SFATA
Smoke-Free Alternatives Trade Association

FDA DEEMING REGULATIONS ANALYSIS

Overview

The U.S. Food and Drug Administration ("FDA" or "the Agency") issued a pre-publication version of its final Deeming Rule on May 5, 2016. This Rule extends FDA's authority to all tobacco products, products derived from tobacco, and devices used with tobacco products (except accessories). With this action, and as of the Rule's effective date, the FDA will or could have authority over the following products:

- Liquids containing nicotine (products without nicotine are not under FDA's authority)
- Batteries
- Tank systems
- Cartomizers
- Atomizers
- Digital Displays
- Device Software

The Rule was published in the May 10, 2016 edition of the Federal Register. The Rule's effective date is 90 days from publication in the Federal Register (*i.e.*, August 8, 2016). Once the Rule is published in the Federal Register, it starts the clock ticking on a number of dates.

The Deeming Rule also creates a distinction among businesses in the industry: retailers and manufacturers.

Retailers: Means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted.

Manufacturers: Means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product. As explained below, if an establishment mixes or prepares e-liquids, or creates or modifies aerosolizing apparatuses for direct sale to consumers, such a firm would be a tobacco product manufacturer. .A manufacturer could also be any business that rebuilds coils or devices beyond simple repairs.

Depending on number of employees and annual revenues, it is possible that a manufacturer could qualify as a "small-scale tobacco product manufacturer." Qualifying for this designation will not reduce the compliance requirements, but will afford such firms with additional time to comply with certain requirements under the Rule. Under the Rule, a "small-scale tobacco product manufacturer" is a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent ("FTE")employees ***and*** has annual total revenues of $5,000,000 or less. FDA considers a manufacturer

to include each entity that it controls, is controlled by, or is under common control with such manufacturer. In other words, if a firm employs 150 or less FTE employees and has $5,000,000 or less in annual total revenues, but is controlled by, controls, or under common control with another manufacturer that puts them over the 150 FTE/$5,000,000 revenue thresholds, they would no longer be considered a small-scale tobacco product manufacturer.

Key Dates For Vapor Businesses

May 10, 2016 The Deeming Rule is officially published and will be effective 90 days thereafter.

August 8, 2016 The Deeming Rule is effective, as it is 90 days after the Rule is published in the Federal Register. This starts the clock on the various premarket pathway options and it also implements some key changes in the near term.

December 31, 2016 As a result of The Deeming Rule manufacturers will now need to submit a list of all products twice a year December and June of each year. Because the Rule will go into effect August 8th December of this year will be the first time that vapor product manufacturers have to submit this information.

February, 2017 Manufacturers will need to submit an ingredient list of all products that are manufactured in February of 2017. It is not clear at this time what items the FDA will be expecting although we do expect that the level of detail required will be significant. As we know more, we will provide updates.

August 8, 2018 Premarket tobacco product application ("PMTAs") are due.

August 8, 2019 Three years after the Rule's effective date. By this time, all products on the market must have been grandfathered or the subject of an FDA marketing authorization order.

The Path to Getting FDA Authorization

Manufacturers of newly-deemed products that are "new tobacco products" will be required to obtain premarket authorization of their products through one of three pathways:

> **(1) substantial equivalence (SE):** This will require a manufacturer to show that a new product is substantially equivalent to a product on the market as of February 15, 2007. It is unlikely that many products will be able to demonstrate SE given both the lack of comparable products on the market in February 2007 and the differences between products then and now. These submissions are due 18 months after the effective date
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> **(2) exemption from SE;** This pathway is intended primarily for cigars and is unlikely to be an avenue for vapor products. These applications are due 12 months after the effective date.
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> **(3) premarket tobacco product application (PMTAs):** This will be the path that almost all vapor products will need to follow. Manufacturers for both e-liquids and devices will have 24 months to submit a PMTA application. After an application has been submitted, manufacturers will have an additional 12 months to market products.

At the close of these compliance periods, products will be subject to FDA enforcement unless they are grandfathered or are the subject of a marketing authorization order.

It should be noted that the administrative costs of compiling a PMTA will cost at least a few hundred thousand dollars PER product. This conservative estimate does not account for the testing that will be required to generate data sufficient to inform a PMTA submission. Such testing could cost at least $1 million per product.

What should Businesses Do?

Short Term:

Nothing will significantly change the way you operate your business until August 8th. Beginning on August 8th, the FDA can and likely will, to some degree, begin to enforce the following requirements:

- Products may not be sold to persons under the age of 18 (both in person and online);
- Age verification required by photo ID;

· Prohibition on the distribution of free samples to consumers. This restriction does not seem to apply to liquid that does not contain nicotine. Shops would still be allowed to let customers try flavors of e-liquids containing nicotine if they charge a fee for such sampling.

· Prohibition on the sale and distribution of products with modified risk descriptors (e.g., "light", "low", and "mild") and claims unless FDA issues an order permitting their use.

Long Term:

Manufacturers of both e-liquids and devices (see list above) will need to begin planning to submit a list of products they manufacture, both liquids and devices, as well as track the ingredients for each different liquid they manufacture. We also suggest that businesses determine which premarket path they plan to take in order to obtain authorization from FDA. SFATA will provide in-depth guidance and updates on how to comply with these premarket requirements, including what information the Agency will expect to see.

- The Rule requires premarket authorization for each flavor prepared. For example, if a firm manufactures e-liquids in five different flavors, the firm would be required to seek premarket authorization from FDA to market each one of the e-liquids AND for each level of nicotine (if the nicotine levels differ).

- To the extent an establishment mixes or prepares e-liquids, or creates or modifies aerosolizing apparatuses for direct sale to consumers, such a firm would be a tobacco product manufacturer under the Act and would thus be subject to the same legal requirements that apply to other tobacco product manufacturers.

- The health warning requirements become effective 24 months from the date of publication of the final rule (*i.e.*, August 8, 2018). The required warning is as follows: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." Warning statements on packages must be printed in at least 12-point font size to be conspicuous and legible.

What Can Be Done?

There are two primary paths that SFATA can pursue and we will be reviewing any and all options that we feel can benefit the industry.

Legislative fix: Cole/Bishop amendment was approved by the House Appropriations Committee last month. If signed into law, it would, among other things, move the February 15, 2007 grandfather date, allowing some or all e-cigarettes and vapor products currently on the market to serve as "predicates" for products introduced after the Deeming Rule's effective date.

- It remains to be seen whether this provision will stay in the Agriculture Appropriations Bill, let alone whether the House and Senate will even vote on a standalone Agriculture Appropriations Bill during this Congress.

- SFATA is also working to get support for the Cole/Bishop amendment to increase the chance of passage through Congress.

In addition to the Cole/Bishop language, SFATA is currently working with other interested organizations and legislative leaders to develop a more comprehensive regulatory framework that will better serve the industry into the future.

We are also considering pursuing litigation efforts but at this time we will need a better understanding of all the legal issues and ramifications of these choices.