

Over-reaching, Right Out of the Starting Gate

Much uncertainty surrounds the FDA's flavored cigarette prohibition. > **BY TROUTMAN SANDERS TOBACCO TEAM**

The Family Smoking Prevention and Tobacco Control Act ("the Act") was signed into law on June 22, 2009. The Act amends the Food, Drug and Cosmetic Act ("FDCA") to give the FDA authority to regulate the advertising, marketing, and manufacturing of tobacco products and contains a number of provisions which take effect on a rolling basis. One of the latest provisions of the Act to take effect provides that, as of September 22, 2009, "cigarettes" that contains certain flavors, other than menthol, are considered "adulterated." Specifically, section 907 (a)(1)(A) the Act provides that:

a cigarette or any of its component parts (including the tobacco, filter or paper) shall not contain, as a constituent...or 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.

Given the language of the Act, cigarettes may still contain the flavorings and ingredients specifically mentioned in the Act as long as the flavor or ingredient is not considered a "characterizing flavor." The problem, however, is that there is no definition of "characterizing flavor" in the Act, and thus, in the absence of FDA regulations addressing this issue, uncertainty exists. Of utmost importance to manufacturers is the fact that the Act requires that any cigarette marketed as being a certain flavor, such as "chocolate" or "clove," the manufacturer has, in effect, already "characterized" the cigarette. In the absence of

such marketing practices, the concept of what constitutes a characterizing flavor is not clear.

STATES TAKE AN ERRONEOUS POSITION, ULTIMATELY RETREAT

States have seemingly undertaken an effort to enact their own version of what the term "characterizing flavor" might mean, without waiting for the promulgation of FDA regulations on the issue. Several states, in an attempt to implement this provision of the Act, sent correspondence which implied that any cigarette brands which contained any ingredients or flavorings other than tobacco or menthol would be removed from the states' directories of approved tobacco products.

This perceived misinterpretation seemed to arise from a failure of the states to appreciate that a cigarette could, for example, contain small amounts of "cocoa" as an ingredient and yet, "cocoa" would not necessarily provide the "characterizing flavor" of the cigarettes. The states backed away from this over-reaching position once this distinction was explained.

NEW YORK CITY PROHIBITS MOST FLAVORED TOBACCO PRODUCTS

States are not the only governmental entities that are not waiting on the FDA on the issue of flavored cigarettes. For example, New York's City Council passed its own tobacco ordinance that is even stricter than the FDA's recent ban on flavored cigarettes. The council, by an overwhelming majority, voted to ban the sale of all flavored tobacco in the City, with the exception of menthol and mint flavors. This enactment goes a step further than the FDA's ban, because the City's ban also specifically includes fla-

vored little cigars, chewing tobacco, pipe and hookah tobacco. Mayor Bloomberg has signed the new law, and it is scheduled to go into effect in late February 2010.

IN THE CROSSHAIRS: FLAVORED LITTLE CIGARS

The House Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have sent correspondence to several tobacco products manufacturers that produce flavored little cigars. The Committee has characterized these companies' practices as an attempt "to circumvent this ban [on flavored cigarettes] and repackage [the] flavored cigarettes as 'little cigars.'" The Committee has launched a series of notices to these manufacturers of flavored little cigars asking them to appear, produce numerous documents, and defend allegations that certain little cigar products are nothing more than flavored cigarettes, and the manufacturers' marketing of such products is simply an attempt to circumvent the Act.

This correspondence and oversight investigation make it clear that Congress is attempting, without the enactment of legislation, to broaden the prohibition of the sale of flavored cigarettes to also include flavored little cigars. The Act as currently written applies only to products that are offered to or purchased by consumers as a cigarettes or roll-your-own tobacco. Based upon these inquiries and the uncertainty of the Act itself, the top distributor of clove-flavored tobacco products in the U.S., Kretek International, has asked a federal court to decide whether its new filtered clove cigars fall under the federal ban on flavored cigarettes.

Amid all of the controversy, at least one thing is certain: there will be much more to come on the issue of flavored tobacco products, including legislative and regulatory enactments as well as continued challenges through litigation. **S**

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