FOOD MARKETING INSTITUTE

December 28, 2009

Via Electronic Portal and U.S. Mail

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

Re: Regulation of Tobacco Products (Docket No. FDA-2009-N-0294)

Dear Sir or Madam,

The Food Marketing Institute[1] is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the implementation of the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Act"), which amends the Federal Food, Drug & Cosmetic Act (FD&C Act) to authorize FDA to regulate tobacco products.[2] 74 Fed. Reg. 31457 (July 1, 2009); 74 Fed. Reg. 51614 (Oct. 7, 2009). The retail stores that FMI represents have implemented programs to prevent sales of tobacco products to minors for many years. Our members stand ready to work with FDA on the implementation of the new Tobacco Act and offer the comments below.

A. Sale and Distribution of Tobacco Products

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

[1] 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.

[2] We have attempted to group our comments within the headings requested by FDA.

HEADQUARTERS:
2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801
T 202.452.8444
F 202.429.4519

WASHINGTON OFFICE:
50 F Street, NW, 6th Floor
Washington, DC 20001-1530
T 202.452.8444
F 202.220.0873

www.fmi.org
fmi@fmi.org

Rule").[3] The Tobacco Act itself and the 1996 Rule together provide for comprehensive regulation of the sale of tobacco products.

1. Prohibit Sale of Tobacco Products to Persons under 18 Years Old

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. 21 CFR 897.14. The 1996 Rule expressly states that no such verification is necessary for persons who are over the age of 26.

As noted above, retailers have well-established programs to ensure that minors do not purchase tobacco products and these programs include age verification. However, failure to verify the age of a person who is 18 years or older is not itself a violation of the 1996 Rule, nor should it be. Retail clerks often know and recognize their customers. Failure to check the identification of a customer 18 years or older who purchases tobacco products is not a prohibited act and should not subject the retailer to penalties.

2. Retailer Training Programs

Congress expressly recognized the importance of retailer training programs in several provisions of the Tobacco Act related to enforcement. For example, retailers with "an approved training program" are subject to lower civil penalties for sales to minors.[4] Moreover, before assessing penalties for violation of the minimum age requirements, FDA must consider whether the retailer has "taken effective steps" such as (1) adopting and enforcing a written policy against sales to minors; (2) informing its employees of all applicable laws; (3) establishing disciplinary sanctions for employee noncompliance; and (4) requiring employees to verify age by way of photographic identification or electronic scanning devices.[5]

The foregoing provisions are part of congressional instructions to FDA to issue guidance documents on certain issues. When FDA issues guidance on the foregoing, we encourage the Agency not only to recognize the express statutory language, but to clarify the language. For example, Congress stated that the "steps" enumerated above are examples of "effective" steps, but the list is not exclusive; therefore, the guidance may provide additional examples and should also leave the door open for other steps that may be considered effective. Certainly, the list of effective steps should include having "an approved training program" in place.

---

[3] Section 102(a) of the Tobacco Act requires the final rule to be published "on the first day of publication of the Federal Register that is 180 days or more after the date of enactment of this Act," which was June 22, 2009; Section 102(a)(3) requires FDA to publish a proposal prior to making any amendments to the rule.

[4] Section 103(q)(2).

[5] Section 103(q)(1)(F), (G).

As noted above, the statute sets forth two different penalty schedules for retailers depending on whether the retailer has "an approved training program." Congress did not, however, define the term "approved training program." In the guidance that FDA is directed to issue, we encourage FDA to clarify the term "approved training program." First, the Agency should set standards for what constitutes an "approved training program". We recommend that FDA model those standards on the We Card program, which was developed by the Coalition for Responsible Tobacco Retailing, Inc. (CRTR)[6] Second, the Agency should recognize that other retailer programs that include the same information should also be considered "approved training programs." In no event, should FDA undertake to review and approve every training program currently used by retailers. In fact, Section 103(q)(2)(B) states that "the term 'approved training program' means a training program that complies with standards developed by the Food and Drug Administration for such programs," and does not require FDA to provide prior review and approval of each program.[7]

Although many retailers use the We Card program, others have tailored We Card to their own particular stores. FDA may want to review the elements of a training program when deciding which penalty schedule should apply but FDA should not require such approval in advance. FDA should also establish a 'safe harbor' for well-established programs, such as We Card.

B. Advertising and Marketing of Tobacco Products

The Tobacco Act and the 1996 Rule both provide direction to retailers and distributors regarding the sale and distribution of tobacco products. Specifically, Section 201 of the Tobacco Act imposes certain labeling and advertising requirements on tobacco products. First, the Tobacco Act requires tobacco products to bear one of the warnings enumerated in the statute, although retailers will not be considered in violation of the Act for selling non-compliant products with packaging that (1) contains a warning label; (2) is supplied to the retailer by an authorized entity; and (3) was not altered by the retailer.

Section 201 further provides that retailers and distributors (among others) may not advertise tobacco products or cause them to be advertised if they do not bear one of the prescribed warnings and requires retailers and distributors (among others) to randomly display in each 12-month period "in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor or retailer, and approved by the Secretary." Retailers are exempt from these requirements unless the retailer "is responsible for or directs the label statements required under this section." Retailers are, however, liable if they display an advertisement that "does not contain a warning label or has been altered by the retailer."

---

[6] Additional information on CRTR and the We Card program can be found at www.wecard.org.

[7] FMI will provide additional comments regarding "approved tobacco retailer training programs" in response to FDA's recent request. 74 Fed. Reg. 65129 (Dec. 9, 2009).

The 1996 Rule further places responsibility on a broad number of entities, including distributors and retailers for ensuring that the tobacco products it distributes, sells or otherwise holds for sale "comply with all applicable requirements." 21 CFR 897.10. Moreover, retailers must "ensure that all self-service displays, advertising, labeling, and other items that are located in the retailers' establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part." 21 CFR 897.14(e).

We recommend that FDA reconcile some of these requirements in the final rule and accompanying preamble. First, FDA should exercise its administrative enforcement discretion to apply the forbearance extended to retailers for selling cigarettes that do not bear a specified warning label to distributors. Specifically, although the Tobacco Act technically renders it unlawful to distribute cigarettes that fail to bear one of the required labels, distributors (like retailers) do not control the labeling of the products supplied by manufacturers. Therefore, if the same circumstances exist -- warning (although not technically correct), product supplied by licensed supplier, and not altered by the distributor -- the distributor should likewise be relieved of liability.

Moreover, to the extent that the 1996 Rule imposes liability on retailers and distributors that exceeds the scope of the Tobacco Act, the 1996 Rule should be amended. Specifically, the Tobacco Act provides specific situations in which retailers should not be held liable for labeling or advertising; those are not recognized in the 1996 Rule (which predated the Tobacco Act) so FDA should remedy that in the rule that the Agency promulgates.

C. Federal, State and Local Government Collaboration

The Tobacco Act requires FDA to coordinate with the States in enforcing the provisions of this Act. For purposes of mitigating a civil penalty to be applied for a violation by a retailer of any restriction promulgated under Section 906(d), FDA is required to consider the amount of any penalties paid by the retailer to a State for the same violation. The report language clarifies that the purpose of this section is to protect retailers against double fines and that FDA must reduce federal fines by the amount of any state fines paid for the same violation.[8]

D. Enforcement

1. Equal Treatment of Retailers

Tobacco products are sold through a wide variety of mechanisms and outlets. In order to ensure that the public health mission of the Tobacco Act is accomplished, all such outlets should be treated equally. The Tobacco Act recognizes some of these different sales mechanisms, but we

[8] See HR Rep. 111-58, Part 1 (2009) at 48 ("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.")

believe it is important for FDA to ensure that all are required to comply with the restrictions on advertising and sales at the same time.

For example, newly added Section 913 requires FDA to promulgate regulations to "require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising, restrictions applicable to retail establishments accessible to individuals under the age of 18." These rules should be promulgated at the same time as regulations that apply to general retailers, such as supermarkets and convenience stores.

Similarly, newly added Section 906(d)(4) requires FDA to promulgate regulations within 18 months of the Tobacco Act's enactment regarding the "sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer" to ensure that minors do not receive tobacco products. As the Tobacco Act establishes an outside limit for the promulgation of such regulations, FDA should ensure that they are issued at the same time as the final rules that restrict face-to-face sales to minors. This is particularly important since the new rules could actually drive minors to internet or other remote sales if access to tobacco products is further curtailed through implementation of the new rules. These rules should require an actual identification check at the point where the product is delivered to the consumer. Delivery companies have services to do this for other age restricted products (such as alcohol) so remote retailers of tobacco products should also be required to use them. FDA should address enforcement resources to ensure that identification is being properly verified for remote sales, just as FDA will be checking retail stores.

The Tobacco Act prohibits FDA from contracting with state authorities to conduct inspections "on Indian country without the express written consent of the Indian tribe involved." The provision does not, however, prevent FDA from conducting inspections using federal inspectors and we would encourage FDA to enforce the law directly in Indian reservations. Often tribes themselves are involved in the sale of tobacco products on reservations. To ensure the greatest likelihood of compliance, FDA should perform this function directly. See, also, Section 102(a)(5) ("The Secretary of HHS shall ensure that the provisions of this division, the amendments made by this division, and the implementing regulations … are enforced with respect to the United States and Indian tribes.")

2. Application of Penalty Provisions to "a Particular Retail Outlet"

As noted above, Section 103(q) establishes a penalty schedule for violations of the minimum age sales requirements. In addition to whether the retailer has an approved training program, the penalty schedule is based on the number of violations within certain periods of time. For example, retailers with an approved training program may be fined no more than $250 for a second violation within a 12-month period and no more than $5,000 in the case of a fifth violation within a 36-month period.

Congressional intent for the application of these penalties is clarified in Section 103(q)(1)(A) in which Congress directs FDA to issue guidance defining the term "repeated violation" for purposes of Section 303(f)(8) of the underlying FD&C Act "as including at least 5 violations of particular requirements over a 36-month period *at a particular retail outlet* that constitute a repeated violation." (emphasis added) In the guidance that FDA is directed to issue under Section 103(q)(1)(A) interpreting "repeated violation," FDA should also unequivocally state that the penalty provisions of Section 103(q)(2) will be applied based on violations as they occur at "a particular retail outlet" rather than across an entire chain.

3. Due Process

The Tobacco Act includes several due process protections that FDA is directed to include in guidance documents. For example, FDA must issue guidance providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check. Notice must be sent to the location specified on the retailer's registration or to the retailer's registered agent if the retailer has provided such agent information to the FDA prior to the violations.[9] Along these lines, the statute also prohibits FDA from charging a person with a violation at a particular retail outlet unless FDA has provided notice to the retailer of all previous violations at that outlet.[10]

FDA must also issue guidance providing for a hearing including (at a retailer's request) a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration and providing for an expedited procedure for the administrative appeal of an alleged violation.[11]

FMI supports the foregoing statutory provisions. Consistent with FDA's good guidance practices, all such guidance documents should be issued in draft with an opportunity for public comment.

4. Recordkeeping

Title III of the Tobacco Act authorizes FDA to promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products for the purpose of preventing illicit trade in tobacco products. Recordkeeping has the potential to be extremely burdensome, particularly for small businesses. The greatest potential for trafficking lies with those who handle large volumes of tobacco products, such as manufacturers and importers. To the extent that FDA imposes recordkeeping requirements on retailers and distributors, FDA should ensure that

---

9 Section 103(q)(1)(B).
10 Section 103(q)(1)(D).
11 Section 103(q)(1)C).

the burden does not exceed the benefit. All requirements should be consistent with the Paperwork Reduction Act.

* * *

We appreciate the opportunity to provide comments on FDA's implementation of the Tobacco Act and stand ready to work with the Agency in the fulfillment of this important public health mission. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to call on us.

Sincerely,

Deborah R. White
Senior Vice President &
Chief Legal Officer

HEADQUARTERS:
2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801
T 202.452.8444
F 202.429.4519

WASHINGTON OFFICE:
50 F Street, NW, 6th Floor
Washington, DC 20001-1530
T 202.452.8444
F 202.220.0873

www.fmi.org
fmi@fmi.org