Letter to Industry on Cigarettes Containing Certain Characterizing Flavors

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September 14, 2009

Dear Sir or Madam:

The Food and Drug Administration (FDA) is providing this notice to remind regulated industry that effective September 22, 2009, cigarettes that contain certain characterizing flavors are considered adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act), as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA).

Smoking is the leading preventable cause of death in the United States. An important way to reduce the death and disease caused by smoking is to prevent children and adolescents from starting to smoke. Congress has stated that flavors make cigarettes more appealing to youth and often result in exposure to additional carcinogens and other toxic constituents. The removal from the market of cigarettes that contain certain characterizing flavors is an important step in FDA's efforts to reduce the burden of illness and death caused by tobacco products.

The FSPTCA provides FDA with regulatory authority over the manufacture, marketing, and distribution of tobacco products. Specifically, section 907(a)(1)(A) of the Act, as amended by the FSPTCA, establishes a tobacco product standard special rule for cigarettes that states in part:

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

This standard applies to all tobacco products that meet the definition of a "cigarette" in section 900(3) of the Act even if they are not labeled as "cigarettes" or are labeled as cigars or as some other product.

As of the September 22, 2009, effective date, cigarettes and their component parts that fail to comply with the special rule established under section 907 are deemed adulterated under section 902 of the Act. Under the Act, adulterated products sold or held for sale in the United States may be subject to seizure under section 304 of the Act. In addition, manufacturers, distributors, and retailers may be subject to injunction actions, civil money penalties, and/or criminal prosecution for violating the requirements of the Act (FFDCA, sections 301, 302, 303). FDA intends to use the full range of enforcement tools within the Agency's authority to ensure compliance with the new requirement.

If you have questions about this provision of the new law, please e-mail them to: Tobacco2@fda.hhs.gov.

Sincerely,

/s/

Lawrence R. Deyton, M.S.P.H., M.D.
Director, Center for Tobacco Products