vagueness or other problematic issues can be pointed out and addressed.

From a substantive perspective, one matter that should be clearly addressed in labeling regulations concerns what retailers may do with any remaining inventory they have that pre-dates the effective date of the new labeling requirements. As a practical matter, based on our members' experience with the flow of inventory in and out of their stores, some retailers could still have inventory with "old" labels in stock on the date that the new label requirements go into effect. Retailers should be permitted to sell out the remaining inventory they possess with the old labels. Any new inventory they purchase after the effective date would, of course, have the new labels required under the Act. Such a rule would be consistent with the Act's intention, as the Act directs that the effective dates of the various labeling requirements "shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with" the labeling requirements.<sup>19</sup> This approach is designed to allow for a reasonable lag in the amount of time it will take product with "old" labels to clear the stream of commerce, and is the most workable, practically and economically, for retailers.

b. Recordkeeping

The Act specifies that recordkeeping rules be established for entities that distribute tobacco products.<sup>20</sup> To the extent the agency decides to establish recordkeeping rules for retailers under this provision (and the Act does not mandate recordkeeping rules for retailers), these rules should be very clear, taking into consideration the fact that they will be applied to small retail operations. For similar reasons, any recordkeeping rules should take into consideration, and minimize, the burdens that would be imposed on retailers.

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<sup>18</sup> See *id.* § 201 (a) (amended Section 4(a)(4) of the Federal Cigarette Labeling and Advertising Act).

<sup>19</sup> See, e.g., *id.* § 103 (q)(5); § 201(b);

<sup>20</sup> *Id.* § 301 (adding Section 920 (b) to the Federal Food, Drug, and Cosmetic Act).

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NACS appreciates this opportunity to comment on the FDA's implementation of rules governing the sale and marketing of tobacco products, and looks forward to sharing its views in future proceedings. If you have any questions concerning these comments, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Lyle Beckwith". The signature is written in a cursive style with a large, looped initial "L".

Lyle Beckwith  
Senior Vice President, Government Relations  
National Association of Convenience Stores