

Federal Regulation of the Retail Sale of Tobacco Products

NACS and Steptoe & Johnson LLP Present:
A Status Update for NACS Members

March 22, 2010

Federal Tobacco Regulation: What We Will Cover Today

- How did we get here? Some brief background on Federal regulation
- The enactment of the Tobacco Act
- FDA's regulations – current and future
- Your questions and answers

A Brief History of Federal Tobacco Regulation

- In 1996, the Clinton administration proposed for the first time to regulate the manufacture, distribution, and sale of cigarettes and smokeless tobacco
- These regulations included specific provisions governing retailers, including age verification, advertising restrictions, and other matters
- After lengthy lawsuits, the courts threw out the regulations, which were ultimately withdrawn altogether

History of Tobacco Regulation

- After the Democratic takeover of the Congress in 2006, lawmakers in the House began moving legislation comprehensively addressing the issues raised in 1996
- NACS played a very proactive role in negotiating provisions of the bill applicable to retailers
- The legislation passed the full House, but ultimately died in the Senate in the face of a presidential veto threat
- The election of President Obama breathed new life into the process
- Tobacco legislation moved very quickly in the House, followed by the Senate
- The President signed the Tobacco Act into law on July 22, 2009

Overview of Current Status

- For retailers, the Tobacco Act has these critical elements: (1) a mandate to reissue the 1996 rule; (2) broad rulemaking authority for the Food and Drug Administration (“FDA”); and, (3) powerful enforcement authorities
- Retailers should familiarize themselves with current and likely regulatory requirements

Regulations Being Enforced Now

- Some of the requirements in the Tobacco Act took effect when it was signed into law:
 - Retailers May Not Market Tobacco Products with other Regulated Products. The Act prohibits retailers from combining tobacco products for sale with other products that are or may be regulated by the FDA. For instance:
 - Adding compressed or powdered tobacco to candy or gum and the candy or gum is identified as containing a tobacco product
 - Selling a pack of cigarettes in a box, bag, or other container with a bottle of mouthwash or a bottle of skin cream
 - Offering a coupon or a 50 cent discount on a specifically identified mouthwash with the purchase of a pack of cigarettes.

Regulations Being Enforced Now

The Act outright banned the sale of “flavored” cigarettes, and FDA has been enforcing this ban over the last six months. The ban applies to “a cigarette . . . (including the tobacco, filter, or paper) [that] contain[s an] . . . additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.”

- Retailers should never advertise or sell flavored cigarettes.

Regulations Effective on June 22, 2010

Last week, the FDA issued an enormous set of regulations that will become effective on June 22, 2010. It contains a number of provisions important to retailers, including:

– Underage sales:

- No retailer may sell cigarettes or smokeless tobacco to anyone under the age of eighteen (18)
- Retailers must verify the age, through a picture identification with a birthdate, prior to making sales to persons under the age of twenty seven (27)
- NACS is advocating that the standards adopted in the We Card program satisfy age verification requirements

Regulations Effective June 22

Face-to-face transactions:

- All sales of tobacco products must be made in face-to-face transactions. Retailers may not use vending machines or other self-service machines to sell tobacco products (important exception: adult-only stores)
- “Self-service displays” will no longer be permitted. Customers may not have independent access to cigarettes or smokeless tobacco; they must be placed “behind the counter” or under lock and key

Regulations Effective June 22

Advertising:

- Each retailer has an obligation to comply with the advertising and labeling requirements of the regulations.
- There could be severe limits on the ability of retailers to advertise tobacco products outside their stores. EPA has already initiated a rulemaking proceeding with respect to outdoor advertising.
- The Act requires that advertising be conducted in black and white colors only. This provision has been challenged successfully (thus far) in Federal court, but the case is on appeal.
- Advertising issues are highly likely to continue to be challenged in court.

Regulations Effective June 22

Packaging:

- Retailers may not break open standard-sized cigarette packages (twenty (20) cigarettes per pack) and sell cigarettes in lesser quantities
- Retailers may not alter or remove the warning labels on tobacco products
- Retailers may not offer free samples of tobacco products.

Regulations Effective June 22

Miscellaneous:

- Retailers may not accept coupons, proofs-of-purchase or similar items received from the purchase of tobacco products in exchange for any gift or item.
- Retailers may not offer a gift or other item in connection with the sale of a tobacco product (for instance, a free Marlboro shirt with the purchase of a carton of Marlboros).
- Until June 22, retailers may sell items (for instance, shorts, hats, or lighters) with the brand name of cigarettes or smokeless tobacco or rolling paper. As of that date, manufacturers and distributors are prohibited from selling such branded merchandise. Although not technically prohibited from selling brand merchandise after June 22, retailers should phase out such sales at the earliest possible time.

Future Regulations

- The Tobacco Act grants very broad authority to the FDA to regulate tobacco retailing in the future.
- The issues that we know FDA will address include:
 - Requiring FDA to regulate tobacco shop advertising in the same way as other retailers, even if they are "adult only"
 - Regulations on age verification for Internet sales and advertising by Internet sellers
 - Guidelines on the enforcement of the Act on Indian reservations
- Consider the regulations announced last week as a first wave of FDA regulation
- NACS will have the opportunity to comment on and challenge these future regulations as appropriate.

Enforcement

The Tobacco Act contains stiff enforcement provisions:

- Penalties. Depending on the violation and the number of violations involved, penalties can range from a warning letter to large financial penalties. In the case of sales to underage individuals, penalties begin with a warning letter, but can quickly rise to \$10,000 per violation.
 - Monetary penalties are reduced if the retailer is participating in an FDA-approved compliance program. NACS is pushing FDA to adopt the We Card program for this purpose.
 - Federal fines are to be reduced by the amount of any State fines paid for the same violation(s)
- No-sale-orders. The Tobacco Act grants the FDA the authority to issue so-called “no-tobacco-sale orders” for repeated and serious violations of the Act relating to illegal sales to minors.
- State enforcement. The Act requires that the FDA contract with the States to carry out inspections and otherwise to coordinate with the States on enforcement matters.

Questions and Answers