VAPOR TECHNOLOGY ASSOCIATION

The following information is being provided for general educational purposes only, and is neither intended nor should be construed as legal advice with respect to the Deeming Regulation. Companies affected by the Deeming Regulation should retain able counsel to advise them with respect to compliance.

Deadline	Rule Implemented / Requirements	Citation
August 8, 2016	**Effective Date of FDA Authority over Electronic Nicotine Delivery Systems–** Newly deemed "tobacco products," including Electronic Nicotine Delivery Systems (ENDS), become subject to FDA authority.	21 CFR part 1100
	Sale to Minors Banned – Sale prohibited to anyone under 18 years of age (or older if state law requires). Retailers must see photo ID of anyone who appears 26 or under.	21 CFR part 1140
	Product Adulteration – All manufacturers must operate their facilities in a sanitary manner such that no products are manufactured or shipped that are contaminated in a manner that might injure the public health beyond the risks that may be inherent in the product.	Food Drug & Cosmetic Act (FDCA) §902(1)
	Modified Risk Claims – Companies may not make any advertising claims or other public statements directed to consumers that their product may have less risk, be less harmful, have fewer or no additives as compared to other tobacco products prohibited. Prohibition on use of "light," "low", "mild" or similar descriptors. For packaging and labeling deadlines, see August 8, 2017 below.	FDCA §902(8)
	New Products – No new products can be introduced until FDA has issued a marketing order authorizing sale based on an SE or PMTA.	FDCA §910(2)(A)
	Misbranding – FDA will begin enforcement on false or misleading labeling and advertising.	FDCA §903(a)(1)
	Vending Machines – Vending machines are prohibited except in facility where retailer ensures that no one under 18 (or higher legal age) is present or permitted to enter at any time.	21 CFR 1140.14(b)

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December 31, 2016	**Establishment Registration –** All domestic facilities ("establishments") that "manufacture, prepare, compound, or process" tobacco products, including those who repackage or otherwise change the container, wrapper, or labeling. Foreign establishments will be required to register in the future through additional regulation. *Notes:* • *Registration required annually.* • *FDA intends to issue revised guidance to clarify scope and timing of registration and listing requirements for newly deemed products.*	FDCA §905(b), (c), (d), (h)
	Product Listing – Upon first registration, owner or operator must list each covered product, including all labeling and representative advertising. Listings must be updated each June and December to add new products not previously listed and delete discontinued products. *Notes:* • *Listing must be updated every June and December thereafter.* • *FDA intends to issue revised guidance to clarify scope and timing of registration and listing requirements for newly deemed products.*	FDCA §905(i)(l), 905(i)(3)
February 8, 2017	**Ingredient Listing –** Large-scale manufacturers must submit full listing of all ingredients by quantity, by brand, and sub-brand. *Notes:* • *For products introduced after effective date, ingredient listing must be submitted 90 days before marketing of such products.* • *Deadline applies to large-scale manufacturers only.* • *Small-scale manufacturers (150 or fewer full time employees & annual revenue of $5M or less), see August 8, 2017 deadline below.*	FDCA §904(a)(1)
	Tobacco Health Documents Submission – Large-scale manufacturers required to submit to the FDA documents developed after June 22, 2009, that relate to "health, toxicological, behavioral, or physiologic effects" of products, constituents (including smoke constituents), ingredients, components and additives. *Notes:* • *FDA intends to issue a guidance document identifying the specific set of documents it will require within the next 3-6 months.* • *Small-scale manufacturers, see August 8, 2017 deadline below.*	FDCA §904(a)(4)

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August 8, 2017	**Substantial Equivalence *Exemption Requests* Due** – Requests for *exemption* from SE requirements for a minor modification to an additive for products on market as of August 8, 2016 must be filed with the FDA. *Notes:* • *Filing will allow your product to remain on the market until at least **August 8, 2018.*** • *But, given the absence of any true predicate for ENDS products, most companies will be unable to use this SE exemption application process.*	FDCA §905(j)(3)
	Ingredient Listing – Small-scale manufacturers must submit full listing of all ingredients by quantity, by brand, and sub-brand. *Notes:* • *For products introduced after effective date, ingredient listing must be submitted 90 days before marketing of such products.* • *Deadline applies to small-scale manufacturers only.*	FDCA §904(a)(1)
	Tobacco Health Documents Submission – Small-scale manufacturers must submit to the FDA documents developed after June 22, 2009, that relate to "health, toxicological, behavioral, or physiologic effects" of products, constituents (including smoke constituents), ingredients, components and additives. *Notes:* • *FDA intends to issue a guidance document identifying the specific set of documents it will require within the next 3-6 months.* • *Deadline applies to small-scale manufacturers only.*	FDCA §904(a)(4)
	Modified Risk Tobacco Product Labels – Tobacco products may not use in labels or labeling with the descriptors "light," "mild," or "low" or similar descriptors. Manufacturers must **end production** of all products in packaging that contains a prohibited descriptor by August 8, 2017. Manufacturers may continue to distribute those products for an additional 30 days, ending September 7, 2017. Retailers may continue to sell those products until their stocks are depleted.	FDCA §911(b)(2)(A)(ii)

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February 8, 2018	**Substantial Equivalence *Applications* Due –** Applications for substantial equivalence authorization for products on market as of August 8, 2016 must be filed. But, given the absence of any true predicate for ENDS products, most companies will be unable to use this SE application process. *Notes:* • *Filing will allow products to stay on the market until at least **February 8, 2019.*** • *Additional time may be given to small-scale manufacturers to respond to SE application deficiency letters on a case-by-case basis.*	FDCA §905(j)(1)
May 10, 2018	**Warning Statements –** All covered ENDS products must bear the following warning statement on labels and in advertising: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." Warnings on packages must comprise 30% of each of the two principal display panels. Alternate means of compliance are available for small packages. Warnings on advertisements must comprise 20% of the top of the advertisement. This applies to all advertising with a visual component – print ads, websites, e-mails, social media postings, videos, etc. Manufacturers of nicotine-free tobacco products may instead certify to FDA that their products contain zero nicotine and that they have the data to prove it. Such products may instead use the statement "This product is made from tobacco" using the same size and format as the nicotine warning statement. Product manufactured prior to that May 10, 2018, without warning statement labels may be distributed by the manufacturer until **June 9, 2018.**	21 CFR part 1143
	Additional Label Requirements – All product labels must bear the following: • Name and location of manufacturer, packer or distributor • Net quantity of contents by weight, measure or count • Percentage of tobacco used in the product that is domestic, percentage foreign • "Sale only allowed in the United States" which must also appear on packaging and shipping cartons.	FDCA §903(a)(2), (a)(4), (a)(8), 920(a)

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August 8, 2018	**Premarket Tobacco Applications Due**– Full premarket tobacco applications must be filed for all products on market as of August 8, 2016. *Notes:* • *Filing will allow your product to remain on the market until at least **August 8, 2019.*** • *PMTA is most likely route for ENDS product manufacturers.*	FDCA §910
	Tobacco Product Standard – Prohibits use of foreign or domestic tobacco that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.	FDCA §907(a)(1)(B)
August 8, 2019	**Reporting of Harmful and Potentially Harmful Constituents –** Requires testing and reporting of Harmful and Potentially Harmful Constituents (HPHCs) pursuant to a guidance and, subsequently, a regulation to be issued by FDA. *Notes:* • *FDA also requires certain HPHC deliveries to be reported and justified as part of SE review for cigarettes and smokeless products, thus implementing the requirement before the 3 years were up.* • *For products introduced after **August 8, 2019**, HPHCs must be reported no later than **90 days** before product is introduced to the market.*	FDCA §904(a)(3), 915
TBD	**Good Manufacturing Practices –** FDA will in the future issue regulations defining Good Manufacturing Practices for ENDS.	FDCA §906(e)