

FINAL RULE – TOBACCO PRODUCTS DEEMED TO BE SUBJECT TO THE FEDERAL FOOD, DRUG, & COSMETIC ACT (“DEEMING RULE”)



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AGENDA

FDA's Tobacco Product Authority

Summary of Proposed Rule

Deemed Products

“Deeming” provision

Additional restrictions for covered tobacco products

Health Warnings

Key Issues

Effective Dates

Other documents published with deeming

FDA'S TOBACCO PRODUCT AUTHORITY

- The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to give FDA authority to regulate tobacco products
 - **Section 901 authority** – FDA has immediate authority over certain tobacco products; allows FDA to deem others subject to its tobacco product authorities that meet the statutory definition of tobacco product under its authority
 - **Section 906(d) authority** – Provides FDA the authority to issue regulations restricting the sale and distribution of tobacco products, including the advertising and promotion of tobacco products

SUMMARY OF THE PROPOSED RULE

- FDA issued a proposed deeming rule on April 25, 2014 (79 FR 23142)
- Two Part Rule:
 - 1) “Deeming” provision
 - 2) Additional restrictions
 - Scientific evidence shows that they are appropriate for the protection of the public health

COMMENTS TO THE PROPOSED RULE

- FDA received over 135,000 comments on the proposed rule
 - Comments were received from tobacco product manufacturers, retailers, academia, medical professionals, local governments, advocacy groups, and consumers
- FDA considered the comments received

DEEMED PRODUCTS

- Final rule deems all products meeting the statutory definition of tobacco product, including components or parts (e.g., e-liquids), but excluding accessories, to be subject to FDA's tobacco product authorities

Deemed Products include but are not limited to:

- Electronic Nicotine delivery systems (ENDS) (including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes)
- Pipe tobacco
- Dissolvables
- Nicotine Gels
- Waterpipe (hookah)
- Cigars
- Future tobacco products

“DEEMING” PROVISION

- Automatic provisions: provisions in the FD&C Act and implementing regulations that generally apply to “tobacco products” extend to and automatically apply to newly deemed tobacco products
- Examples: establishment registration, product and ingredient listing, user fees for certain products, premarket review and authorization of new tobacco products, adulteration and misbranding
- FDA can now use its authorities in Chapter IX of the FD&C act to issue future regulations, such as record retention regulations, that would extend to newly deemed products

ADDITIONAL RESTRICTIONS FOR COVERED TOBACCO PRODUCTS

- Applies to “covered tobacco products” - deemed products except for components or parts that are not made or derived from tobacco
- 1) Prohibits sale to individuals under the age of 18 years and requires age verification if under age 27
 - 2) Prohibits sale using electronic or mechanical devices, e.g., vending machines, with limited exception
 - 3) Requires the display of health warnings

HEALTH WARNINGS

- In the final rule, the addiction warning statement reads:
 - “**WARNING:** This product contains nicotine. Nicotine is an addictive chemical.”
- The final rule includes a self-certification option for tobacco products that do not contain nicotine.
 - For these products, the required statement reads,
 - “This product is made from tobacco.”
- Small product packages- for tobacco product packages that are too small to bear the warning, the warning may appear on the outer carton or other outer container or wrapper or be placed on a tag permanently affixed to the tobacco product package

HEALTH WARNINGS

- Required Cigar Warnings - In addition to the addictiveness warning, cigar packages and advertisements must bear the following:
 - “**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.”

HEALTH WARNINGS

- The final rule is adding an additional warning statement for cigar packages and advertisements:
“**WARNING:** Cigar use while pregnant can harm you and your baby.”
- Optional alternative warning statement to reproductive health warning statement:
“**SURGEON GENERAL’S WARNING:** Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.”

HEALTH WARNINGS

- Requires display on cigarette tobacco, roll-your-own tobacco, and covered tobacco product packages and in advertisements
- Product package: 2 principal display panels (PDP); warning area shall comprise at least 30% of each PDP
- Advertisement: occupy at least 20% of the area of the ad
- Specific format, layout, and marketing requirements (similar to the requirements for smokeless tobacco)

HEALTH WARNINGS

- For cigars sold individually and not in product packages – all warnings will be placed on a placard near register
- Health warning requirement effective dates:
 - publication date plus 24 months to stop manufacturing;
 - publication date plus 25 months to stop distributing, regardless of manufacturing date

HEALTH WARNINGS- CIGAR WARNING PLANS

- Marketing requirements for the random display and distribution of the cigar warning statements on packaging and quarterly rotations of cigar warnings statements for advertisements in accordance with a warning plan submitted to and approved by FDA
- Submission deadline for cigar warning plans by applicable manufacturers, distributors, importers, and retailers
 - One year after the date of publication of the final rule

KEY ISSUES: PREMIUM CIGARS

- All cigars, including premium cigars, are deemed under the final rule
- All cigars pose serious negative health risks
- The available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion
- Premium cigars are used by youth and young adults

KEY ISSUES: COMPONENTS, PARTS, ACCESSORIES

- The final rule deems components and parts of newly deemed tobacco products
- The final rule defines “component or part” as:
any software or assembly of materials intended or reasonably expected:
 - 1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or
 - 2) to be used with or for the human consumption of a tobacco product.Component or part excludes anything that is an accessory of a tobacco product

KEY ISSUES: COMPONENTS, PARTS, ACCESSORIES

- The final rule does not deem accessories of newly deemed tobacco products
- The final rule defines “accessory” as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco

KEY ISSUES: COMPONENTS, PARTS, ACCESSORIES

- To meet the definition of “accessory,” the product must also meet either of the following:
 - 1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or
 - 2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but
 - (i) solely controls moisture and/or temperature of a stored product or
 - (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product

KEY ISSUES: PREMARKET REVIEW OF NEWLY DEEMED TOBACCO PRODUCTS

- As a result of this rule, newly deemed tobacco products are subject to premarket review requirements
- “New tobacco product” means 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
 - “grandfather date” is found in the statute (TCA)

KEY ISSUES: PREMARKET REVIEW OF NEWLY DEEMED TOBACCO PRODUCTS

- 3 pathways to market for “new tobacco products”:
 - 1) Premarket tobacco application (PMTA);
 - 2) Substantial equivalence (SE) report; and
 - 3) SE exemption
- Predicate tobacco product (comparison product) for the SE pathway
 - Commercially marketed in the U.S. as of 2/15/2007 or has been previously determined to be SE

KEY ISSUES: PREMARKET REVIEW OF NEWLY DEEMED TOBACCO PRODUCTS

- For newly deemed tobacco products that are on the market as of the effective date, FDA is providing two compliance periods, one for submission and FDA receipt of applications and one for obtaining premarket authorization.
- FDA does not intend to initiate enforcement action for failure to have premarket authorization during these respective compliance periods.

KEY ISSUES: PREMARKET REVIEW OF NEWLY DEEMED TOBACCO PRODUCTS

- The staggered compliance period for submission and FDA receipt of applications under the 3 premarket pathways is as follows:
 - Exemption requests - 12 months from the effective date of this final rule
 - SE Reports - 18 months from the effective date of this final rule
 - PMTAs - 24 months from the effective date of this final rule

KEY ISSUES: PREMARKET REVIEW OF NEWLY DEEMED TOBACCO PRODUCTS

- Unless FDA has issued an order denying or refusing to accept the submission, newly deemed tobacco products for which timely premarket submissions have been submitted will be subject to a continued compliance period for up to 12 months after the initial compliance period
- Compliance period closes:
 - Exemption requests - 24 months from the effective date of this final rule
 - SE Reports - 30 months from the effective date of this final rule
 - PMTAs – 36 months from the effective date of this final rule

KEY ISSUES: VAPE SHOPS

- Establishments that mix and/or prepare combinations of e-liquids or create or modify aerosolizing apparatus for direct sale to consumers for use in ENDS are tobacco product manufacturers
 - The combinations vape shops mix and/or prepare and the new or modified aerosolizing apparatuses are new tobacco products
 - Vape shops that are manufacturers are subject to all of the statutory and regulatory requirements that apply to manufacturers, including the requirements to register their establishments, list their products, and obtain premarket authorization

KEY ISSUES: FREE SAMPLE BAN

- As a result of the final rule, distribution of free samples of newly deemed tobacco products is prohibited
- prospective adult buyers may smell or handle one of the newly deemed products as long as:
 - the free product is not actually consumed, in whole or in part, in the retail facility and
 - the prospective buyer does not leave the facility with a free tobacco product

KEY ISSUES: SMALL SCALE TOBACCO MANUFACTURERS

- Targeted relief for small-scale tobacco product manufacturers – a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of \$5,000,000 or less
- Ingredient reporting: one-time allowance of an additional six months for initial reporting
- Submission of health information: one-time allowance of an additional six months for submission
- SE extension requests: For the first 30 months following the effective date, FDA intends to grant extensions to small-scale tobacco product manufacturers for SE reports that need additional time to respond to SE deficiency letters

EFFECTIVE DATES

- Generally: the rule is effective on the final rule publication date plus 90 days
- Applies to “deeming” provision and associated automatic provisions, age restriction, and prohibition on vending machine sales
- Compliance periods, during which FDA does not intend to initiate enforcement action for certain automatic provisions to give firms additional time to comply, are included in preamble

OTHER DOCUMENTS AND RULES PUBLISHED WITH DEEMING

- Draft guidance on PMTA submissions for electronic nicotine delivery systems (ENDS)
- Final guidance on the use of tobacco product master files
- Final rule establishing user fees for pipe tobacco and cigars
- Advance Notice of Proposed Rulemaking on nicotine exposure warnings and child-resistant packaging (published July 1, 2015, Docket closed September 30, 2015)

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