



September 14, 2010

**VIA ELECTRONIC FILING – [www.regulations.gov](http://www.regulations.gov)**

Ms. Leslie Kux  
Acting Assistant Commissioner for Policy  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re:** Draft Guidance for Tobacco Retailers  
on Tobacco Retailer Training Programs  
Docket No. FDA-2010-D-0350

Dear Ms. Kux:

The National Association of Convenience Stores (“NACS”) appreciates this opportunity to provide comments to the Food and Drug Administration (“FDA”) on the Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs (the “Draft Guidance”).<sup>1</sup> NACS is an international trade association representing more than 2,100 retail and 1,500 supplier company members. NACS member companies do business in nearly 50 countries worldwide, with the majority of members based in the United States.

While 49 of the top 50 convenience store companies in the United States are members of NACS, the majority of our members are small, independent operators. More than 70 percent of our total membership is composed of companies that operate ten stores or less, and more than 60 percent of our membership operates five stores or less. Nearly 40 percent of our membership operate a single store.

Sales of cigarettes and other tobacco products comprise more than 36 percent of the in-store sales at convenience stores, and thus are vital to the economic viability of the convenience store industry. NACS has devoted a substantial amount of time and resources to ensuring that convenience store operators are equipped to comply with federal, state, and local tobacco regulations. NACS and its members are committed to the principle of selling all of our merchandise in compliance with the letter and the spirit of the law.

**NACS’ Relationship with *We Card***

As part of our efforts to help store operators comply with tobacco rules and regulations, NACS is a founding member of *We Card*, a non-profit organization providing tobacco retailers with multi-level training and educational products and services.<sup>2</sup> *We Card* helps retailers to prepare employees, set clear expectations, and

<sup>1</sup> 75 Fed. Reg. 41498 (July 16, 2010).

<sup>2</sup> I have served on the *We Card* Board of Directors for the past ten years..

provide continuous feedback in an effort to prevent underage access to tobacco. In light of the *We Card* relationship and similar efforts, NACS strongly advocated the two-tier system contained for penalties<sup>3</sup> in the Family Smoking Prevention and Tobacco Control Act (the “Tobacco Control Act”).<sup>4</sup> *We Card*’s program, which is employed by many NACS members, by our estimate already encompasses approximately 90 percent of the content of the Draft Guidance. Because of *We Card*’s successful experience in this field, and NACS members’ familiarity with its program, we encourage FDA to utilize *We Card*’s expertise and stipulate that full compliance with the *We Card* program is an effective training program warranting the lower schedule of penalties.

### **Comments on the Draft Guidance**

NACS shares the FDA’s goal of preventing the sale of tobacco products to minors, but there are some components of the Draft Guidance that need improvement. Our comments and suggestions below are based on our years of experience in tobacco retailing, and a thorough understanding of the business realities of the retail industry.

### **Overall Regulatory Certainty**

We believe that the final guidance should be more specific and clear-cut than the Draft Guidance. Our members need to know exactly what FDA is looking for in effective retailer training programs before they invest in them. Our experience teaches us that retailers are more likely to create training programs if they are certain to reap benefits from doing so – and those benefits will only be attainable if their prerequisites are very clear.

Some examples of the uncertainty in the Draft Guidance include:

1. The FDA does not prioritize the various recommendations contained in the Draft Guidance. Instead, FDA states that these recommendations “should be included in an effective retailer training program.”<sup>5</sup> It would be far more helpful for FDA to note those attributes it considers most essential to an effective training program.

2. In a number of instances, FDA suggests that store operators provide their employees with certain information. It would encourage store operators to create training programs if FDA were to include sample language in its final guidance, and state explicitly that store operators who use such language satisfy their obligation.

3. Overall, the final guidance should be tailored to meet industry realities. Perhaps most importantly, the convenience store industry has an extremely high employee turnover rate, averaging 100-300% annual aggregate turnover. NACS suspects that other tobacco retailers have similar turnover rates, which are simply endemic to the

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<sup>3</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(2) (2010) (setting civil penalties for violations of 21 U.S.C. 333 (f)(8))

<sup>4</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 (2010)

<sup>5</sup> Draft Guidance, 75 Fed. Reg. at 41499

industry, and have no relationship to tobacco sales. The FDA, therefore, should keep this fact in mind as it finalizes its guidance because high turnover makes some of the recommendations extremely difficult and burdensome (such as keeping records for all past employees' test scores for four years).

### **Applicable Laws and Penalties/Products Covered by Applicable Laws**

The Draft Guidance suggests that store operators inform their employees of federal, state, and local tobacco laws during employee training sessions. We agree that all operators should inform their employees of pertinent federal and state laws (indeed, *We Card* already provides such information to retailers). However, providing information regarding local laws and ordinances would be exceedingly difficult and complex for many of our members, as there are a plethora of local tobacco laws within every state. A multi-store operator would be unfairly and unnecessarily burdened by having to assess and educate on all such laws. Even a single-store operator, without the benefit of counsel or a program like *We Card*, could have difficulty informing employees about local law, particularly if that is interpreted broadly to include matters like zoning, hours of operation, and other issues that regulate all retailers, including tobacco retailers. FDA should recommend, but not require, the provision of information relative to local law in its final guidance and any future rule in this area.

### **Health Effects of Youth Tobacco Use**

The final guidance should provide more specificity regarding exactly what information FDA wants retailers to provide to employees regarding the health and economic effects of tobacco use, as well as how (*i.e.*, what language and means of communication) it should be provided. Doing so would appear to be a simple exercise, particularly if FDA were to offer examples and provide some flexibility.

### **Age Verification Requirements**

NACS agrees that it is crucial that convenience stores have the means in place to confirm that all purchasers of tobacco products are of age. However, in recommending that retailers "include pictures of acceptable forms of identification in their training materials," it is important for FDA to harmonize its recommendations with various Department of Homeland Security regulations and state laws restricting the use of images of forms of identification.

## **Record Retention**

We agree with FDA that all convenience store employees should be aware of the rules and regulations restricting the sale of tobacco products to youth, and have worked diligently to achieve our shared goals in this regard. However, as indicated above, we believe that requiring retailers to retain training documentation for four years is excessively burdensome and generally unnecessary. Many of our members do not have computer systems in their stores capable of retaining such records, and in light of the high employee turnover in our industry, it is unreasonable and unnecessary to ask them to maintain hard copy records.

The FDA justifies its recommendation that retailers retain written records for four years so that retailers are “able to provide evidence of a training program during the 48-month time period covered by the civil money penalty schedules in section 103(q)(2)(A).” However, that section of the statute applies to violations that have already been adjudicated (and thus FDA would presumably already have a record of a store’s training program). In determining civil penalties within a four year window, compliance with the record-retention requirement seems irrelevant to the calculus. NACS therefore would appreciate a substantial reduction to the length of time stores are suggested to retain testing records, or alternatively a clarification as to why the four year period is necessary.

The final guidance should decrease the period of time that records must be maintained, and also expressly permit the use of electronic recordkeeping. Electronic recordkeeping would facilitate compliance with the recommendation, and better enable our members to keep records for extended periods of time. Additionally, *We Card* is able to assist store operators in their efforts to create and maintain electronic records.

## **Conclusion**

NACS appreciates this opportunity to comment on the Draft Guidance. Please do not hesitate to contact us and use us as a resource in finalizing the Draft Guidance.

Sincerely yours,



Lyle Beckwith  
Senior Vice President, Government Relations