FOOD MARKETING INSTITUTE

January 11, 2011

Via Electronic Portal

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

Re: Required Warnings for Cigarette Packages and Advertisements (Docket No. FDA-2010-N-0568; RIN 0910-AG41)[1]

Dear Sir or Madam,

The Food Marketing Institute (FMI)[2] is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the "required warnings for cigarette packages and advertisements" element of the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Act") (P. L. 111-31).

Advertising and Marketing of Tobacco Products

Section 201 of the Tobacco Act modifies section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements. The Tobacco Act and the 1996 Rule[3] both provide direction to retailers and distributors regarding the sale and distribution of 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-

[1] 75 Fed. Reg. 75936 (December 7, 2010).

[2] 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.

[3] The Tobacco Act requires FDA to reissue a final rule that is substantially identical to part 897 of the final rule promulgated in 1996 for the regulation of tobacco products (the "1996 Rule").

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

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."

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)).

FDA should exercise its administrative enforcement discretion to retailers and distributors for selling cigarettes that do not bear a specified warning label. The Tobacco Act technically renders it unlawful to distribute cigarettes that fail to bear one of the required labels, but retailers do not control the labeling of the products supplied by manufacturers. In addition, if a product is provided by a licensed supplier, and not altered by the distributor, the distributor should likewise be relieved of liability.

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. In particular, 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.

Sell Through Date

FMI is concerned about an ample "sell through date;" that is, the date by which all inventory must be sold or distributed before the new warning labels are required to be placed on a cigarette carton or package. Retailers and distributors should be given ample time to sell and distribute tobacco products that were furnished to them by manufacturers before the deadline requiring graphic warnings. Section 201, subsection (a) of the Tobacco Act amends the FCLAA by requiring that

the graphic warning and labeling amendment take effect 15 months after FDA issues its final rule (no later than September 22, 2012), and beginning 30 days after the effective date (no later than October 22, 2012), manufacturers will no longer be allowed to distribute for sale in the United States any cigarettes that do not display the new graphic health warnings. Retailers should be allowed to sell all cigarette products that do not have the additional warnings, and received no later than October 22, 2012 from the distributor or manufacturer, at least through their "sell by" date, as indicated on the cigarette package by the manufacturer, which ensures freshness. Therefore, those cigarette cartons or packs should be allowed to remain on retailers' shelves through their "sell by" dates.

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,

Erik R. Lieberman
Regulatory Counsel

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Arlington, VA 22202-4801
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