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retail did you know?

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Dear Retail Clients and Friends,

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed into law by President Obama on June 23, 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) to grant the U.S. Food and Drug Administration (FDA or the Agency) authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health and reduce tobacco use by minors. This grant includes the authority to inspect tobacco retailers and enforce the tobacco-related provisions of the FD&C Act. This edition of ***Morgan Lewis Retail Did You Know?*** describes the FD&C Act and its application and highlights recent Agency enforcement efforts.

**Background**

At a recent briefing on the continued success of the Agency's tobacco retailer compliance check inspections, FDA Commissioner Margaret Hamburg emphasized the Agency's commitment to the enforcement of the Tobacco Control Act through sweeping inspections affecting all tobacco retailers. In 2011, FDA demonstrated its plan to increase retailer inspections in terms of both frequency and scope, awarding compliance contracts to 37 states and the District of Columbia to conduct compliance check inspections of tobacco retailers. To date, FDA-commissioned inspectors have conducted more than 27,500 inspections of retailers. **As a result of this inspection and enforcement initiative, FDA has issued more than 1,200 Warning Letters to tobacco retailers for violations of the FD&C Act.**

**The Law**

Any entity that sells cigarettes, smokeless tobacco, or loose cigarette tobacco (regulated tobacco products) to individuals for their own use, or that operates a facility where a vending machine or self-service display is present, is considered a "retailer" under the FD&C Act, and therefore must comply with the Act's provisions to avoid incurring penalties. And any entity that creates tobacco product advertising that appears in a retail setting must comply with the Act's provisions.

Under the law, both states and FDA can conduct retailer inspections. The FD&C Act requires FDA to contract with states and territories to inspect retail establishments that sell regulated tobacco products. In conducting inspections, FDA is checking to ensure that retailers are complying with the Tobacco Control Act's sales and marketing requirements.

*Retailer Compliance*

If FDA issues a retailer a Warning Letter for violating the FD&C Act, the retailer must take immediate corrective action to address the violation(s) assessed and submit a response letter to FDA. A Warning Letter reflects FDA's conclusion that the recipient has violated the requirements of the Act in a significant manner, and, if these violations are not addressed, further enforcement action could ensue. Under the FD&C Act, FDA also has the authority to (1) levy civil money penalties (CMPs) against a retailer that does not take corrective action after receiving a Warning Letter, (2) pursue a No Tobacco Sale Order, (3) seize tobacco products from the retailer, and/or (4) issue an injunction against the retailer. While FDA has not yet levied CMPs, inspectors are conducting follow-up inspections of retailers that have received Warning Letters to determine if the retailers have taken the required corrective action(s).

FDA has encouraged, but has not yet issued, regulations requiring retailers to have training programs in place for employees to learn the federal laws restricting the sale and distribution of tobacco products, including restrictions on the access to, and the advertising and promotion of, cigarettes and smokeless tobacco products. When FDA issues its regulations and/or guidance regarding the elements of an approved retailer training program, the Agency will have two different CMP schedules in place: a CMP schedule with lower penalty amounts for retailers that have approved training programs in place, and a separate schedule with higher penalty amounts for retailers that do not have such programs in place. Until FDA issues its training program regulations, all retailers will be subject to the CMP schedule with lower penalty amounts.

*Tobacco Warning Plans*

Currently, the Federal Trade Commission (FTC) has authority over cigarette warning plans. FDA was slated to obtain authority over such plans on September 22, 2012, when its cigarette warning plan final rule was to take effect. However, in *R.J. Reynolds Tobacco Company, et al. v. U.S. Food and Drug Administration, et al*., the U.S. District Court for the District of Columbia (D.C. Circuit) preliminarily enjoined FDA from enforcing any of the new requirements in its final rule until 15 months after a final ruling by the D.C. Circuit on the constitutionality of the final rule.

Under the Act, it is unlawful for smokeless tobacco manufacturers, importers, distributors, or retailers to advertise any smokeless tobacco product unless such advertising bears one of the required warning statements, and unless the required warning statement on the advertising is rotated quarterly, in accordance with an FDA-approved warning plan.

Generally, the entity that creates the advertising (i.e., the manufacturer) submits the warning plan to FDA. However, retailers also can submit plans to FDA. Retailers' compliance responsibilities differ depending on whether they are creating advertising or whether advertising is supplied to them (e.g., by the manufacturer).

**Practical Advice**

If you are a retailer that sells regulated tobacco products, you must do the following:

- Sell regulated tobacco products only to those individuals age 18 or older.[1]
- Refrain from selling flavored cigarettes.[2]
- Refrain from making modified-risk health claims (i.e., "low," "light," or "mild" cigarette claims).

The above examples represent just a few of the FD&C Act's numerous sales and marketing provisions with which tobacco retailers must comply. For a complete detailing of the Act's tobacco sales and marketing requirements, view a copy of the Tobacco Control Act at http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf.

To ensure you are prepared for an FDA inspection, it is important that you do the following:

- Become familiar with the Act's tobacco sales and marketing requirements.
- Educate your employees on proper age and ID verification procedures.
- Submit a smokeless tobacco warning plan to FDA (if you are responsible for creating advertising).

**How We Can Help**

If we can be of assistance to you in these matters, please feel free to get in touch with your Morgan Lewis contact, our Retail Practice leaders, or our FDA & Healthcare attorneys. Our practice includes attorneys with recent experience at FDA, including the FDA's Center for Tobacco Products.

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1. Some states and localities have more restrictive tobacco sale laws with which retailers must comply.
2. Menthol cigarettes are not included in FDA's flavored cigarette ban.

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These individuals are part of our international Retail Practice. Attorneys from our 22 offices regularly represent national, regional, and local retailers in a broad array of subject matters including litigation, labor and employment, real estate, tax, transactional, and regulatory.

**About *Morgan Lewis Retail Did You Know?*** This message is part of our effort to educate our retail clients and friends about important legal developments. One thing we hear frequently from our retail clients is that it is hard to keep track of new and emerging laws and lawsuit trends that affect retailers. All too frequently, the first notice comes in the form of a lawsuit seeking millions of dollars. To help you be more proactive in managing legal compliance, we are providing these emails.

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