VAPOR TECHNOLOGY ASSOCIATION

VTA GUIDANCE

INITIAL REACTIONS TO FDA'S DEEMING REGULATION
May 5, 2016

FDA'S DEEMING REGULATION WENT FROM BAD TO WORSE FOR THE VAPOR INDUSTRY; THE COLE-BISHOP AMENDMENT NOW THE ONLY WAY TO SAVE VAPOR

OUR INITIAL THOUGHTS

Today, the FDA released its final Deeming Regulation (the "Deeming") sweeping all vapor devices and liquids made, derived from, or used with tobacco under its regulatory authority by deeming them to be *tobacco products*.

The Deeming (including preamble) is 499 pages long and is accompanied by a Final Rule regarding User Fees and four FDA "guidance" documents. We have conducted a cursory review and want to share some of our initial thoughts. We will provide more detailed, expert analysis soon.

It is clear that the FDA essentially 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. Instead, the FDA asserted that its new rules were designed to protect youth, by declaring that retailers no longer will be allowed to sell to those under 18. The FDA failed to mention that virtually every state already bans sales to minors. In addition, the FDA proclaimed that its new rules will implement child resistant packaging but failed to mention that this too is already federal law. In fact, the Deeming will have little impact on protecting youth.

The Deeming now thrusts a debilitating amount of paperwork equally upon every vapor company regardless of *size*. The Deeming creates a remarkably unfair system in which our new game-changing technologies are being treated *worse than* all forms of combustible tobacco products.

For these reasons, we must unite – both industry and consumers – to save our industry, adult consumer choice and the right to vape. Today's action by the FDA makes passing the Cole-Bishop Amendment all the more urgent and imperative. In short, **the Cole-Bishop Amendment is our only viable path to survival.**

HIGHLIGHTS OF THE DEEMING

Here are answers to just some of the questions that we have been fielding today which highlight what the Deeming contains and the scope of products covered.

When Does the Deeming Go Into Effect? The Deeming will be "officially" published on May 10, 2016. The regulations will be effective 90 days thereafter on August 8, 2016 ("Effective Date").

What Happens on August 8, 2016? Any product that you do not have on the market by August 8, 2016, cannot be brought to market without *prior* FDA approval (i.e., filing an application that ultimately receives an FDA marketing order).

What About Products On the Market Now or Before August 8, 2016? The FDA says you have three options:

(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 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.

What About the Predicate Date? The FDA ignored calls to change the predicate date, which remains **February 15, 2007**.

- FDA admitted that it has identified only ONE e-product that might serve as a predicate for an SE application.

- This "predicate" is not publicly available for use by companies as a predicate for SE purposes. Even if it were, a first generation e-cigar is likely so vastly different from currently marketed e-products that FDA is unlikely to issue an SE marketing order on such an application. (Note: To date, the FDA has applied the SE standard to require that the predicate be *virtually identical* to the SE product.)
- FDA additionally implied that it would be reluctant to accept cross-product category comparisons.
- As such, **there is no apparent predicate** for any electronic cigarette or vapor product.
- And, therefore, the SE pathway and SE exemption are not available.

Doesn't the FDA's Moving Timeline Make It Easier? No. Even if filing a PMTA or SE application is economically feasible for vapor companies, which it is not, the moving timeline completely disadvantages vapor products.

- The Deeming imposes strict requirements and an artificial deadline for FDA action that, given its track record, the agency is unlikely to meet.
- Every 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 will essentially have to pull your product from the market.
- To provide context, the FDA is currently sitting on 3,500 provisional SE applications filed for currently marketed tobacco products over the last 5 years. Also, the FDA is sitting on 2,000 new SE applications filed through FY2015 for products that have not yet been allowed to go to market.

What If I Only Sell A Device or Component? The same rules apply to you whether you sell an open or closed system, a device, or component. Here is the FDA's "non-exhaustive list" of components and parts used with vapor products:

- e-liquids;
- batteries (with or without variable voltage);
- digital display/lights to adjust settings;
- tank systems;
- vials that contain e-liquids;
- atomizers;
- cartomizers (atomizer plus replaceable fluid-filled cartridge);
- clearomisers;
- flavors; and
- programmable software.

When Is A Vape Shop Not a Vape Shop? If you own a vape shop and you either mix or combine product in your shop, you are no longer a vape shop; you are a manufacturer pursuant to the Deeming.

What About Labels? New labeling requirements will be imposed, including accurate nicotine content. Note that the Deeming states, "No State or local laws in effect at the close of the public comment period were identified that FDA determined would be preempted by this final rule." We at VTA vehemently oppose this interpretation of the Family Smoking Prevention and Tobacco Control Act's preemption clause.

What About Sampling? Sampling – even in vape shops – is banned.

Is There Any Good News? The only two bright spots, at this juncture of our review, is that vapor products will not be subject to user fees. Also, the FDA clearly spoke about the fact that it will be implementing new regulations to extend the flavor ban from cigarettes to cigars but did not indicate that it would apply such a ban to vapor products. In fact, the FDA notes that the "availability of alternatives to traditional tobacco flavors in some products (e.g., ENDS) may potentially help some adult users who are attempting to transition away from combusted products."

WHERE DO WE GO FROM HERE?

Fortunately, we already have the Cole-Bishop Amendment, which cleared its first big hurdle in Congress last month. During a mark-up of the Agriculture, Rural Development, Food and Drug Administration bill, Representatives Tom Cole (R-OK) and Sanford Bishop (D-GA) offered a bipartisan approach that would accomplish the goal of protecting small businesses and preserving the industry, while setting the stage for commonsense regulations that will protect youth and ensure the safety of consumers. This is exactly the type of legislative solution that we need. Unlike the FDA's one-size-fits-all approach, the Cole/Bishop approach seeks to regulate vapor products as the new technology they are, not as the tobacco products that they are not.

The Cole-Bishop Amendment is the only immediate vehicle that can change the predicate date. The former Cole Bill (HR2058) has been supplanted, and Rep. Cole has endorsed the new approach publicly.

Given the comments made by the FDA and the anti-vaping groups, a stand-alone bill to only change the predicate date (i.e., HR 2058) has no chance of success.

We all must fight to keep the Cole-Bishop Amendment in the House Appropriations Bill if small and mid-sized vapor companies will ever have a chance to survive. Join us in this fight!

To learn more about the Cole-Bishop Amendment or VTA
please sign up at www.vaportechnolgy.org or email us at guidance@vaportechnology.org