THE “DEEMING RULE”: VAPE SHOPS

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FDA REGULATION OF TOBACCO PRODUCTS

The Federal Food, Drug, and Cosmetic Act (FD&C Act):

- Gives the Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, and marketing of cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco and other tobacco products that the agency, through regulation, deems to be subject to the law.

- The Deeming rule extends FDA's regulatory authority to cover all products that meet the definition of a tobacco product under section 201(rr)of the FD&C Act, **except** accessories of those newly deemed products.

DEEMING RULE –REGULATED TOBACCO PRODUCTS

Previously Regulated by FDA	Now Also Regulated by FDA
• Cigarettes • Cigarette tobacco • Roll-Your-Own tobacco • Smokeless tobacco *This includes the components, parts, and accessories of these products.*	• Electronic Nicotine Delivery System (ENDS) • Pipe Tobacco • Cigars • Hookah • E-liquid • Any other product that meets the definition of “tobacco product” under the FD&C Act, except accessories of newly regulated products. *This includes the components and parts of these products.*

FDA REGULATION OF TOBACCO PRODUCTS

Finished Tobacco Products

- A tobacco product **including** all components and parts, sealed in final packaging intended for consumer use.
- Examples: Pipe Tobacco, Cigars, Electronic Nicotine Delivery Systems, and Liquid Nicotine, Cigar Tobacco Filler, Hookah Tobacco, Filters, Cigar Tips, and e-liquid sold separately to consumers

Covered Tobacco Products

- All newly regulated tobacco products **excluding** components and parts not made or derived from tobacco.
- Examples: Pipe Tobacco, Cigars, Electronic Nicotine Delivery Systems, Liquid Nicotine, Cigar Tobacco Filler, and Hookah Tobacco

DEEMING RULE – ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

- Among the newly deemed products are the many types of electronic nicotine delivery systems (ENDS) and the components and parts used with ENDS.

- FDA generally considers ENDS to be tobacco products that use an electronic or other power source to heat e-liquids, tobacco, or other material derived from tobacco.

DEEMING RULE – ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

Examples of ENDS Products	Examples of ENDS Components and Parts
• E-cigarettes • E-cigars • E-hookah • Vape pens • Personal vaporizers • Electronic pipes	• E-liquids • Aerosolizing Apparatus o Atomizers o Batteries (with or without variable voltage) o Cartomizers (atomizer plus replaceable fluid-filled cartridge) o Digital display/lights to adjust settings o Clearomisers, tank systems, flavors, vials that contain e-liquids o Programmable software

WHAT IS A VAPE SHOP?

A **vape shop** is an Electronic Nicotine Delivery System (ENDS) establishment and can engage in a variety of activities. For example:

- Vape shops can sell a variety of products to consumers including ENDS devices, ENDS replacement pieces, ENDS hardware, ENDS pre-mixed flavored e-liquids, and other ENDS-related products.
- Vape shops can mix or prepare combinations of liquid nicotine, flavors, and/or other liquids for direct sale to consumers for use in ENDS or create or modify aerosolizing apparatus for direct sale to consumers for use in ENDS.

Depending on the activities a vape shop engages in, it can be a tobacco product retailer, a tobacco product manufacturer, or both. Retailers and manufacturers are subject to inspection by FDA.

WHAT MAKES A VAPE SHOP A RETAILER?

You are considered a retailer if you sell tobacco products to individuals for personal consumption. For example if you sell ENDS devices, ENDS replacement pieces, ENDS hardware, ENDS e-liquids, and other ENDS-related products to individuals for personal consumption.

This includes retailers who sell tobacco products in brick and mortar establishments or thorough the internet.

WHAT REQUIREMENTS APPLY TO VAPE SHOP RETAILERS?

Requirements for Newly Regulated Tobacco Products

Requirement and Authority	Effective/Compliance Date
Prohibition against free samples (21 CFR 1140.16(d))	Effective - Publication Date of Deeming Rule + 90 days
Prohibition against selling a new tobacco products with a without a marketing authorization (FD&C Act §910)	Staggered Compliance Periods
Prohibition against the distribution in interstate commerce modified risk tobacco products whose label, labeling, or advertising claim are "lower risk," "less harmful," or "contain a reduced level of a substance" than another commercially marketed tobacco product without an FDA order in effect (FD&C Act §911)	Effective - Publication Date of Deeming Rule + 90 days
Prohibition against the distribution in interstate commerce modified risk tobacco products whose label, labeling, or advertising using the modified risk claims "low," "light" or "mild" without an FDA order in effect (FD&C Act §911)	Effective - Publication Date of Deeming Rule + 90 days + 13 months

WHAT REQUIREMENTS APPLY TO VAPE SHOP RETAILERS?

Requirements for Covered Tobacco Products

Requirement and Authority	Effective Date
Prohibition against sale to minors (anyone under the age of 18) (21 CFR 1140.14(a))	Publication Date of Deeming Rule + 90 days
Verification of the date of birth by photo ID for anyone under the age of 27 (21 CFR 1140.14(b))	Publication Date of Deeming Rule + 90 days
Prohibition against vending machine sales unless in a facility where no person under 18 is present or permitted to enter at any time (21 CFR 1140.16(c))	Publication Date of Deeming Rule + 90 days
Required nicotine warning on product package labels and advertisements: "Warning: This product contains nicotine. Nicotine is an addictive chemical."	Publication Date of Deeming Rule + 24 months

WHAT MAKES A VAPE SHOP A MANUFACTURER?

A “tobacco product manufacturer” is defined as:

> “any person, including any repacker or relabeler, who (A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States.”

You are considered a manufacturer if you, for example, mix or prepare e-liquids, create or modify aerosolizing apparatus, repackage ENDS products, or relabel ENDS products.

WHAT REQUIREMENTS APPLY TO VAPE SHOP MANUFACTURERS?

Requirements for Finished Tobacco Products

Requirement and Authority	Compliance Date	Compliance Date for Small-Scale Tobacco Product Manufacturers
Ingredient listing (FD&C Act §904)	Publication Date of Deeming Rule + 90 days + 6 months	Publication Date of Deeming Rule + 90 days + 12 months
Tobacco health documents submissions (FD&C Act §904)	Publication Date of Deeming Rule + 90 days + 6 months	Publication Date of Deeming Rule + 90 days + 12 months
Harmful and potentially harmful constituent (HPHC) testing and reporting (FD&C Act §§ 904, 915)	Publication Date of Deeming Rule + 90 days + 3 years	Publication Date of Deeming Rule + 90 days + 3 years
Registration of establishments and listing of products (FD&C Act §905)	Initial Registration and Listing On or Before December 31, 2016	Initial Registration and Listing On or Before December 31, 2016

WHAT REQUIREMENTS APPLY TO VAPE SHOP MANUFACTURERS?

Warning Requirements for Covered Tobacco Products

Requirement and Authority	Effective Date - Stop Manufacture	Effective Date - Stop Distribution
Nicotine warning statement on packaging	Publication Date of Deeming Rule + 24 months	Publication Date of Deeming Rule + 25 months
Nicotine warning statement on advertising	Publication Date of Deeming Rule + 24 months	Publication Date of Deeming Rule + 24 months

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

WHAT REQUIREMENTS APPLY TO VAPE SHOP MANUFACTURERS?

Requirements for All Newly Regulated Tobacco Products

Requirement and Authority	Compliance Date
Prohibition against modified risk tobacco products whose label, labeling, or advertising using the modified risk claims “lower risk,” “less harmful,” or “contain a reduced level of a substance” than another commercially marketed tobacco product without an FDA order in effect (FD&C Act §911)	Publication Date of Deeming Rule + 90 days
Prohibition against modified risk tobacco products whose label, labeling, or advertising using the modified risk claims “low,” “light” or “mild” without an FDA order in effect (FD&C Act §911)	Publication Date of Deeming Rule + 90 days + 13 months

WHAT REQUIREMENTS APPLY TO VAPE SHOP MANUFACTURERS?

Packaging, Labeling, and Advertising Requirements for All Newly Regulated Tobacco Products

Requirement and Authority	Compliance Date
Prohibition on false and misleading statements on labeling or in ads (FD&C Act §§903(a)(1) and (a)(7)(A))	Publication Date of Deeming Rule + 90 days
Required label statements (FD&C Act §903(a)(2)): • The name and place of business of the tobacco product manufacturer, packer, or distributor; • An accurate statement of the quantity of the contents; • An accurate statement of the percentage of domestic and foreign grown tobacco; and • The statement "Sale only allowed in the United States."	Publication Date of Deeming Rule + 24 months
Prominent placement and conspicuousness of label statements (FD&C Act §903(a)(3))	Publication Date of Deeming Rule + 90 days + 1 year
Required statements on labeling and ads (FD&C Act §§903(a)(4) and (a)(8)) (established name, relevant warnings)	Publication Date of Deeming Rule + 24 months

WHAT REQUIREMENTS APPLY TO VAPE SHOP MANUFACTURERS?

Premarket Requirements:

- As a result of this final rule, all newly-regulated tobacco products will require premarket authorization, unless they are eligible for grandfather status (were on the market as of Feb. 15, 2007).
- However, for a period of time, the FDA does not intend to enforce the requirements of premarket review against manufacturers whose tobacco products are on the market as of the effective date if they submit applications seeking marketing authorization within specific timeframes after the effective date of the rule.

WHAT REQUIREMENTS APPLY TO VAPE SHOP MANUFACTURERS?

Premarket Requirements:

- These submission dates are: 12 months for an Exemption from Substantial Equivalence (SE); 18 months for an SE report; and 24 months for a premarket tobacco application (PMTA).
- Unless the FDA has issued an order denying or refusing to accept the submission, manufacturers who submit applications by these deadlines will be subject to a continued compliance period for 12 months. As a result, we expect that these products will remain on the market for up to three years while manufacturers seek authorization under staggered compliance periods and FDA reviews submissions.

THE END


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