VTA

VAPOR TECHNOLOGY ASSOCIATION

VTA GUIDANCE

May 16, 2016

VTA's Next Level Thoughts on the Deeming Regulation

On May 5, 2016, the Vapor Technology Association (VTA) issued its Initial Thoughts on the Deeming Regulation. As noted, the 500+ pages of Deeming Regulations and guidance documents are very complex and require significant analysis. We have prepared for you our *next level* thoughts on the Deeming and hope you find it helpful. Rest assured, this will not answer all of your questions. However, VTA has assembled a group of FDA and regulatory experts in Washington, D.C. on June 7 and 8, 2016, who will be able to provide specific *practical* information on how to survive in a post-deeming world. Very shortly, we will be providing more details on our conference. Click here to learn more: **VAPE & THE FDA: Understand It. Manage It.**

The FDA Attempts to Kill the Hope of Vape

On May 10, 2016, the FDA issued its long-awaited Deeming Regulation that reflects little advanced thinking about how to regulate the only ground-breaking technology that shows remarkable promise for reducing cigarette smoking.

One thing is clear: the FDA has ignored all industry comments, giving little consideration to the advances in vapor technology, the industry's survival as a whole, or the broader objective of advancing public health. Given that the law of the land already prohibits the sale of vapor products to youth and requires child resistant packaging, the FDA's primary justifications for imposing the Deeming are fictions.

Instead, by targeting for extinction the overwhelming majority of companies that manufacture or supply vapor products, the FDA has demonstrated a certain callousness to the millions of adult consumers of cigarettes who have been relying on vapor products. And, by imposing an antiquated tobacco regulatory scheme on non-tobacco products, the FDA has demonstrated a lack of vision for how to regulate a revolutionary technology and the innovative companies that are driving that technology forward.

Locked in its antiquated mindset, the FDA now subjects vapor products to a regulatory bramble which will squander a decade of technological innovation and replace it with the burden of papering over untenable demands. Understanding the Deeming comes first. But, shortly we will take the next step to level the playing field for the industry and hope that you join us.

– Vapor Technology Association

In this Guidance

GENERAL OVERVIEW

WHY IS FDA NOW REGULATING VAPOR PRODUCTS?

In 2009, Congress enacted The Family Smoking Prevention and Tobacco Control Act. The law imposed significant new requirements on the sale and advertising of cigarettes, roll-your-own tobacco (RYO), and smokeless tobacco and placed those products under the authority of FDA. Congress also stated that FDA could expand its jurisdiction to other tobacco products if it so chose by issuing regulations. Five years later, FDA issued proposed regulations that would bring under its control vape products and e-cigarettes, e-liquids and other components. After considering comments from the general public, health groups, industry and other interested parties, FDA published its final Deeming Regulations (the "Deeming") on May 10, 2016.

WHAT DO THE NEW REGULATIONS DO?

What we call vapor products, the FDA is calling Electronic Nicotine Delivery Systems (ENDS). In short, under the Deeming the FDA exercises extensive control over ENDS products through all stages – development, manufacturing, advertising, and retail sales – by deeming them covered tobacco products.

EXPANSIVE LIST OF PRODUCTS COVERED BY DEEMING

WHAT IS A "COVERED TOBACCO PRODUCT"?

A "covered tobacco product" is a product that contains, is made or is derived from tobacco – in no matter how small an amount – and is intended for human consumption.

Electronic Nicotine Delivery Systems. ENDS products that contain nicotine or any other ingredient or component derived from tobacco are covered by the new rule. Currently, FDA generally considers ENDS as tobacco products that use an electronic or other power source to heat e-liquids, tobacco, or other material derived from tobacco.

FDA had defined 3 sub-classes of ENDS products:

- E-liquids,
- aerosolizing apparatus and
- ENDS products that package e-liquids and aerosolizing apparatus together.

In other words, while these sub-classes may be considered *components* of tobacco products (as discussed below), if they themselves contain tobacco they are also "covered tobacco products." The easiest example is an e-cigarette cartridge filled with e-liquid *derived from* tobacco. However, if an e-liquid, which does not contain tobacco, is intended or reasonably expected to be mixed with an e-liquid made from or derived from tobacco, it will be treated as a covered tobacco product.

WHAT OTHER PRODUCTS ARE AFFECTED BY THE NEW REGULATIONS?

Components. Basically, a component is *anything* (software, assembly materials, you name it) that is intended or reasonably expected to either: (1) alter or affect the performance, composition, constituents or characteristics of a tobacco product, OR (2) be used with or for the consumption of a tobacco product. The FDA considers e-liquids, atomizers, batteries (with or without variable voltage), cartomizers (atomizer plus replaceable fluid-filled cartridge), digital display/lights to adjust settings, clearomisers, tank systems, flavors, bottles that contain e-liquids, and programmable software all to be examples of components regulated under the new rules.

However, products that meet FDA's definition of "accessory" are not "components" and are not regulated at this time.

Accessories. FDA defines an "accessory" as a product that is intended or reasonably expected to be used with or for consumption of a tobacco product, but is not made or derived from tobacco and meets either one of these two tests:

(1) the product is not intended or reasonably expected to affect or alter the performance, composition, constituents or characteristics of the tobacco product; OR

(2) the product is intended to do so only by:

(a) Controlling the moisture or temperature of a stored tobacco product (e.g., humidors) or

(b) Providing an initial heat source for ignition of a tobacco product, but not to maintain combustion (e.g., lighters). If an item used with your product does not meet the definition of accessory, it is more than likely a component.

FDA Says All of the Following Are Regulated "Components"

• • •

E-liquids
Atomizers
Batteries
Cartomizers
Replaceable cartridges
Digital display/lights
Clearomisers
Tank systems
Flavors
Bottles containing e-liquids
Software

• • •

And, this is not an exhaustive list.

COMPANIES THAT ARE REGULATED

WHO DOES THE DEEMING APPLY TO?

Most of the regulations are directed at manufacturers and importers of tobacco products. FDA defines **manufacturer** broadly to include any facility or establishment that handles the tobacco product during its manufacture, including assemblers, re-packers and re-labelers. FDA also regulates any **retailer** which is defined as any person or entity that that sells covered tobacco product to anyone for personal consumption. A retailer may also include the owner of an adult-only venue that operates a vending machine containing ENDS or other self-service offerings of ENDS.

However, as discussed below, a retailer (even a small vape shop) may be considered a manufacturer if it engages in manufacturing activities.

WHAT IF I MAKE COMPONENTS?

If you make components of vape systems, but only sell them for use in the manufacture of other products, you will still be subject to the deeming. *However,* while you are subject to deeming under the rule, FDA currently plans to limit its enforcement of some of the most demanding requirements (i.e., market authorization applications, HPHC testing) to manufacturers of "finished tobacco products" – products (including components) that are packaged for final retail sale.

Thus, if you make **e-liquids** sold only to manufacturers of other ENDS products, you need not submit a market authorization application. However, you will likely need to work closely with

your customers to make sure they have the information they need to file a successful application for the final retail product.

Importantly, manufacturers of components that are not made or derived from tobacco (e.g., an atomizer or e-liquid tank sold packaged alone at retail) are not required to comply with certain provisions of the rule, such as required warning statements on packages and in advertising, minimum age verification requirements, and the ban on vending machine sales. *However*, components of tobacco products that are not "covered tobacco products," i.e., are not made or derived from tobacco, must comply with all other provisions of the Deeming, including filing product authorization applications.

WHAT IF I AM SMALL OPERATION?

Retailers. Retailers, even single vape shop owners, are required to comply with numerous regulations set forth in the Deeming:

- The sale of covered ENDS products is prohibited to those under 18 years of age (or higher under state or local laws).
- Retailers must require photo ID of anyone who appears to be 26 years old or younger beginning August 8, 2016.
- It appears at this point that FDA also will require photographic ID for internet and mail order sales. Self-certification of age is prohibited.
- Product labels and advertising must not contain any representation that ENDS might help cessation of or reduction in tobacco use.
- Free samples of tobacco products are prohibited, beginning August 8, 2016.
- No vending machines will be allowed except in an "adult only" facility.

In addition, if you operate a retail shop but engage in "manufacturing" activities, FDA will regulate you as a manufacturer regardless of how small your "manufacturing" operations may be. These activities include the blending of liquids, assembling vape components or devices, and/or repackaging products.

Small Scale Manufacturers. If you are a small manufacturer, the FDA has provided what it believes to be some relief with respect to deadlines. A **small-scale manufacturer** is one who employs 150 or less full-time equivalent employees and has annual total revenues of $5 million or less. Small-scale manufacturers are given a six-month extension on reporting ingredients and providing health documents to FDA, and may be treated more generously with respect to extensions of time.

APPLICATIONS ABOUND?

WILL I NEED TO FILE A COSTLY APPLICATION?

The FDA now requires all manufacturers of tobacco products on the market on or before August 8, 2016, to file costly applications to simply keep those products on the market. However, the manufacturer of any tobacco product that was sold domestically on February 15, 2007 (the "Predicate Date"), and has not been modified since February 15, 2007, will not need to file any product authorization applications with the FDA.

WHAT ARE MY APPLICATION OPTIONS?

The FDA says it offers three potential pathways for companies to keep their products on the market: (1) file a **Premarket Tobacco Application** (PMTA) within 24 months of the Effective Date; (2) file a **Substantial Equivalence Application** (SE) within 18 month of the Effective Date; or (3) file a **Substantial Equivalence exemption** request within 12 months of the Effective Date. However, as discussed below, these are false choices for the vast majority of the industry since companies will not be able to take

advantage of either of the less expensive substantial equivalence pathways.

WHY CAN'T I FILE A SUBSTANTIAL EQUIVALENCE APPLICATION?

The substantial equivalence exemption and substantial equivalence pathways are the two least burdensome applications for a company seeking to keep its products on the market. However, both pathways require the existence of a *predicate* product, which must be a grandfathered product (at least until other products receive a SE marketing order).

It is well accepted that virtually no ENDS products will qualify for such "grandfather" status since virtually no ENDS products were on the market on the Predicate Date – February 15, 2007. In fact, in the Deeming, the FDA admitted that it has been able to identify only one e-product that *might* serve as a predicate for either substantial equivalence pathway.

But, the "predicate" identified is not publicly available for use by companies as a predicate for substantial equivalence purposes. Even if it were, the first generation e-cigar identified is likely so vastly different from any currently marketed e-products that FDA is unlikely to issue either a substantial equivalence exemption or marketing order on such an application.

To date, the FDA has applied the substantial equivalence standard to require that the predicate product be *virtually identical* to the product for which the application is filed. Moreover, the FDA has implied that it would be reluctant to accept cross-product category comparisons. For all of these reasons, two out of the three pathways are simply foreclosed. Hence, manufacturers of ENDS products will be required to file a full Premarket Tobacco Product Application (PMTA) simply to keep their products on the market.

WHAT MUST I DO TO FILE A PREMARKET TOBACCO APPLICATION?

FDA's **PMTA Guidance for ENDS Products** contains more detail on FDA's initial expectations for ENDS applications. A PMTA requires a detailed showing through scientific analysis, public literature, and testing that the marketing of the product would be "appropriate for the protection of the public health," including effects on quit rates and uptake. That standard remains ill-defined. New clinical and non-clinical studies may be required.

It is important to note that FDA Guidances are not binding law. They only state FDA's current thinking. However, FDA has a track record of *requiring more,* not less, than what the guidance provides. Both FDA and industry may take a different approach if it reaches the same goal.

Manufacturers can get FDA input as it begins structuring its PMTA by scheduling a meeting as set forth in FDA Guidance **Meetings with Industry and Investigators on the Research and Development of Tobacco Products.** As detailed in the guidance, manufacturers should be prepared with the specific questions or issues they'd like to discuss and need to provide detailed supporting information prior to that meeting. FDA does not answer broad, open questions with respect to the requirements of a specific application. The best approach is to have developed a proposed answer to your questions, fully justify that to the agency, ask them for input, and confirm that you and the agency have an agreed-upon approach before you leave. Make sure that approach is reflected in FDA's meeting minutes and send a confirming letter post-meeting stating your understanding of all points of agreement.

HOW WILL THE FDA APPLICATION AND REVIEW PROCESS AFFECT MY CURRENT PRODUCTS?

Products introduced or changed since the Predicate Date and on the market prior to August 8, 2016, will be required to undergo the PMTA process. PMTAs for each new product must be filed by August 8, 2018, in order to stay on the market beyond that date. FDA then – in theory but likely not in practice – has 180 days to review the application. FDA announced it will allow for "continued compliance," meaning it will not take products off the market for another 12 months after August 8, 2018, if a PMTA was timely filed. If FDA decides the product does not meet the standards set forth in the Tobacco Control Act or the manufacturer fails to provide additional information requested during review, FDA may order the product be removed from the market at the end of the "continued compliance" period.

WILL I BE ABLE TO INTRODUCE NEW PRODUCTS AND NEW BRANDS?

After August 8, 2016, no new products or brands can be introduced into the marketplace without *prior authorization* by FDA, and no changes to current products, however small, may be made. Given the detailed review process, the backlog of existing and new applications, and the uncertain level of resources FDA will commit to newly deemed products, it will almost certainly be a number of years before any new tobacco products of any sort will be able to enter the market after August 8, 2016.

HOW QUICKLY WILL FDA REVIEW PMTA APPLICATIONS?

Frankly, we're not sure. That depends on FDA. FDA still has a significant backlog of applications dating back to when cigarette, RYO and smokeless tobacco products were first regulated. FDA only authorized new products under a PMTA for the first time in November 2015, for products which were already well-known and well characterized in a product category familiar to the agency. The new regulations will result in a huge number of new applications being filed by manufacturers of cigars, pipes, e-cigarettes and liquids, vape products, hookahs and other tobacco products.

FDA will need to hire and train new staff and educate itself about the new products now under its authority. To date, despite the fact that tobacco product manufacturers pay the costs of tobacco regulation through "user fees", only a small amount of those fees have been devoted to review of tobacco product applications. Most of that money is spent on public education programs, the setting up and funding of tobacco research centers, and administrative costs.

FDA TRACK RECORD ON APPLICATIONS

The FDA is sitting on 3,500 provisional substantial equivalence applications (for tobacco products currently on the market). These applications, which have not been ruled on by FDA, have been pending for up to 5 years.

Through FY2015, 2,000 *new* substantial equivalence applications are also still awaiting a decision by the FDA.

The likelihood that FDA can or will process hundreds if not thousands of more complicated and more burdensome PMTAs within 12 months is, frankly, not encouraging.

WHAT HAPPENS IF THE FDA DOESN'T APPROVE MY APPLICATION IN 12 MONTHS?

Every PMTA application filed must be decided upon by FDA within 12 months after the respective filing deadline. If FDA fails to issue a marketing order by the end of this 12 month "Continued Compliance Period," you could be required to pull your product from the market by FDA until it decides on your application. Given the FDA's track record on processing less complicated substantial equivalence applications, it is highly unlikely that, without a dramatic change of procedure and manpower, the FDA will be able to process any PMTA in 12 months' time.

LABELING AND ADVERTISING

WHAT ARE THE NEW WARNING REQUIREMENTS?

Beginning August 8, 2018, retail packages of all ENDS products sold at retail that are made from or derived from tobacco must contain a permanently affixed label that contains the following Warning Statement:

"*WARNING: This product contains nicotine. Nicotine is an addictive chemical.*"

Labels. Warning statements must take up 30% of *both* sides of the product package label. Alternate means of compliance are available for small packages.

Advertisements. For advertisements, warning statements must comprise 20% of the top of the advertisement. This applies to all advertising with a visual component, including print advertisements, websites, e-mails, social media postings, videos, etc.

Nicotine-Free. If your tobacco product does not contain nicotine, you may certify to FDA that the product contains no nicotine and that you have the data to prove it. Based on that certification, you may use the statement "*This product is made from tobacco*" following the same size, format and style requirements of the Warning Statement.

Detailed specification with respect to type style and size, placement and borders is included in the regulations and accompanying FDA guidance.

WHAT OTHER CHANGES WILL BE REQUIRED ON MY LABEL?

In addition to the warning statement, FDA imposes numerous other product label requirements:

(1) Product labels must include the statement "*Not for sale outside the United States*" and a statement of the percentages of foreign and domestic tobaccos used. It is unclear yet how the latter requirement will be applied to e-liquids and components that do not contain tobacco.

(2) Product labels must also contain an established name (i.e., vapor pen, e-cigarette, e-liquid, etc.).

(3) Product labels must include net quantity of content.

(4) Product labels must identify the product's manufacturer, distributor or packer.

(5) Product labels ***and advertising*** may not use the terms "light", "low", or "mild", *or other terms that might suggest that the product is safer than or contains less additives than other tobacco products*.

ARE STATE LAW PRODUCT LABELING REQUIREMENTS PRE-EMPTED ?

The new warning statement requirements are characterized by FDA as "minimum requirements". FDA is attempting to leave the door open to require additional federal warning statements and/or continued use of warning statements required

under state law. We believe FDA's interpretation of the law is incorrect and that all other warning statements are prohibited.

OTHER COMPLIANCE REQUIREMENTS

WHAT ELSE WILL I NEED TO DO TO COMPLY?

The Deeming requires domestic tobacco product manufacturing establishments to comply with more general FDA controls including the following:

(1) Registering all domestic manufacturing facilities with the FDA.

(2) Filing a full listing of products and advertising;

(3) Filing with FDA a *full* list of ingredients, and certain "smoke" constituents for all products;

(4) Notifying FDA of changes in ingredients;

(5) Providing FDA with certain internal tobacco health related documents; and

(6) Conducting other reporting and recordkeeping requirements.

In addition, domestic tobacco product establishments must comply with FDA's adulteration (unsanitary manufacturing conditions, contaminated product, etc.) and misbranding (false or misleading labeling, failure to include required information, etc.) requirements.

Further, domestic manufacturers and importers must create consumer complaint files, determine whether consumer complaints present a health or safety risk other than those inherent in the tobacco product, take action to cure such risks, maintain complaint files, and where necessary conduct recalls in conjunction with FDA.

At some point, FDA also will issue regulations setting Good Manufacturing Practices for all tobacco products.

WILL I BE SUBJECT TO FDA INSPECTIONS?

Yes. FDA intends to inspect each facility approximately every 2 years. During an inspection, FDA investigators will want to inspect and take samples of products, review your physical plant, manufacturing process, on-site warehouses, quality control procedures, recordkeeping and other aspects of your operations. Full inspections can take from 2-3 days to a couple of weeks.

First-time inspections will tend to be less rigorous, more of an introductory meeting and review, absent extreme circumstances. Manufacturers should start work on developing procedures to react and respond to FDA inspections, e.g., who is responsible for accompanying inspectors, procedures for requested documents, parallel sampling, etc.

DEADLINES

WHEN MUST I COMPLY WITH ALL OF THESE REGULATIONS?

The Deeming includes numerous regulations that are applicable to virtually all companies in the vapor industry. The first regulations become enforceable on August 8, 2016 and various regulations become effective at differing times thereafter. Moreover, the FDA has staggered some compliance deadlines for small-scale manufacturers.

For informational purposes only, we have created this **Deeming Compliance Calendar** which provides you an overview of the potentially applicable regulatory compliance dates included in the Deeming.

You should consult with your own FDA attorney to determine which regulations are applicable to your company and when you must comply with those regulations.