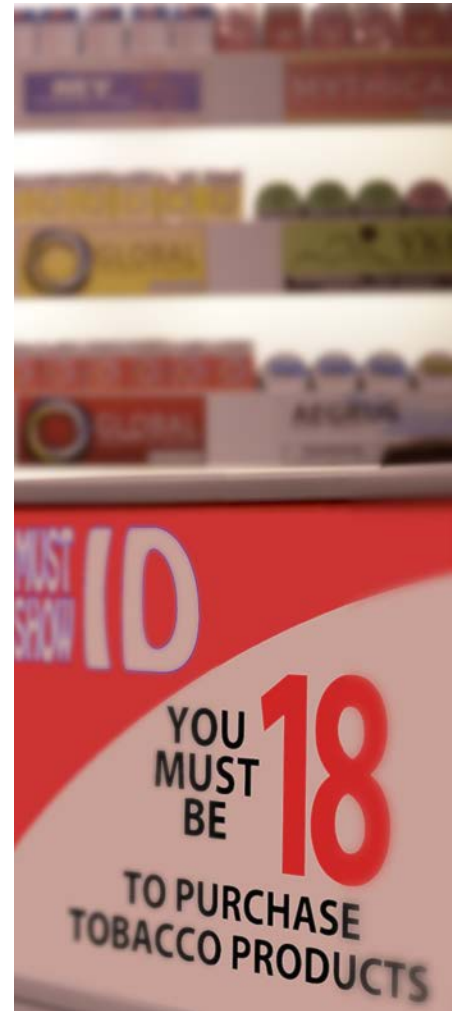


# THE “DEEMING RULE” - NEW REQUIREMENTS FOR TOBACCO RETAILERS

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# FDA AUTHORITY

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

- Gives 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.

# DEFINITIONS

## Retailer:

- Any person, government, or entity who sells tobacco products to individuals for personal consumption; or
- Operates a facility where self-service displays of tobacco products are permitted.

Includes owner of a brick and mortar or on-line tobacco retail outlet that otherwise meets the statutory or regulatory definition.

Note: Vape shops that mix, prepare, or combine liquid nicotine and other components of tobacco products meet the legal definition of a ‘tobacco product manufacturer’ and are therefore also subject to the same provisions of the Federal Food Drug & Cosmetic (FD&C Act) as other manufacturers.

## Cigar:

- A tobacco product that (1) Is not a cigarette and (2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

## Covered Tobacco Product:

- Any tobacco product deemed by the final rule to be subject to the FD&C Act.
- Excludes any component or part that is not made or derived from tobacco.

# FDA REGULATED TOBACCO PRODUCTS

## Examples of Tobacco Products Previously Regulated

- Cigarettes
- Cigarette tobacco
- Roll-Your-Own tobacco
- Smokeless tobacco

## Examples of Newly Regulated Tobacco Products

- ENDS (meeting the statutory definition of a tobacco product)
- Pipe tobacco
- Cigars
- Hookah/Waterpipe tobacco
- Dissolvables (not currently regulated as smokeless tobacco)
- E-liquid meeting the statutory definition of a tobacco product

\*ENDS = Electronic Nicotine Delivery System (example: e-cigarette, e-hookah, vape pens)

# PROHIBITION AGAINST SALES TO MINORS AND AGE VERIFICATION REQUIREMENT BY PHOTO ID IF UNDER 27

Already in Effect	Effective on Pub + 90 Days
Cigarette	ENDS (containing components or parts made or derived from tobacco)
Cigarette tobacco	Pipe tobacco
Roll-Your-Own tobacco	Cigars
Smokeless tobacco	Hookah/Waterpipe tobacco
	E-liquid made or derived from tobacco
	Any other “covered tobacco product”

Pub = Publication date of Deeming Rule

# PROHIBITION AGAINST FREE SAMPLES

Already in Effect	Effective on Pub + 90 days
Cigarette	ENDS
Cigarette tobacco	Pipe Tobacco
Roll-Your-Own tobacco	Cigars
*Smokeless tobacco	Hookah/Waterpipe tobacco
	E-liquid made or derived from tobacco
	Any other newly deemed tobacco product

\* Exception - Allowed in very limited circumstances (“qualified adult only facility”)

# PROHIBITION AGAINST VENDING MACHINE SALES\*

Already in Effect	Effective on Pub + 90 days
Cigarette	ENDS (containing components or parts made or derived from tobacco)
Cigarette tobacco	Pipe tobacco
Roll-Your-Own tobacco	Cigars
Smokeless tobacco	Hookah/Waterpipe tobacco
	E-liquid made or derived from tobacco
	Any other “covered tobacco product”

\* Exception - Vending machine sales are allowed if in a facility where those under 18 years of age are neither present nor permitted at any time.

# PROHIBITION AGAINST SELF SERVICE DISPLAYS\*

Already in Effect	Not Applicable
Cigarette	Not applicable to newly deemed tobacco products
Cigarette tobacco	
Roll-Your-Own tobacco	
Smokeless tobacco	

\* Exception - Self service displays of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco are allowed if in a facility where those under 18 years of age are neither present nor permitted at any time.



# CIGARS – WARNING STATEMENTS

Provision	Effective Date
<p>Required on all* cigar package labels offered for sale, distribution, or import for sale/distribution in US. Specific placement and formatting requirements.</p> <p>* Point-of-sale warning required for cigars sold individually without packaging.</p>	<p>Manufacturers should not distribute cigar products without the required warning statement beginning 25 months after the publication date of the final deeming rule.</p>
<p>Required in print advertisements and other advertisements with a visual component for cigars. Specific placement and formatting requirements.</p> <p>Additional details on these requirements are found in the Small Entity Compliance Guide Guidance.</p>	<p>Retailers who direct their own advertisements for cigars must comply beginning 24 months after the publication date of the final deeming rule.</p>

# CIGARS – WARNING STATEMENTS

## 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.

# CIGARS – WARNING STATEMENTS

If the retailer is not responsible for or does not direct their own ads and/or packaging, the retailer will not be in violation if:

- The packaging or advertising of the cigars sold contains a warning statement;
- The warning on the package or ad is not altered or covered up in whole or part in a manner that is material to the warning statement requirements. (example – placing a sticker over the warning statement);
- The package is supplied to the retailer by a license or permit holding manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB) issued license or permit, if applicable.

# SINGLE UNPACKAGED CIGARS – POINT OF SALE WARNING STATEMENTS REQUIREMENTS

Provision	Effective Date
<p>If single unpackaged cigars sold, warning statements requirement at point of sale. Specific placement and formatting requirements:</p> <ul style="list-style-type: none"><li>• 8.5 x 11 inches.</li><li>• Clear, legible, and conspicuous.</li><li>• Statements printed in black Helvetica bold or Arial bold type against a solid white background, in at least 17 point type with appropriate space between the warning statements.</li><li>• Statements must be printed in a manner that contrasts by typography, layout, or color, with all printed material.</li><li>• Capitalized and punctuated as indicated in the regulation.</li><li>• Posted on or within 3 inches of each cash register where payment may be made.</li><li>• Signs are unobstructed in their entirety and can be read easily by each consumer making a purchase.</li></ul>	Pub + 24 months

# CIGARS – WARNING PLAN – ADVERTISEMENTS

Requirements	Effective Date
Warning statements in advertisements for cigars must be rotated quarterly in alternating sequence for each brand.	Retailers who direct their own advertisements for cigars must comply and submit a cigar warning plan within 12 months after the publication date of the final deeming regulation or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later.
Specific placement and formatting requirements.	
Additional details on these requirements are found in the Small Entity Compliance Guide Guidance.	

# NICOTINE WARNING

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

Requirements	Effective Date
<ul style="list-style-type: none"><li>• Required to appear on all product package labels of cigarette tobacco, roll-your-own tobacco, and covered tobacco products* made or derived from tobacco if offered for sale, distribution, or import for sale or distribution within the U.S.</li><li>• Specific requirements for appearance and placement.</li></ul>	Manufacturers should not distribute packaging for these products without the nicotine warning statement beginning 25 months after the publication date of the final deeming regulation.
<ul style="list-style-type: none"><li>• Must also be included in print ads and other ads with a visual component for ads or cigarette tobacco, roll-your-own tobacco, and covered tobacco products.</li></ul>	Retailers who direct their own advertisements for these products must comply beginning 24 months after the publication date of the final deeming regulation.

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

# NICOTINE WARNING

If the retailer is not responsible for or does not direct his/her own ads and/or packaging, the retailer will not be in violation if:

- The packaging or advertising of the tobacco product sold contains a health warning;
- The warning on the package or ad is not altered or covered up in whole or part in a manner that is material to the health warning requirement (example – placing a sticker over the warning statement);
- The package is supplied to the retailer by a license or permit holding manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB) issued license or permit, if applicable.

# TOBACCO PRODUCTS THAT DO NOT CONTAIN NICOTINE

- If a tobacco product does not contain nicotine, then the product is not required to bear the nicotine warning, provided that:
- Manufacturers submit to FDA a confirmation statement, and
- Such products bear the warning, “This product is made from tobacco.” on all on all packages and advertisements for these products in place of the nicotine warning.



# PROHIBITION AGAINST MODIFIED RISK TOBACCO PRODUCTS WITHOUT AN FDA ORDER IN EFFECT

Already in Effect	Effective on Pub + 90 days
Cigarette	ENDS (meeting the statutory definition of a tobacco product)
Cigarette Tobacco	Pipe Tobacco
Roll-Your-Own tobacco	Cigars
Smokeless tobacco	Hookah
	E-Liquid meeting the statutory definition of a tobacco product
	All other products meeting statutory definition of a tobacco product

Beginning 90 days after publication of the final deeming rule, modified risk tobacco products cannot be introduced into interstate commerce unless an FDA order is in effect.

# MODIFIED RISK TOBACCO PRODUCTS – RETAILER RESPONSIBILITIES

- Examples of the modified risk tobacco products that will require an FDA order are those whose label, labeling, or advertising claim are “lower risk”, “less harmful”, or “contains a reduced level of a substance” than another commercially marketed tobacco product.
- For a retailer, this means that any modified risk tobacco product that is in violation of section 911 becomes adulterated 90 days after publication of the rule.
- It is illegal to sell or distribute those products across state lines and it will be also illegal for retailers to receive in interstate commerce and offer for further distribution or sales such modified risk tobacco products.

# PROHIBITION AGAINST MRTPS DESCRIBED AS “LOW”, “LIGHT” OR “MILD” WITHOUT AN FDA ORDER IN EFFECT

Already in Effect	Stop US Distribution beginning 13 months after the effective date. ( Which is Date of pub +90 days)
Cigarette	ENDS (meeting the statutory definition of a tobacco product)
Cigarette Tobacco	Pipe Tobacco
Roll-Your-Own tobacco	Cigars
Smokeless tobacco	Hookah
	E-liquid meeting the statutory definition of a tobacco product
	All other products meeting statutory definition of a tobacco product

# NEWLY DEEMED PRODUCTS

- All newly-regulated tobacco products will require premarket authorization, unless they are eligible for grandfather status (that is, were on the market as of Feb. 15, 2007).
- 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: 12 months for an Exemption from Substantial Equivalence (SE); 18 months for an SE report; and 24 months for a premarket tobacco application (PMTA).

# NEWLY DEEMED PRODUCTS

- 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.

# REVIEW – EFFECTIVE DATES FOR NEWLY DEEMED TOBACCO PRODUCTS \*

Requirement	Effective Date
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The following apply to ENDS, Pipe Tobacco, Cigars, Hookah, e-liquid containing nicotine or tobacco, and other tobacco products meeting the definition of a “covered tobacco product”:

Prohibition against sales to minors under age 18	Publication date + 90 days
Age Verification by Photo ID if under 27	Publication date + 90 days
**Prohibition against Vending Machine sales	Publication date + 90 days

The following applies to all newly deemed products:

Prohibition against free samples	Publication date + 90 days
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\* Not a complete list

\*\* Exception - Vending machines sales are allowed if in a facility where those under 18 years of age are neither present nor permitted at any time.

# REFERENCES

- Small Entity Compliance Guides can be found on the Center's guidance page. Visit [www.fda.gov/tobaccoproducts](http://www.fda.gov/tobaccoproducts) and search on "guidance"
- Submit your questions to [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov)

