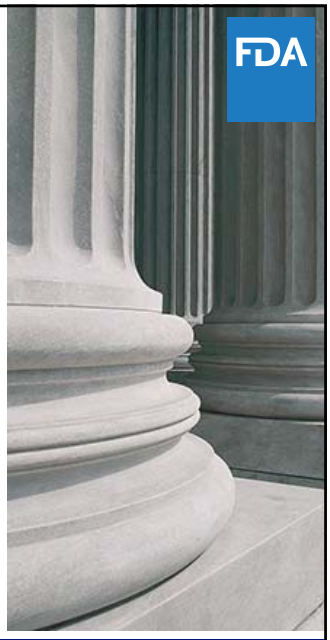
FDA'S IMPLEMENTATION OF THE "DEEMING" RULE TO REGULATE ALL TOBACCO PRODUCTS



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March 23, 2017

CENTER FOR TOBACCO PRODUCTS

- Summary of the Deeming Rule Requirements
- Vape Shops
- "Covered" Tobacco Products
- Warning Statements

SUMMARY OF THE DEEMING RULE REQUIREMENTS

Swati Kabaria
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FDA'S TOBACCO PRODUCT AUTHORITY

- FDA has the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, including components, parts and accessories, 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, deemed all products that met the definition of a tobacco product under the law, including components and parts, but excluding accessories of those newly deemed products, to be subject to FDA's tobacco product authorities. This rule became effective on August 8, 2016.
- FDA regulates those entities involved in the manufacture, distribution, importation, sale, or marketing of tobacco products.

SUMMARY OF THE DEEMING RULE

Two part rule:

1. "Deeming" provisions – Extends FDA's authority to all products and it's components and parts that meet the statutory definition of a tobacco product except accessories. Most of these requirements apply to "finished tobacco products"* only.
2. Additional restrictions – Modifications to the 96 Rule and required warning statements (Part 1143) for "covered tobacco products."‡ Nicotine warning also applies to cigarette tobacco and roll-your-own tobacco.

**"Finished tobacco product" means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use.*

‡ *"Covered tobacco product "means any tobacco product deemed subject to the FD&C Act by this rule but excludes any component or part that is not made or derived from tobacco.*

STATUTORY AUTOMATIC PROVISIONS

Prohibition on Adulteration and Misbranding of Tobacco Products	Ingredient Listing Submission
Harmful and Potentially Harmful Constituent (HPHC) Reporting	Registration of Tobacco Product Manufacturing Establishments and Product Listing
Prohibition on the Sale and Distribution of Modified Risk Tobacco Products (MRTP)	Premarket Review Requirements
Tobacco Health Document Submissions	User Fees (Limited to specific classes of tobacco products, including cigar and pipe tobacco)

"COMPONENTS OR PARTS" OF NEWLY REGULATED TOBACCO PRODUCTS

"Component or part" means any software or assembly of materials that is intended or reasonably expected to:

- Alter or affect the tobacco product's performance, composition, constituents or characteristics; or
- Be used with or for the human consumption of a tobacco product.
- Is not an accessory of a tobacco product.

EXAMPLES OF "COMPONENTS OR PARTS" OF NEWLY REGULATED TOBACCO PRODUCTS

FDA

Newly Regulated Tobacco Product	Component/Part Examples
ENDS	Atomizers, cartomizers, coils, e-liquid sold as part of a closed system
Pipe Tobacco	Pipe assembly, 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

"Accessory" means 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; and meets 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."

*Note that accessories of the newly regulated tobacco products have not been deemed under FDA's tobacco product authorities through the rule.

EXAMPLES OF ACCESSORIES* OF NEWLY REGULATED TOBACCO PRODUCTS

FDA

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

*Note that accessories of the newly regulated tobacco products have not been deemed under FDA's tobacco product authorities through the rule, therefore retailers, importers, manufacturers, and distributors of these accessories do not need to comply with any of the new requirements of the deeming rule.

ACCESSORIES* OF NEWLY REGULATED TOBACCO PRODUCTS




*Note that accessories of the newly regulated tobacco products have not been deemed under FDA's tobacco product authorities through the rule, therefore retailers, importers, manufacturers, and distributors of these accessories do not need to comply with any of the new requirements of the deeming rule.

FDA REGULATED TOBACCO PRODUCTS

Examples of Tobacco Products Regulated Before the Deeming Rule	Examples of Newly Regulated Tobacco Products Under the Deeming Rule
• Cigarettes • Cigarette tobacco • Roll-Your-Own tobacco • Smokeless tobacco	• ENDS* • Pipe Tobacco • Cigars • Hookah/Waterpipe tobacco • E-liquid
This includes the components, parts, and accessories of these products.	*This includes the components and parts of these products, but not their accessories.*

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

DEEMING RULE – ELECTRONIC NICOTINE DELIVERY SYSTEMS (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 included as part of a closed system • 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

REQUIREMENTS FOR MANUFACTURERS

Requirements for Finished Tobacco Products

Provision	Compliance Date	Compliance Date for Small-Scale Tobacco Product Manufacturers
Ingredient listing	For products on the market on August 8, 2016: August 8, 2017 For products entering the market after August 8, 2016: 90 days prior to marketing	For products on the market on August 8, 2016: February 8, 2018 For products entering the market after August 8, 2016: 90 days prior to marketing
Tobacco health documents	February 8, 2017	August 8, 2017
Harmful and potentially harmful constituent (HPHC) testing and reporting	August 8, 2019 or For products entering the market after August 8, 2019: 90 days prior to marketing	August 8, 2019 or For products entering the market after August 8, 2019: 90 days prior to marketing

REQUIREMENTS FOR MANUFACTURERS

Requirements for Finished Tobacco Products

Provision	Compliance Date	Compliance Date for Small-Scale Tobacco Product Manufacturers
Registration of establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product and product listings	For entities engaged in the manufacture, preparation, compounding, or processing of tobacco products in the U.S. prior to August 8, 2016 and continuing operations after August 8, 2016: June 30, 2017 For entities engaged in the manufacture, preparation, compounding, or processing of tobacco products in the U.S. on or after August 8, 2016 : Immediately upon first engaging in the manufacturing of a tobacco product	For entities engaged in the manufacture, preparation, compounding, or processing of tobacco products in the U.S. prior to August 8, 2016 and continuing operations after August 8, 2016: June 30, 2017 For entities engaged in the manufacture, preparation, compounding, or processing of tobacco products in the U.S. on or after August 8, 2016 : Immediately upon first engaging in the manufacturing of a tobacco product

REQUIREMENTS FOR MANUFACTURERS

Warning Requirements for "Covered" Tobacco Products (such as nicotine containing E-liquids)*

Provision	Effective Date - Stop Manufacture	Effective Date - Stop Distribution
Addictiveness warning statement on packaging	May 10, 2018	June 11, 2018

- Advertisements must bear the addictiveness warning statement: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." beginning May 10, 2018.

**Note: Additional rotational warnings for cigars.*

REQUIREMENTS FOR MANUFACTURERS

Requirements for All Newly Regulated Tobacco Products

Provision	Compliance Date
Prohibition against modified risk tobacco products whose label, labeling, or advertising uses claims other than "light," "low," or "mild" (e.g., "lower risk," "less harmful," or "contains reduced level of [a substance]" without an FDA order in effect	August 8, 2016
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	Stop manufacturing: August 8, 2017 Stop distribution into interstate commerce: September 8, 2017

REQUIREMENTS FOR 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.

REQUIREMENTS FOR 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.

GUIDANCES FOR INDUSTRY

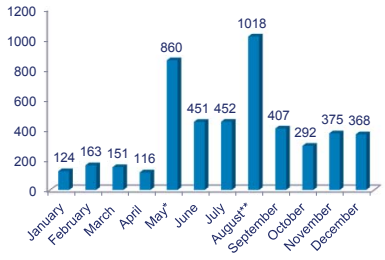
- Prohibition of Distributing Free Samples of Tobacco Products (Draft Guidance)
- Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops (Draft Guidance)
- Compliance Policy for Required Warning Statements on Small-Packaged Cigars (Draft Guidance)

OFFICE OF SMALL BUSINESS ASSISTANCE (OSBA) – IMPACT OF DEEMING RULE

Frequently Asked Deeming Topics in 2016

1. Establishment Registration and Product Listing
2. Imported Products
3. Labeling
4. Free Samples
5. Vape Shops
6. Zero Nicotine Products
7. Cigars
8. Retailer Provisions
9. Premarket Tobacco Applications (PMTA)

OSBA inquiries in 2016



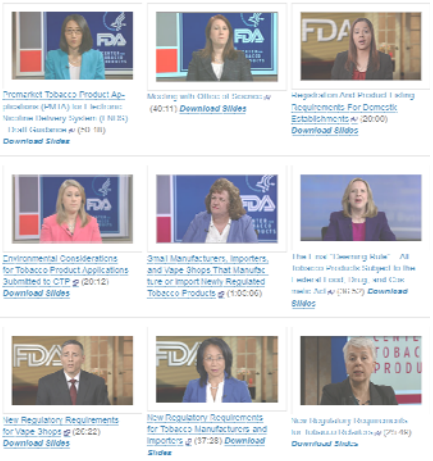
*May 8, 2016 – Deeming rule published.

** August 8, 2016 – Effective Date of Deeming Rule

In 2015 there were 2479 OSBA inquires received. In 2016 that number increased to 4777.

COMPLIANCE TRAINING AND EDUCATION WEBINARS

- CTP hosts a series of webinars on Federal tobacco regulations. These webinars are designed to provide FDA tobacco compliance information to retailers and to small businesses.
- We have hosted 15 webinars related to the Final Deeming regulation. Webinars are archived and available on our website.



VAPE SHOPS

VAPE SHOPS

- 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.

VAPE SHOPS AS RETAILERS

- A vape shop is considered a retailer if they sell tobacco products to individuals for personal consumption. For example if the shop sells 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 through the internet.

VAPE SHOPS AS MANUFACTURERS

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."

- Vape shops that mix or prepare e-liquids, create or modify aerosolizing apparatus, repackage ENDS products, or relabel ENDS products are considered manufacturers.

- "Small-scale tobacco product manufacturer" - 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.

VAPE SHOP INSPECTIONS

- FDA conducts routine inspections of tobacco retailers and manufacturers to determine compliance with the law.
- FDA also conducts inspections of vape shops.

"COVERED" TOBACCO PRODUCTS

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Office of Compliance and Enforcement

"COVERED" TOBACCO PRODUCTS

Certain requirements under the final Deeming rule apply only to "covered tobacco products".

Covered Tobacco Products

- 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.

"COVERED" TOBACCO PRODUCTS

FDA

Key Questions

1. Does the product meet the statutory definition of a "tobacco product"?
   (made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product)
2. Is the tobacco product deemed by the final rule to be subject to the FD&C Act?
3. If the "deemed" tobacco product is a part or component, is it made or derived from tobacco?

If the answers to any of these questions is NO, then the product is NOT a "covered" tobacco product.

"COVERED" TOBACCO PRODUCTS

FDA

1. Does the product meet the statutory definition of a "tobacco product"?
   (made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product)
2. Is the tobacco product deemed by the final rule to be subject to the FD&C Act?
3. If the "deemed" tobacco product is a part or component, is it made or derived from tobacco?

✓

✓

NA

Meets the definition of a "Covered" tobacco product.

Cigar sold to directly to consumers

"COVERED" TOBACCO PRODUCTS

1. Does the product meet the statutory definition of a "tobacco product"? (made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product) ✓
2. Is the tobacco product deemed by the final rule to be subject to the FD&C Act? ✓
3. If the "deemed" tobacco product is a part or component, is it made or derived from tobacco? **NA**

Pipe Tobacco sold to consumers

Meets the definition of a "Covered" tobacco product.

"COVERED" TOBACCO PRODUCTS

1. Does the product meet the statutory definition of a "tobacco product"? (made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product) ✓
2. Is the tobacco product deemed by the final rule to be subject to the FD&C Act? ✓
3. If the "deemed" tobacco product is a part or component, is it made or derived from tobacco? ✗

E-cigarette replacement battery sold separately to consumers

Does not meet the definition of a "Covered" tobacco product.

"COVERED" TOBACCO PRODUCTS

1. Does the product meet the statutory definition of a "tobacco product"? (made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product) ✓
2. Is the tobacco product deemed by the final rule to be subject to the FD&C Act? ✓
3. If the "deemed" tobacco product is a part or component, is it made or derived from tobacco? ✗

Refillable, empty vaporizer, sold separately to consumers

Does not meet the definition of a "Covered" tobacco product.

"COVERED" TOBACCO PRODUCTS

1. Does the product meet the statutory definition of a "tobacco product"? (made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product) ✓
2. Is the tobacco product deemed by the final rule to be subject to the FD&C Act? ✗
3. If the "deemed" tobacco product is a part or component, is it made or derived from tobacco? NA

Hookah tongs sold separately to consumers

Does not meet the definition of a "Covered" tobacco product.

RESTRICTIONS FOR "COVERED" TOBACCO PRODUCTS

1) No sale to individuals under the age of 18 years and requirement for age verification by photo ID if under 27.
2) No sale using electronic or mechanical devices, e.g., vending machines, unless in a facility where no person under 18 is allowed to enter at any time.
3) All "covered" tobacco products must display health warnings on package labels and advertisements.*
4) Cigar products must bear one of 6 warnings on product packages and those warnings must be rotated quarterly on cigar advertisements. The display, distribution, and rotation of cigar warnings must be done in accordance with an approved warning plan.

** Note the health warning requirement also applies to cigarette tobacco and roll-your-own tobacco.*

RETAILER REQUIREMENTS FOR CIGARS, PIPE TOBACCO, ENDS, HOOKAH, AND OTHER "COVERED" TOBACCO PRODUCTS UNDER THE DEEMING RULE

Provision	Cigars	Pipe Tobacco	ENDS	Hookah
Only sell to customers age 18	✓	✓	✓	✓
Check photo ID of everyone under age 27	✓	✓	✓	✓
Do not sell products in a vending machine (unless in a facility where those under 18 years of age are neither present nor permitted at any time)	✓	✓	✓	✓
Do not give away free samples*	✓	✓	✓	✓

* The prohibition against free samples applies to all newly deemed products.
Note: There is no prohibition of the use of self-service displays for the newly deemed products.

ENFORCEMENT: WARNING LETTERS ISSUED FOR SALE OF NEWLY REGULATED PRODUCTS TO MINORS

- In September 2016, FDA issued the first 55 warning letters to retailers for selling (in stores and online) newly regulated tobacco products, such as e-cigarettes, e-liquids and cigars, to minors.
- During compliance checks at major national retail chains, tobacco specialty stores and online retailers, FDA found that minors were able to purchase some of these newly regulated tobacco products in a variety of youth-appealing flavors, including bubble gum, cotton candy and gummy bear, silly strawberry, cookie monsta, honey bear, grape jolly rancher, vanilla whipped cream, and crunch berry.
- As of February 1, 2017 FDA has issued 2500 Warning Letters for sale of these products to minors.

WARNING STATEMENTS

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ADDICTIVENESS WARNING STATEMENT

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

Requirements	Effective Date
• Required to appear on all product package labels of cigarette tobacco, roll-your-own tobacco, and covered tobacco products* made or derived from tobacco. • Specific requirements for placement and formatting for packages.	Manufacturers cannot manufacture products with non-compliant packages beginning May 10, 2018 and cannot distribute packaging for these products without the addictiveness warning statement beginning June 11, 2018.
• Must also be included in all advertisements for cigarette tobacco, roll-your-own tobacco, and covered tobacco products. • Specific requirements for placement and formatting for advertisements.	May 10, 2018

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

ADDICTIVENESS WARNING REQUIREMENT FOR SMALL PACKAGING

- A special provision applies to packages that are too small to display the required addictiveness warning statement.
- If packaging is too small or otherwise unable to accommodate a label with sufficient space to display the required addictiveness warning statement, the information and specifications required under the deeming rule must be displayed on one of the following:
  - on a product carton, outer container or wrapper that provides sufficient space to bear the information; or
  - on a tag firmly and permanently affixed to the tobacco product package.
- The carton, outer container, wrapper, or tag will serve as the location of the principal display panels.

TOBACCO PRODUCTS THAT DO NOT CONTAIN NICOTINE

- If a "covered" tobacco product, cigarette tobacco, or roll your own tobacco does not contain nicotine, then the product is not required to bear the addictiveness warning statement, provided that:
- Manufacturers submit to FDA a confirmation statement, and
- Such products bear the alternative statement, "This product is made from tobacco." on all packages and advertisements for these products.

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

Provision	Effective Date
Required on all* cigar package labels. Specific placement and formatting requirements. * Point-of-sale warning required for cigars sold individually without packaging.	Manufacturers cannot manufacture products with non-compliant packages beginning May 10, 2018 and cannot distribute cigar products without the required warning statement beginning June 11, 2018.
Required in print advertisements and other advertisements with a visual component . Specific rotation, placement, and formatting requirements.	May 10, 2018.

Additional details on these requirements are found in the Small Entity Compliance Guide Guidance.

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 is May 10, 2017 or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later.
- Retailers who are responsible for and/or direct their own advertisements for cigars must comply and submit a cigar warning plan by the deadline.

SINGLE UNPACKAGED CIGARS – POINT OF SALE WARNING STATEMENTS REQUIREMENTS

Provision	Effective Date
If single unpackaged cigars sold, warning statements requirement at point of sale. Specific placement and formatting requirements: • A minimum of 8.5 x 11 inches. • Clear, legible, and conspicuous. • Statements printed in black Helvetica bold or Arial bold type (or other similar sans serif font) against a solid white background, in at least 17 point type with appropriate space between the warning statements. • Statements must be printed in a manner that contrasts by typography, layout, or color, with all printed material. • Capitalized and punctuated as indicated in the regulation. • Posted on or within 3 inches of each cash register where payment may be made. • Signs are unobstructed in their entirety and can be read easily by each consumer making a purchase.	May 10, 2018

DRAFT GUIDANCE – COMPLIANCE POLICY FOR REQUIRED WARNING STATEMENTS ON SMALL-PACKAGED CIGARS

- In the draft guidance, it states that FDA does not intend to take enforcement action with respect to such cigars that do not comply with the size and placement requirements, when the information and specifications required under the deeming rule appear on the following:
  - carton or other outer container or wrapper that could accommodate the required warning statements, or
  - on a tag otherwise firmly and permanently affixed to the cigar package.
- The draft guidance does not apply to the other provisions of 21 CFR § 1143.5, including the random display and distribution of cigar warning statements on packaging in accordance with an FDA-approved warning plan.

ADDICTIVENESS WARNING AND CIGAR WARNINGS – RETAILER SAFE HARBOR

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

- The packaging or advertising of the tobacco product sold contains a warning statement;
- The warning on the package or advertisement 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.

CIGAR PACKAGING EXAMPLES

FDA

SUMMARY

SUMMARY

- The Final Deeming rule was published on May 10, 2016 and became effective on August 8, 2016.
- The Final Deeming rule extends FDA's tobacco product authorities over all products that meet the definition of a tobacco product under the law, including components and parts, but excluding accessories of those newly deemed products.
- Examples of newly deemed tobacco products include: cigars, hookah, pipe tobacco, and ENDS.
- Some regulatory requirements became effective on August 8, 2016, while others will become effective over the next 2-3 years.

SUMMARY

- Certain requirements under the Final Deeming rule apply only to “covered” tobacco products (e.g., no sale if under 18 and age verification by photo ID if under 27).
- A vape shop can be a tobacco product retailer, a tobacco product manufacturer, or both. Tobacco product retailers and manufacturers are subject to inspection by FDA.
- The Final Deeming rule adds new warning statement requirements beginning in 2018.

QUESTIONS