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Deciphering Smoke Signals — FDA's New Tobacco Product Rules and Their Impact on the Cannabis Industry

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Synopsis: Dual-use cannabis consumption products and their off-label uses may cause those products to fall within the new FDA rules governing tobacco products.

Manufacturers and retailers of vape pens and atomizers will face a brave new world come August 8 when the Federal Food and Drug Administration's (FDA) new rules take effect defining "tobacco products." This new, expansive definition of "tobacco products" contains enough ambiguity to give many manufacturers and retailers of cannabis-related vape pens fear that they could be swept up in a regulatory tide. Indeed, the regulation's text and policy bases suggest that it could, at minimum, become a precursor for future regulation of "cannabis products."

The FDA released the new rules in early May with nearly 500 pages of explanatory comment. Buried amidst all of the dense type are fairly simple concepts in the context of true "tobacco products," but these concepts are less than clear when it comes to cannabis-related products. The FDA's new rules operate in a two-step process: (1) defining "what" is regulated, and then (2) establishing "how" it is regulated. In the first step, the FDA has created a new category of "tobacco products," which it broadly defines (or in FDA-speak "deems") to include just about anything that can be used to consume tobacco. Second, because of that expanded definition, the FDA has imposed new and existing regulations on manufacturers and retailers of those newly-deemed "tobacco products."

What Are the "Tobacco Products" Covered by the New Rules?

Up until now, the existing FDA statutes and rules have addressed just cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. The new rules add a more generic term, "tobacco products," which the FDA says includes "components and parts" but not "accessories." The FDA defines "components and parts" as anything that is "intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of tobacco products or to be used with or for human consumption of a tobacco product." The FDA's non-exhaustive list of components and parts includes e-cigarettes, e-liquids, atomizers, batteries, flavors, vials that contain e-liquids, flavor enhancers, water filtration based additives, flavored water pipe tobacco charcoals and their wrappers or boxes, and bowls, valves, hoses and heads.

The rules exclude "accessories," which are any products intended or reasonably expected to be used with or for the human consumption of tobacco, and is not intended or reasonably expected to alter the performance, composition or constituents of a tobacco product. Examples include ashtrays, spittoons, hookah tongs, cigar clips and stands, pipe pouches, humidors and refrigerators — all products that do not contain tobacco and do not affect its performance, composition, constituents or characteristics.

Could the New Regulation Apply to Cannabis Products?

The FDA's use of the phrase "tobacco product" and its rationale for regulation based on the public health risk due to "highly addictive" nicotine establish that the rules do not directly affect cannabis-related products. Indeed, the FDA commentary prefacing the rules mentions "marijuana" only in the context of surveys regarding perceptions about e-cigarettes and minimum age requirements.

Dual use of cannabis products as tobacco component may trigger "tobacco product" status under the new FDA rules.

But could the rules indirectly apply to cannabis products? As tempting as it may be, manufacturers and retailers of cannabis-related products should not simply assume they are exempt. A key phrase the FDA uses in defining "component or part" is whether the product is "intended or reasonably expected to" be used for human consumption of a tobacco product or alter or affect a tobacco product. This "intended or reasonably expected to" language could be the proverbial back door for the FDA to regulate cannabis-related products if there is a possibility of dual use with tobacco. Vape pens that can be used for either tobacco-derivatives or cannabis-derivatives are a prime example. Thus, the packaging, labeling and advertising of cannabis-related products with a conceivable dual purpose could be an important factor in determining whether the FDA will "deem" the product a "tobacco product" subject to the new rules.

How and When Will the Rules Apply?

The FDA rules will have differing effects depending on timing. The most immediate are restrictions on the sale and marketing of these newly-deemed tobacco products to minors. Later, and more significantly, the automatic inclusion of these newly-deemed components and parts, such as e-cigarettes, under the Federal Food, Drug and Cosmetic Act and its regulations will require registration, testing, premarket submissions and labeling.

- ***Immediate impacts***. After August 8, it will be illegal under federal law to sell a deemed tobacco product, such as an e-cigarette, to anyone younger than 18 years of age. (Note: this already is the case under a bill passed by the Washington state legislature in 2016 making it illegal to advertise and sell a vapor product to a minor, but the Washington state definition of a "vapor product" specifically excludes marijuana.) This also means a ban on vending machine sales (unless in an adult-only facility) and distribution of free samples. The new FDA rule also requires the same minimum warning statements on packaging and in advertisements regarding the addictive nature of nicotine.

- ***Longer-term impacts***. One aspect of the new FDA rule that gives manufacturers and retailers greater heartburn is the cumbersome and costly FDA approval process for marketing a tobacco product. Every product will have to go through one of three approval pathways:

    - ***Premarket Tobacco Product Application Pathway (PMTA)***. This process requires a manufacturer to provide information to the FDA about the product's ingredients, additives, properties, manufacture, processing, labeling and health risks. If the FDA determines that the product protects the public health, it will grant permission to market the product. This is a highly subjective, case-by-case determination that is based on the "continuum of risk of nicotine-delivering products."

    - ***Substantial Equivalence Pathway (SE)***. This process allows a manufacturer to demonstrate to the FDA that its product is "substantially equivalent" to a tobacco product that was marketed before February 15, 2007. If the FDA determines that the product has the same characteristics as the prior product, based on clinical data, it will grant permission because the product does not raise different questions of public health.

    - ***Minor Change Pathway***. Under this process, the FDA will grant permission to market if it determines that the only change to the product is minor and involves only a change to an additive in an approved tobacco product.

By far, the greatest impacts on time and expense for manufacturers will come under the PMTA pathway. The FDA estimates that it will take approximately 1,500 hours to prepare the application and another 213 hours to prepare an environmental assessment. Retailers could come under the manufacturing rules, and be required to go through one of these pathways, if they engage in activities that could be considered "manufacturing, preparation, compounding or processing" a tobacco product. Thus, a retailer who mixes or prepares e-liquids or creates or modifies an aerosolizing apparatus, would be subject to manufacturing rules.

The FDA will be phasing in these regulations. For a manufacturer taking the PMTA pathway, and whose product was already on the market as of August 8, 2016, the compliance period is 24 months after the August 8, 2016, effective date. A manufacturer must submit the PMTA application by the 24-month deadline and then will be allowed to keep its product on the market for an additional 12 months while the FDA considers the application.

Conclusion

As a practical matter, the FDA has so far limited contact with the cannabis world — primarily regulating products containing cannabis compounds, particularly those that make inaccurate claims in labels or present human health risks. That appears to remain the case after the new rules take effect on August 8. So long as cannabis-related products do not have a dual-purpose or make claims about being safer or healthier than other delivery methods, those products should fall outside the FDA's limited scope. That is not to say that at some point in the future, particularly if the federal government legalizes cannabis, the FDA will not embark on similar rulemaking related to cannabis products.

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