FDA Expands Regulatory Authority to All Tobacco Products, Including E-Cigarettes

May 9, 2016
*Sandler, Travis & Rosenberg Trade Report*

The Food and Drug Administration has issued a final rule expanding its regulatory authority to all tobacco products, including electronic cigarettes and items that may be developed in the future. The FDA states that this rule subjects all importers, manufacturers and retailers of newly-regulated tobacco products to any applicable provisions, including registering manufacturing establishments, providing product listings to the FDA, reporting ingredients and harmful and potentially harmful constituents, requiring FDA premarket review and authorization of new tobacco products, placing health warnings on product packages and advertisements, and not selling modified risk tobacco products unless authorized by the FDA.

**Covered Items.** The FDA already regulates cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. The new rule brings all tobacco products under FDA oversight, including dissolvables not already regulated by the FDA, gels, waterpipe tobacco, electronic nicotine delivery systems (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers and electronic pipes), cigars and pipe tobacco.

This rule also deems any additional current and future tobacco products that meet the statutory definition of “tobacco product” (except accessories) to be subject to FDA regulation. For example, there could be tobacco products developed in the future that provide nicotine delivery through means (e.g., dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products but that are not drugs or devices.

Components and parts of regulated tobacco products are also regulated under this rule. These are defined as any software or assembly of materials intended or reasonably expected to alter or affect the product’s performance, composition, constituents or characteristics or to be used with or for the human consumption of a tobacco product.

Accessories for regulated tobacco products are not regulated. These are defined as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product, does not contain tobacco and is not made or derived from tobacco, and either (a) is not intended or reasonably expected to affect or alter the performance,
composition, constituents or characteristics of a tobacco product or (b) is intended or reasonably expected to affect or maintain the performance, composition, constituents or characteristics of a tobacco product but either solely controls moisture and/or temperature of a stored produce or solely provides an external heat source to initiate but not maintain combustion of a tobacco product. Examples of accessories include ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe pouches.

Requirements. Effective Aug. 8, the newly deemed products will be subject to the same Federal Food, Drug and Cosmetic Act provisions and relevant regulatory requirements to which cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco are subject with respect to the following.

- enforcement action against products determined to be adulterated or misbranded (other than actions based on lack of a marketing authorization during an applicable compliance period)

- submission of ingredient listing and reporting of harmful and potentially harmful constituents

- registration of tobacco product manufacturing establishments and product listing

- prohibition against sale and distribution of products with direct and implied claims of reduced risk (e.g., "light," "low" and "mild") unless the FDA issues an order authorizing their marketing

- FDA review prior to marketing new tobacco products

To restrict youth access to regulated tobacco products, this rule prohibits selling to persons under 18, requires age verification by photo ID, prohibits the selling of tobacco products in vending machines (unless in an adult-only facility) and prohibits the distribution of free samples.

Effective Dates. After Aug. 8, no importer, manufacturer, packager, distributor or retailer of covered tobacco products may advertise any such product if the advertisement does not comply with this rule; no distributor or retailer may sell, offer to sell, distribute or import for sale or distribution within the U.S. any such product the package of which does not comply with this rule (unless the product was manufactured before Aug. 8), and no person may manufacture for sale or distribution within the U.S. any such product the package of which does not comply with this rule.

Beginning Sept. 7, a manufacturer may not introduce any such product into domestic commerce, irrespective of the date of manufacture, if its package does not comply with this rule (i.e., non-compliant products manufactured prior to Aug. 8 may not be distributed for retail sale after Sept. 7).

The minimum age, identification and vending machine restrictions will be effective as of Aug. 8. The health warning requirements will be effective May 10, 2018, with an additional 30-day period in which a manufacturer may continue to introduce into interstate commerce existing inventory manufactured before Aug. 8, 2016, that does not contain the required warning statements on packaging.
User Fee Data. Because this rule subjects importers and domestic manufacturers of cigars and pipe tobacco to the FD&C Act’s user fee requirements, the FDA has issued a separate final rule requiring such entities to begin submitting the information needed to calculate the amount of those fees no later than Aug. 20. These entities will become subject to user fee assessments on Oct. 1.

To get news like this in your inbox daily, subscribe to the Sandler, Travis & Rosenberg Trade Report.