



September 14, 2010

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

**Re: Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs, 75 Fed. Reg. 41498 (July 16, 2010)**

**Docket No. FDA-2010-D-0350**

The Food Marketing Institute (FMI)<sup>1</sup> is pleased to respond to the Food and Drug Administration's (FDA) request for comments on the Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs ("Draft Guidance"), pursuant to the implementation of the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Act"), which amends the Federal Food, Drug & Cosmetic Act to authorize FDA to regulate tobacco products.<sup>2</sup>

The supermarket industry which FMI represents has made great strides over the past two decades in implementing programs at the retail level that are designed to prevent sales of tobacco products to individuals who are not of legal age to purchase these items, and FMI member companies stand ready to work with FDA on the implementation of the Tobacco Act. FMI offers the following comments and observations to the agency in response to the Draft Guidance.

### **III. B. What are the recommended elements to be included in a retailer training program?**

Retail grocery stores have been actively involved in providing effective tobacco training to those employees who will have the responsibility of conducting sales and transactions of tobacco products with customers. These training programs may be of the retailers' own creation or based

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<sup>1</sup> FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

<sup>2</sup> 75 Fed. Reg. 41498 (July 16, 2010).

on the popular We Card Program.<sup>3</sup> In fact, a significant number of retailers already have in place many of the elements of the training program that are suggested by FDA in the agency's Draft Guidance and which can also be found in the We Card Program. To this end, FMI wishes to underscore the positive results of our industry's retail training programs which are clearly evident and documented as provided by the steady decrease in tobacco sales to minors, per the recent annual Synar Report.<sup>4</sup>

Thus to continue building upon this successful activities that are preventing minors from purchasing tobacco products in grocery stores, FMI urges FDA to keep its guidance straightforward and simple, reflecting the law as passed by Congress so that retailers will easily and fully understand their obligations in terms of checking the identification of any person under 27 years of age who seeks to purchase cigarettes or smokeless tobacco and preventing the sale of tobacco products to underaged young people.

#### Health Effects of Youth Tobacco Use

FDA's Draft Guidance recommends that a description of the health and economic effects of tobacco use be a part of a retailer training program. FMI does not believe this should be a component of the training program. FDA states in the Draft Guidance that an effective retailer training program should ensure that employees understand their obligations under the Tobacco Control Act, verify that customers are of the legal age to purchase tobacco products and successfully refuse purchase attempts by underage buyers. FMI believes a retailer training program should be focused on these elements. Mandating a discussion of FDA's assessment of policy justifications for the Tobacco Act is unnecessary and will serve as a distraction from the key components of a training program.

#### Methods for Ensuring and Documenting that Employees Have the Knowledge Required to Comply with Laws Restricting the Access to, and Advertising and Promotion of, Tobacco Products

FDA states that, "Retailers should retain the written records for 4 years in order to be 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)." This length of record keeping has the potential to be extremely burdensome and costly, for both large and small grocery stores. That's because there is significant turn-over of employees at the retail level every year. FDA should ensure that the recordkeeping burden associate with the retailer training program does not serve as a disincentive to retailer participation. The agency should minimize any recordkeeping burdens as consistent with the Paperwork Reduction Act.<sup>5</sup>

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<sup>3</sup> See <http://www.wecard.org>.

<sup>4</sup> 2008 Annual Synar Report; see: <http://prevention.samhsa.gov/tobacco/synarreportfy2008.pdf>

<sup>5</sup> 44 U.S.C. § 3501 *et seq.*

Furthermore, FMI recommends that “electronic” be added to “... retain the written *or electronic* records ...” It should be noted, however, that electronic records at store level are typically maintained for no more than a year, based on a store’s storage space. A central location, such as a corporate office, would likely be able to provide a longer time frame for electronic storage. FMI also asks FDA to give a retailer at least 30 days, from the time a request is made, to provide information back to FDA.

### **III. C. What hiring and management practices are elements of an effective retailer training program?**

#### Hiring Practices

FDA’s Draft Guidance states that “applicants for positions that involve selling tobacco should be notified both verbally and in writing of the importance of complying with laws prohibiting the sale of cigarettes and smokeless tobacco to youth, and should be required to sign an acknowledgement stating that they have read and understand the information.” While FMI readily agrees with providing training for all new and current employees, we disagree with the suggestion that potential applicants receive instruction prior to hiring. This simply makes no sense for a retailer to expend the time and money on all applicants before a determination is made as to whether or not the applicant is qualified for a position. FMI is also concerned with FDA's suggestion that retailers should not allow store level associates who are under 18 years of age to sell tobacco products. A retailer should be permitted to allow an associate who is under 18 years of age to sell tobacco products, especially if that person has received appropriate training.

#### Management Practices

FDA suggests that retailers should consider “implementing an internal compliance check program, also known as a mystery shopper program,” and “retailers should consider establishing company policies that take employee performance on compliance checks into account in company decisions about compensation, promotion, and retention. In particular, retailers should strongly consider establishing disciplinary sanctions for employee noncompliance. Retailers should also consider making a store’s compliance rate a component of a retail supervisor’s performance reviews.”

While a useful tool, compliance checks could become problematic, as one suggestion by FDA is to use a person of legal age, but younger than 27, to verify that clerks are checking for identification.

The Tobacco Act requires FDA to reissue a final rule that is substantially identical to part 897 of the final rules promulgated in 1996 for the regulation of tobacco products (the “1996 Rule”). The Tobacco Act itself and the 1996 Rule together provide for comprehensive regulation of the sale of tobacco products. For example, the 1996 Rule prohibits the retail sale of tobacco products to any

person who is younger than 18 years of age and requires retailers to verify that no person purchasing the product is younger than 18 years old.<sup>6</sup> The 1996 Rule expressly states that no such verification is necessary for persons who are over the age of 26.

Therefore, it should be noted that failure to verify the age of a person who is 18 years or older is not itself a violation of the 1996 Rule. Since this is not a prohibited act, FDA should not subject the retailer to penalties, or the clerk to disciplinary action. In fact, retail clerks often know and recognize their customers.

Moreover, the statement that “retailers should strongly consider establishing disciplinary sanctions for noncompliance” could be difficult to administer, as many states operate under collective bargaining agreements that place conditions on the type of discipline for first-time offenses. In fact, these collective bargaining agreements may cover not only wages, but hiring practices, disciplinary actions and promotions. With many different state laws regulating these agreements, it would be hard to devise an internal compliance check program that would work across state lines for chain retailers.

FMI appreciates the opportunity to provide comments on FDA’s Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Erik R. Lieberman". The signature is fluid and cursive, with the first name "Erik" being the most prominent.

Erik R. Lieberman  
Regulatory Counsel

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<sup>6</sup> 21 C.F.R. 897.14.