THE "DEEMING RULE":
TOBACCO PRODUCT MANUFACTURERS AND IMPORTERS

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FDA'S REGULATION OF TOBACCO PRODUCTS

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

- Gives the Food and Drug Administration (FDA) authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco and other tobacco products that the agency, through regulation, deems to be subject to its tobacco product authorities.

- The Final Deeming rule, published on May 10, 2016, deems all products that meet the definition of a tobacco product under section 201(rr) of the FD&C Act, including components and parts, **except** accessories of those newly deemed products, subject to FDA's tobacco product authorities.

FINAL DEEMING RULE

- Tobacco manufacturers of newly regulated tobacco products must comply with the requirements of the FD&C Act(automatic provisions) as well as its implementing regulations.
  - Examples: establishment registration, product and ingredient listing, user fees for certain products, premarket requirements, adulteration and misbranding, and modified risk provisions.

FINAL DEEMING RULE

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 flavor cartridges 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, and Liquid Nicotine, Cigar Tobacco Filler, and Hookah Tobacco.

FDA REGULATED TOBACCO PRODUCTS

Tobacco Products Currently Regulated	Examples of Newly Regulated Tobacco Products
• Cigarettes • Cigarette tobacco • Roll-Your-Own tobacco • Smokeless tobacco *This includes the components, parts, and accessories of these products.*	Any other product that meets the definition of "tobacco product" under the FD&C Act, including components or parts, but excluding accessories, such as: • Electronic Nicotine Delivery System (ENDS) • Pipe Tobacco • Cigars • Hookah • E-liquid containing nicotine

COMPONENTS OR PARTS OF NEWLY REGULATED TOBACCO PRODUCTS

Newly Regulated Tobacco Product Category	Component/Part Examples
ENDS	Atomizers, cartomizers, coils, e-liquid
Pipe Tobacco	Pipe, pipe mouthpieces, pipe bowls
Cigars	Cigar wrapper, cigar tobacco filler, flavoring
Hookah/Waterpipe tobacco	Heating charcoal or wood cinders, bowls, valves, hoses, hookah foil, mouthpieces

ACCESSORIES OF NEWLY REGULATED TOBACCO PRODUCTS

Newly Regulated Tobacco Product Category	Accessory Examples
ENDS	Carrying cases, lanyards, holsters
Pipe Tobacco	Pipe pouches, pipe stands
Cigars	Humidors, tip cutters, ash trays
Hookah/Waterpipe tobacco	Tongs, external burners

Accessories of the newly regulated tobacco products have not been deemed subject to FDA's tobacco product authorities under the rule.

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.

- ENDS include 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

DEFINITION OF TOBACCO PRODUCT MANUFACTURER

FD&C Act § 900(20) defines "tobacco product manufacturer" 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."

- Compliance policy for small-scale tobacco product manufacturer - Employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less.

VAPE SHOP AS A MANUFACTURER

A **vape shop** is an Electronic Nicotine Delivery System (ENDS) establishment that may 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 and/or prepare combinations of e-liquids for direct sale to consumers for use in ENDS or create or modify aerosolizing apparatuses for direct sale to consumers for use in ENDS.

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

- Vape Shop Webinar

WHAT REQUIREMENTS APPLY TO TOBACCO PRODUCT 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 TOBACCO PRODUCT IMPORTERS?

Requirements for Importers of 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

WARNING REQUIREMENT FOR CIGARETTE TOBACCO, RYO TOBACCO, AND COVERED TOBACCO PRODUCTS* (21 CFR PART 1143)

Requirement	Effective Date - Stop Manufacture	Effective Date - Stop Distribution
Addictiveness warning statement on packaging	Publication Date of Deeming Rule + 24 months	Publication Date of Deeming Rule + 25 months
Addictiveness 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."

*The addictiveness warning is only one of the six required warning statements for cigars.

WARNING STATEMENT REQUIREMENTS

- Addictiveness warning required on all cigarette tobacco, roll-your-own tobacco, and covered tobacco product packages and advertisements.
  - "WARNING: This product contains nicotine. Nicotine is an addictive chemical."
- Product package: 2 principal display panels (PDP); warning area shall comprise at least 30% of each PDP.
- Advertisement: occupy at least 20% of the upper portion of the ad.
- Specific format, layout, and marketing requirements (similar to smokeless tobacco).

WHAT REQUIREMENTS APPLY TO TOBACCO PRODUCT MANUFACTURERS AND IMPORTERS?

Label, Labeling, and Advertising Provisions for All Newly Regulated Tobacco Products

Requirement and Authority	Compliance Date
Prohibition on false or 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 for products in package form (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 labeling statements (FD&C Act §903(a)(3))	Publication Date of Deeming Rule + 90 days + 1 year
Required statements on labels and ads (FD&C Act §§903(a)(4) and (a)(8)) (established name, relevant warnings)	Publication Date of Deeming Rule + 24 months

WARNING STATEMENTS – CIGARETTE TOBACCO, RYO TOBACCO, AND COVERED TOBACCO PRODUCTS OTHER THAN CIGARS (21 CFR 1143.3)

- Self-certification submission to FDA for tobacco products that are made or derived from tobacco but do not contain nicotine.
  - These products must include the statement on their packages and advertising — "This product is made from tobacco."
- Small product packages- tobacco product packages that are too small to bear the required warning label statement, the warning may be displayed on a tag permanently affixed to the tobacco product package.

WARNING STATEMENTS—CIGARS (21 CFR 1143.5)

- Five additional warning statements for cigars, in addition to the addictiveness warning.

- Cigar packages and advertisements must contain one of the six warning statements in accordance with an FDA-approved warning plan.
  - Exception: individual cigars sold without packaging (the warning statements must be posted on a sign at the retailer's point(s) of sale).

WARNING STATEMENTS—CIGARS (21 CFR 1143.5)

CIGAR WARNING STATEMENTS	
WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.	WARNING: Cigar smoking can cause lung cancer and heart disease.
WARNING: Cigars are not a safe alternative to cigarettes.	WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
WARNING: Cigar use while pregnant can harm you and your baby. Or SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.	WARNING: This product contains nicotine. Nicotine is an addictive chemical.

WARNING STATEMENTS – CIGARETTE TOBACCO, RYO TOBACCO, AND COVERED TOBACCO PRODUCTS

- Warning statement effective dates:
  - 24 months after the publication date of the rule, packages of newly manufactured products and all advertisements must display the new warning(s);
  - 25 months after the publication date of the rule, manufacturers must include the new warning(s) on packages of products introduced into domestic commerce, regardless of the date of manufacture.

CIGAR WARNING PLANS

- Regulation includes marketing requirements for the random display and distribution of the cigar warning statements on product packages and quarterly rotation in advertisements in accordance with an FDA-approved warning plan.

- Submission deadline for cigar warning plans by applicable manufacturers, distributors, importers, and retailers:
  - One year after the date of publication of the final rule, however, firms may submit earlier.

MODIFIED RISK TOBACCO PRODUCT (MRTP) REQUIREMENTS FOR NEWLY DEEMED PRODUCTS

Requirements for All Newly Regulated Tobacco Products

Requirement and Authority	Effective/Compliance Date
Prohibition against marketing all other types of modified risk tobacco products, e.g., products whose label, labeling, or advertising use modified risk claims such as “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 marketing modified risk tobacco products whose label, labeling, or advertising use the descriptors “low,” “light,” or “mild,” or similar descriptors without an FDA order in effect (FD&C Act §911)	Publication Date of Deeming Rule + 90 days + 12 months (manufacturing) Publication Date of Deeming Rule + 90 days + 13 months (distribution)

USER FEE FINAL RULE

User Fees

- The rule requires cigar and pipe tobacco manufacturers and importers to pay user fees in accordance with Section 919 of the Tobacco Control Act.

PREMARKET AUTHORIZATION OF NEWLY DEEMED PRODUCTS

- A “new” tobacco product is any tobacco product not commercially marketed in the U.S. as of 2/15/2007; or any modification of a tobacco product where the modified product was commercially marketed in the United States after 2/15/2007 .
- Newly regulated tobacco products are subject to the premarket requirements even if they were on the market on the date of final publication of the rule.
- Newly regulated tobacco products eligible for grandfather status (were on the market as of Feb. 15, 2007) are not subject to premarket review requirements.

PREMARKET AUTHORIZATION OF NEWLY DEEMED TOBACCO PRODUCTS

- 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).
- For a period of time, the FDA does not intend to enforce the requirements of premarket review against manufacturers whose newly deemed 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.

PREMARKET AUTHORIZATION OF NEWLY DEEMED TOBACCO PRODUCTS

- 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.
- 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.

ADDITIONAL RESOURCES

- Final Rule: User Fees for Cigars and Pipe Tobacco
- Final Guidance: Tobacco Product Master Files
- Draft Guidance: PMTAs for ENDS
- Small Entity Compliance Guide: Deeming Final Rule
- Small Entity Compliance Guide: User Fee Final Rule

OFFICE OF SMALL BUSINESS ASSISTANCE (OSBA)

- OSBA – serves as primary point-of-contact to provide technical assistance in conjunction with subject matter experts for small tobacco product manufacturers
- Smallbiz.tobacco@fda.hhs.gov
- Provides education and other assistance to enable small tobacco product manufactures to comply with requirements of the Act

OCE CONTACT

- Additional information can be found at the FDA Center for Tobacco Products Website at: http://www.fda.gov/TobaccoProducts

- Please direct any additional questions to : AskCTP@fda.hhs.gov

THE END


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