THE VOICE OF FOOD RETAIL

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April 9, 2013

Re: Draft Guidance for Industry and FDA Staff;
Civil Money Penalties for Tobacco Retailers:
Responses to Frequently Asked Questions; Availability

Docket No. FDA-2012-D-1083

Dear Sir or Madam:

The Food Marketing Institute (FMI) is respectfully submitting comments in response to the Food and Drug Administration's (FDA) issuance of Draft Guidance for Industry and FDA Staff, Civil Money Penalties for Tobacco Retailers: Reponses to Frequently Asked Questions.

By way of background, FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U. S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly $650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Our international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of goods and services to our retail and wholesale members. On behalf of those supermarkets who offer for sale tobacco products to consumers, we appreciate the opportunity to comment on FDA's Draft Guidance for Industry and FDA Staff.

FMI commends FDA for issuing its Draft Guidance as this document will go a long way toward educating grocery stores that sell tobacco products about their obligations under the Family Smoking Prevention and Control Act (P. L. 111-31) and the process by which a complaint and civil money penalties may be assessed against retailers for violations promulgated under section 906(d) and section 303(f)(9) of the Federal Food Drug and Cosmetic Act. The Draft Guidance further provides helpful information about how respondents may go about appealing an agency compliant and the assessment of a civil money penalty for an alleged violation.

While FMI believes that this information contained in the Draft Guidance will be very useful for retailers that sell tobacco products, FMI is of the opinion that the Draft Guidance is critically lacking in terms of common sense procedures that should be followed by FDA when a store is served with a complaint and a civil money penalty. For example, under FAQ Number 39, Does FDA have proof of the violations? It states

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FDA inspectors are instructed to collect evidence, as appropriate, to document violations found during retail compliance check inspections. Examples of such evidence include photographs taken during an inspection; written statements from inspectors describing their observations and physical evidence collected during an inspection. However, the Draft Guidance does not elaborate on what type of physical evidence agency inspectors should collect. In this regard, FMI strongly recommends that FAQ Number 39 be revised to instruct agency inspectors to collect the following evidence: sales or credit card receipt, date and time of the alleged illegal sale of a tobacco product to a minor, the name and/or description of the sales clerk who conducted the alleged illegal sale and the name of cigarette brand (Marlboro, Salem, Newport) and the style (100's, Gold, Silver, Smooth, Skyline, Special Blend). If a retailer is provided this type of physical evidence by an FDA inspector, the retailer would be able to ascertain if an alleged violation actually occurred and to take appropriate corrective action to minimize or prevent violations in the future such as retraining a sales clerk who conducts tobacco sales.

While it is our understanding that FDA commissioned compliance inspectors are required to submit electronically within 24-hours a violation to the agency's Tobacco Control Center, there is currently no guidance or requirement for FDA to provide timely notification to a retail store that an alleged violation may have occurred. A number of FMI member companies have reported that they have received complaints from FDA two, three or four months after an alleged sale occurred. This lengthy delay on the part of FDA hinders the ability of a supermarket company to conduct an internal investigation and take corrective action when appropriate. For companies that are unionized at store level, that company will encounter strong objections by the union if disciplinary action is taken against a union member three months after an alleged violation especially if there is no evidence to prove that a union member associate actually failed to check photo identification or made an illegal transaction sale of a tobacco product to a minor.

Many grocery stores utilize video surveillance systems to monitor tobacco sales to customers. Video tape is typically kept for no more than 60 days and then is purged or taped over. This means that if a supermarket company receives a complaint or civil money penalty from FDA after 60 days, there is no way in which the company can review a video to determine if an illegal sale to a minor actually took place. We, therefore, urge the Draft Guidance be revised to stipulate that timely notification must be given to a retail store if a violation may have occurred. It is FMI's position that FDA should notify a retail store within 10 working days regarding the sale of a tobacco product to a minor. Prior to enactment of the Family Smoking Prevention and Control Act, when states conducted tobacco compliance checks, a retailer was notified immediately after an illegal sale has taken place. If agency commissioned compliance inspectors are required to submit electronically within 24-hours a violation to the Tobacco Control Center, FDA should respond accordingly and issue a complaint and a civil money penalty more expeditiously to a company or retail store.

Moreover, because these lengthy delays when FDA notifies a retail store of an alleged violation, retailers are not afforded their due process rights. This problem is further compounded by the fact that FDA provides the retailer with very little in the way of documentation or evidence that would prove a violation actually occurred. It should not be the responsibility of grocery store to request the evidence from FDA. FDA as a matter of policy should provide the retailer with all relevant inspector collected evidence which would include sales or credit card receipt, date and time of the alleged illegal sale, the name and/or description of the sales clerk who conducted the alleged illegal sale, and the name of cigarette brand (Marlboro, Salem, Newport) and the style (100's, Gold, Silver, Smooth, Skyline, Special Blend) when issuing a complaint and a civil money penalty. It is, therefore, our hope that FDA will revised its Draft Guidance to incorporate these recommendations on what type of evidence will accompany a complaint and a civil money penalty.

In closing, FMI appreciates the opportunity to provide FDA with our views on how to improve the Draft Guidance document so that it will facilitate better compliance and cooperation between supermarkets that sell tobacco products and FDA on how it conducts compliance checks and issues complaints and civil money penalties when an illegal sale occurs.

Sincerely,

Erik R. Lieberman
Regulatory Counsel