

# **FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)\***

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## **Guidance for Industry**

### **Small Entity Compliance Guide**

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products**

**November 2018**

\* This is the third revision to the first edition of this guidance, which issued in May 2016. Revisions are noted by date at the end of the guidance.

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# **FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements**

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## **Guidance for Industry<sup>1</sup> Small Entity Compliance Guide**

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

### **I. INTRODUCTION**

This Small Entity Compliance Guide is intended to help small businesses understand and comply with FDA's final rule deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (the Deeming Rule). The Deeming Rule extends FDA's tobacco product authorities in chapter IX of the FD&C Act to include all tobacco products, except accessories of newly deemed tobacco products. The Deeming Rule also prohibits the sale of covered tobacco products to individuals under the age of 18, prohibits vending machine sales unless sold in adult-only facilities, and requires warning labels on packages and advertisements. These provisions are discussed in detail, below.

The Agency prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory

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<sup>1</sup> This guidance was prepared by the Office of Regulations in the Center for Tobacco Products (CTP) at FDA.

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requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

## II. DESCRIPTION OF THE RULE

### A. Background

The Tobacco Control Act, enacted on June 22, 2009, amends the FD&C Act and provides FDA with the authority to regulate tobacco products (Pub. L. 111–31, 123 Stat. 1776). Cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco were immediately subject to the provisions of the Tobacco Control Act and FDA’s regulatory authority. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a(b)) grants FDA authority to deem those products subject to the law as well. In addition to the provisions in the FD&C Act, and implementing regulations that apply automatically to the newly deemed products, FDA may require restrictions on the sale and distribution of a tobacco product if FDA determines such restrictions are appropriate for the protection of public health (section 906(d) of the FD&C Act (21 U.S.C. 387f(d))). Pursuant to these authorities, FDA published a proposed rule on April 25, 2014, seeking to deem all products that meet the statutory definition of *tobacco product* set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), with the exception of accessories of newly deemed products, and proposed additional provisions requiring warning statements and other restrictions on the sale and distribution of tobacco products (79 FR 12342). After review and consideration of comments on the proposed rule, the Deeming Rule was published.

The statutory definition of *tobacco product* in section 201(rr)(1) of the FD&C Act reads:

The term “tobacco product” means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

Products that meet the statutory definition of *drug* (section 201(g)(1)), *device* (section 201(h)), or *combination product* (section 503(g)) are excluded from the definition of *tobacco product* (section 201(rr)(2)) of the FD&C Act. Otherwise, all products made or derived from tobacco and intended for human consumption — including components and parts of tobacco products whether or not they are themselves made or derived from tobacco — fall under the definition of *tobacco product*. Under the Deeming Rule, all tobacco products, except for accessories of newly deemed tobacco products are now subject to the Tobacco Control Act and the regulations issued by FDA under the FD&C Act. These products include a number of widely used and previously unregulated products, such as cigars, pipe tobacco, waterpipes (or hookah), dissolvable products, e-cigarettes and other electronic nicotine delivery systems (ENDS), collectively, the “newly deemed products.”<sup>2</sup>

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<sup>2</sup> The requirements set forth in the Deeming Rule will also apply to future products that meet the statutory definition of *tobacco product*, except accessories of newly deemed products.

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For the purposes of the Deeming Rule, the following terms are defined as follows:

***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 tobacco product; or
  - (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product (parts 1100, 1140, 1143 (21 CFR parts 1100, 1140, 1143)).

***Cigar*** means 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 (part 1143).

***Cigarette*** (1) Means a product that: (i) Is a tobacco product and (ii) Meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and (2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco (part 1140).

***Cigarette tobacco*** means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco (parts 1140, 1143).

***Component or part*** means 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 (parts 1100, 1140, 1143).

***Covered tobacco product*** means any tobacco product deemed to be subject to the FD&C Act pursuant to § 1100.2 of this chapter (i.e., subchapter K), but excludes any component or part that is not made or derived from tobacco (parts 1140, 1143).

***Distributor*** means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of part 1140 (part 1140).

***Importer*** means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States (part 1140).

***Manufacturer*** means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product (part 1140).

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***Nicotine*** means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or C[10]H[14]N[2], including any salt or complex of nicotine (part 1140).

***Package or packaging*** means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers (parts 1100, 1140, 1143).

***Point of sale*** means any location at which a consumer can purchase or otherwise obtain tobacco products for personal consumption (parts 1140, 1143).

***Principal display panels*** means the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer (part 1143).

***Required warning statement*** means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products (part 1143).

***Retailer*** means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part (parts 1140, 1143).

***Roll-your-own tobacco*** means any tobacco product that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes (parts 1140, 1143).

***Smokeless tobacco*** means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity (part 1140).

***Tobacco product*** As stated in section 201(rr) of the FD&C Act in relevant part, a tobacco product: (1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and (2) Does not mean an article that is a drug defined under section 201(g)(1) of the FD&C Act, a device defined under section 201(h) of the FD&C Act, or a combination product described in section 503(g) of the FD&C Act (parts 1100, 1140, 1143).

### **B. Automatic Provisions of the Tobacco Control Act and FDA's Tobacco Regulations**

Upon the effective date of the Deeming Rule (i.e., 90 days from the date of publication), the newly deemed products will be subject to the FD&C Act provisions and FDA regulations that apply to tobacco products, such as those covering:

1. Adulterated or misbranded tobacco products;

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2. Required submission of ingredient listing and reporting of harmful and potentially harmful constituents (HPHCs);
3. Required registration of tobacco product manufacturing establishments and product listing;
4. Prohibition against sale and distribution of modified risk tobacco products unless FDA issues an order authorizing their marketing;
5. Prohibition on the distribution of free samples (same as cigarettes); and
6. Premarket authorizations/orders for new tobacco products.

Per the preamble to the final deeming regulation, dates for compliance with the automatic provisions, along with descriptions of the provisions and sources for further information are provided throughout this guidance document and in Table A below.

### **C. Restrictions on the Sale and Distribution of Tobacco Products to Minors**

The Deeming Rule also amends the Code of Federal Regulations, 21 CFR part 1140, to prohibit the sale of covered tobacco products to persons under the age of 18 and requires retailers of covered tobacco products to verify the purchaser's birth date by reviewing the individual's photographic identification (§ 1140.14). The Deeming Rule defines ***covered tobacco product*** to include all tobacco products that are subject to the Deeming Rule, but “excludes any component or part that is not made or derived from tobacco” (§ 1140.3). Therefore, the definition of covered tobacco products includes all deemed tobacco products, including components and parts, made or derived from tobacco.

To comply with the age and identification verification requirements, retailers are required to verify a purchaser is at least 18 years of age by reviewing the purchaser's photographic identification. However, retailers are not required to verify the age of any person who is more than 26 years of age (§ 1140.14(b)(2)(ii)).

The Deeming Rule also amends part 1140 to prohibit the sale of covered tobacco products through the assistance of any electronic or mechanical device (such as a vending machine), except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time (§ 1140.14(b)(3)).

The prohibition on the distribution of free samples applies to all newly deemed tobacco products, including their components and parts, but not their accessories.

### **D. Required Warning Statement(s) on Labels and Advertisements**

The Deeming Rule requires that the packages and advertisements of all cigarette tobacco, RYO tobacco, and covered tobacco products bear an addictiveness warning label statement (as described in sections II.E.1 and II.F.1 below). In addition to the addictiveness warning label statement, cigar packaging and advertising are also required to include additional warning label statements (as described in sections II.E.2 and II.F.2 below). For cigarette tobacco, roll your

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own tobacco, and covered tobacco products<sup>3</sup> that do not contain nicotine there is an alternative warning label statement for packages and advertisements (as described in section II.G below). On product packaging, the required warning(s) must appear on the two principal display panels of the package.

### **E. Required Warning Label Statement on Packages**

#### *1. Nicotine Addictiveness Warning Label Statement for Cigarette Tobacco, RYO Tobacco, and Covered Tobacco Products (Except Cigars)*

For cigarette tobacco, RYO tobacco, and covered tobacco products other than cigars,<sup>4</sup> the Deeming Rule requires that the tobacco product package bear the following required warning label statement on packages: “WARNING: This product contains nicotine. Nicotine is an addictive chemical.”

This required warning statement must appear on all cigarette tobacco, RYO tobacco, and covered tobacco product package labels. It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States these products without the required warning label statement on the tobacco product package (§ 1143.3(a)(1)).

Section 1143.3(a)(2) provides that the required warning statement on package labels must also appear directly on the package, and be clearly visible underneath any cellophane or other clear wrapping as follows:

- Be displayed in a conspicuous and prominent place on the two principal display panels of the package;
- Comprise at least 30 percent of each of the principal display panels (warning label area);
- Be printed in at least 12-point font size and must occupy the greatest possible proportion of the warning label area set aside for the required text;
- Be printed in conspicuous and legible Helvetica bold or Arial bold type or other similar sans serif fonts and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;
- Be capitalized and punctuated as indicated in § 1143.3(a)(1); and
- Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panels have the same orientation.

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<sup>3</sup> Components or parts that are not made or derived from tobacco do not meet the definition of “covered tobacco product,” and would not be required to carry an addiction warning or submit a self-certification.

<sup>4</sup> The cigar warning statement requirements for packages and advertisements are covered in detail below.



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A special provision in § 1143.3(d) applies to packages that are too small to display the required warning statement. A covered tobacco product that is too small or otherwise unable to accommodate a label must contain the information and specifications required under § 1143.3(a)(1) and (2) on one of the following:

- The covered tobacco product carton
- The outer container or wrapper that provides sufficient space to bear the information
- 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.

### *2. Minimum Required Warning Label Statements for Cigar Packages*

For cigars, § 1143.5(a)(1) of the Deeming Rule requires that the tobacco product package bear one of the following required warning statements on the package label:

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.**<sup>5</sup>

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

These required warning statements must appear on all cigar package labels if the cigar product is manufactured, packaged, sold, offered for sale, distributed, or imported for sale or distribution within the United States (§ 1143.5(a)(1)).<sup>6</sup>

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<sup>5</sup> You may choose to display either one of the warning statements regarding reproductive health. FDA is allowing the use of the reproductive health warning statement as required by the Federal Trade Commission (FTC) consent decrees as an optional alternative to the fifth FDA warning, “WARNING: Cigar use while pregnant can harm you and your baby.” FDA expects that providing this optional alternative will benefit entities bound by the FTC consent decrees, and the statement is appropriate for the protection of public health.

<sup>6</sup> See guidance, Compliance Policy for Required Warning Statements on Small-Packaged Cigars (August 2018), <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM536924.pdf>.

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These required warning statements must also meet the same requirements that apply to cigarette tobacco, RYO tobacco, and other covered tobacco products, with respect to font, text, size, placement and formatting of the package labels (§ 1143.5(a)(2)).

An exception exists for cigars that are sold individually, and not in a product package. In this circumstance, the retailer must display all six of the required warning statements on a sign posted at the point-of-sale (§ 1143.5(a)(3)).

The sign must meet the following requirements, as described in § 1143.5(a)(3):

- The sign must be at least 8.5 × 11 inches in size.
- The sign must be clear, legible, and conspicuous.
- The sign must be printed in black Helvetica bold or Arial bold type or other similar sans serif fonts against a solid white background, in at least 17-point font size with appropriate spacing between the warning statements.
- The required warning statements must be printed in a manner that contrasts by typography, layout, or color, with all other printed material.
- The required warning statements must be capitalized and punctuated as indicated in § 1143.5(a)(1).

The sign must be posted according to the following requirements stated in § 1143.5(a)(3):

- The sign must be posted on or within 3 inches of each cash register where payment may be made.
- The sign(s) must be unobstructed in its entirety and can be read easily by each consumer making a purchase.

Section 1143.5(c)(1) provides that except for cigars sold individually and not in a product package, the six required warning statements must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging. The six warning statements must also be randomly distributed in all areas of the United States where the product is marketed, in accordance with a plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to, and approved by, FDA.

### **F. Required Warning Statement on Advertisements**

#### ***1. Nicotine Addictiveness Warning Statement for Cigarette Tobacco, RYO Tobacco, and All Covered Tobacco Products (Except Cigars)***

Section 1143.3(b) provides that for cigarette tobacco, RYO tobacco, and covered tobacco products other than cigars, the required addictiveness warning statement from § 1143.3(a)(1)

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must be displayed on advertisements. Advertisements include print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, Internet Web pages, and electronic mail correspondence). On print advertisements and other advertisements with a visual component, the required warning statement, as described in § 1143.5(b)(2), must:

- Appear on the upper portion of the advertisement within the trim area.
- Occupy at least 20 percent of the area of the advertisement (warning area).
- Be printed in at least 12-point font size and ensure that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required warning statement.
- Be printed in conspicuous and legible Helvetica bold or Arial bold type or other similar sans serif fonts and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the advertisement.
- Be capitalized and punctuated.
- Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation.
- Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 millimeters (mm) or more than 4 mm.

### *2. Minimum Required Warning Label Statements for Cigar Advertisements*

Advertisements for cigars must include one of the six required warning statements from § 1143.5(a)(1). As there are six required warning statements for cigars, these warning statements must be rotated quarterly in advertisements, in alternating sequence, for each brand of cigar in accordance with a warning plan<sup>7</sup> submitted by the responsible cigar manufacturers, importers, distributors, or retailers to, and approved by, the FDA (§ 1143.5(c)). Cigar advertisements must follow the same format and content requirements as described above for cigarette tobacco, RYO tobacco, and other covered tobacco products (§ 1143.5(b)).

### **G. Self-certification and Alternative Required Warning Statement**

The nicotine addictiveness warning statement required on packages and advertisements in § 1143.3(a)(1) for cigarette tobacco, roll your own tobacco, and covered tobacco products other than cigars is not required where such products do not contain nicotine<sup>8</sup> if the tobacco product manufacturer has submitted to FDA a confirmation statement certifying to be true and accurate

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<sup>7</sup> See guidance entitled, Submission of Warning Plans for Cigars (August 2018), <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM534739.pdf>

<sup>8</sup> As stated previously in footnote 3, components or parts that are not made or derived from tobacco do not meet the definition of “covered tobacco product,” and would not be required to carry an addiction warning or submit a self-certification.

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that the product does not contain nicotine (e.g., no nicotine at detectable levels) and that the tobacco product manufacturer has data to support that assertion. The alternative statement, under § 1143.3(c), for applicable package labels and advertisements reads: “This product is made from tobacco.” This statement must appear on at least 30 percent of the two principal display panels of the package and at least 20 percent of the upper area of the advertisement as described in § 1143.3(a) and (b).

If you have any questions on the self-certification, you can contact FDA at: 1-877-CTP-1373. Please submit your self-certification statement to the following address at FDA:

Food and Drug Administration  
Center for Tobacco Products  
Office of Compliance and Enforcement  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

### **H. Retailer Warning Statement Exceptions**

#### *1. Package or Packaging*

The Deeming Rule (in §§ 1143.3(a)(3) and 1143.5(a)(4)) provides that a retailer of any tobacco product covered by §§ 1143.3(a)(1) and (a)(2) and 1143.5(a)(1) and (a)(2), respectively, will not be in violation of these sections for packaging that:

- Contains a health warning
- Is supplied to the retailer by the tobacco product 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
- Is not altered by the retailer in a way that is material to the requirements of §§ 1143.3(a) and 1143.5(a)

#### *2. Advertisements*

The warning statement requirement for advertisements outlined in §§ 1143.3(b) and 1143.5(b) apply to a retailer only if that retailer is *responsible for or directs* the health warning required under the paragraph. However, this does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that:

- Does not contain a health warning
- Contains a health warning that has been altered by the retailer in a way that is material to the requirements of §§ 1143.3(b) and 1143.5(b)

### III. QUESTIONS AND ANSWERS

#### A. Deeming of Tobacco Products

##### 1. Where can I find the Deeming Rule and any additional explanation?

The Deeming Rule is codified in the Code of Federal Regulations at 21 CFR parts 1100 (the deeming provisions), 1140 (sales and distribution restrictions), and 1143 (warning label requirements). You can also find a detailed explanation of all the provisions in the preamble to the Deeming Rule in the *Federal Register* or at CTP's Deeming Rule webpage: <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm388395.htm>.

##### 2. What products are deemed subject to FDA's authority by the Deeming Rule?

Under the Deeming Rule, all products that meet the statutory definition of *tobacco product* in section 201(rr) of the FD&C Act are subject to FDA's authority to regulate tobacco products except for accessories of newly deemed tobacco products. Section 201(rr) of the FD&C Act defines *tobacco product* as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." However, a product that is a *drug* under section 201(g)(1), a *device* under section 201(h), or a *combination product*, as described in section 353(g) of the FD&C Act is not a *tobacco product* and is not subject to FDA authority to regulate tobacco products (but may be subject to FDA authority to regulate drugs, devices, and combination products).

Cigarettes, smokeless tobacco, cigarette tobacco, and RYO tobacco and their components, parts, and accessories are tobacco products and have been subject to the FDA authority since the Tobacco Control Act was enacted in 2009. With the Deeming Rule, FDA's tobacco product authorities are extended to all other tobacco products that were not previously regulated, except accessories of newly deemed tobacco products. The newly deemed products include electronic nicotine delivery systems (ENDS), cigars, pipe tobacco, cigar tobacco, pipes, waterpipe tobacco, and dissolvable nicotine products that do not meet the definition of smokeless tobacco, among others.

##### 3. Does the Deeming Rule deem components, parts, and accessories subject to FDA's tobacco product authorities?

Under the Deeming Rule, components and parts of the newly deemed tobacco products are subject to FDA's tobacco product authorities, but the accessories of newly deemed tobacco products are not. Components, parts, and accessories of cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco are already subject to FDA authority.

##### 4. How does the Deeming Rule define a component or part? How is that different from an accessory?

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The Deeming Rule defines ***component or part*** and ***accessory***. Accessory is defined in § 1100.3 as follows:

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 tobacco product; or
  - (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

***Component or part*** is defined in § 1100.3 as follows:

Component or part means 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.

The following is a nonexhaustive list of examples of components and parts used with electronic nicotine delivery systems (ENDS) (including e-cigarettes):

- E-liquids
- Atomizers
- Batteries (with or without variable voltage)
- Cartomizers (atomizer plus replaceable fluid-filled cartridge)
- Digital display/lights to adjust settings
- Clearomisers
- Tank systems
- Flavors
- Programmable software

Similarly, the following is a nonexhaustive list of examples of components and parts used with waterpipe tobacco:

- Flavor enhancers and the vial in which they are contained
- Hose cooling attachments
- Water filtration base additives (including those which are flavored)
- Flavored waterpipe tobacco charcoals and the wrappers or boxes that contain charcoals
- Bowls, valves, hoses, and heads

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The following is a nonexhaustive list of objects used with waterpipe tobacco that would likely be considered accessories:

- Hookah glow balls
- Foil poker
- Shisha oyster forks
- Tongs
- Bags.

The following is a nonexhaustive list of examples of objects used with e-cigarettes or other ENDS that would likely be considered accessories:

- Screwdrivers
- Lanyards.

FDA recognizes that in some circumstances some assemblies of materials can operate as both an aspect of the package and a component or part of the tobacco product. In such situations, FDA is only examining a distinct subset of packaging materials that are intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics. Packaging materials that are not intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics are not components or parts of a tobacco product.

For example, a vial containing an e-liquid is a component or part of the tobacco product, as it is intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics, such as by leaching chemicals into the e-liquid itself, whereas a hard plastic blister pack in which the vial of e-liquid is distributed and sold to consumers is not.

### **5. Are products that are a drug, device, or combination product covered by the Deeming Rule?**

No. Products that meet the FD&C Act definition of drug, device, or combination product are excluded from the definition of tobacco product and are not subject to FDA's tobacco authority (section 201(rr)(2) of the FD&C Act). See section 201(g)(1) of the FD&C Act for the definition of drug, section 201(h) of the FD&C Act for the definition of device, and section 503 of the FD&C Act for the definition of combination product. A tobacco product may not be marketed in combination with any other product regulated by FDA (drug, biologic, food, cosmetic, medical device, or a dietary supplement) (section 201(rr)(4) of the FD&C Act).

### **6. When does part 1100, which deems certain tobacco products to be subject to the tobacco product authorities in the FD&C Act, become effective?**

Part 1100 took effect on August 8, 2016, which was 90 days after the Deeming Rule was published. As of that date, newly deemed products became automatically subject to all provisions in the FD&C Act and FDA regulations applicable to tobacco products. However, for certain provisions that require labeling changes or information submission to the Agency, FDA

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has provided an extended compliance date, before which the Agency does not intend to enforce such provisions. These compliance timeframes will provide time after the effective date for firms to come into compliance with those provisions of the law. See Tables A and B, below, for a list of provisions and the compliance dates.

### **7. Once products are deemed, what additional statutory and regulatory restrictions will they be subject to?**

The newly deemed products are subject to the FDA's tobacco product authorities in Chapter IX of the FD&C Act and FDA's existing regulations for tobacco products, as well as parts 1100, 1140, and 1143, and any future applicable regulations issued under FDA's tobacco product authorities. Part 1100 deems certain tobacco products to be subject to the tobacco product authorities in the FD&C Act. Part 1140 extends the requirement to prohibit the sale and distribution of products to individuals under 18 to covered tobacco products, prohibits vending machine sales of covered tobacco products except in adult-only facilities, and prohibits the distribution of free samples of newly deemed products. Part 1143 mandates the use of required warning statements for covered tobacco products, as well as for RYO and cigarette tobacco.

### **8. Can FDA take action against newly deemed tobacco products that are adulterated or misbranded?**

Yes. FDA can take action against newly deemed tobacco products that are adulterated or misbranded.

### **9. Do newly deemed tobacco products need to have premarket authorization prior to commercial distribution?**

A newly deemed product that is considered a "new tobacco product"<sup>9</sup> is required to have premarket authorization prior to commercial distribution. Grandfathered products (products that were commercially marketed – other than exclusively in test markets – in the United States as of February 15, 2007) are not considered new tobacco products and thus are not subject to the premarket authorization requirements of the statute.

### **10. How does FDA intend to enforce the premarket requirements for newly deemed products that are currently marketed as of the effective date of the Deeming Rule, but are not grandfathered products?**

Section 910 of the FD&C Act requires FDA authorization in order to market a new tobacco product. The FD&C Act provides three pathways for obtaining premarket authorization:

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<sup>9</sup> A new tobacco product is defined in section 910(a)(1) of the FD&C Act as: (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.



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substantial equivalence (SE) exemptions; SE reports; and premarket tobacco applications (PMTAs).

Tobacco products that were on the market as of February 15, 2007, are grandfathered and do not require premarket authorization. FDA has published guidance relating to the premarket authorization pathways. Please reference CTP's guidance page for additional information: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm>.

For newly deemed tobacco products that were on the market as of the effective date of the Deeming Rule, but that were not on the market as of February 15, 2007 (i.e., are not grandfathered), FDA extended the premarket review compliance dates for SE exemption requests, SE reports, and PMTAs (See the guidance, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (November 2018)*).<sup>10 11</sup> The compliance dates were extended to August 8, 2021 for SE Exemption request, SE reports, and PMTAs for deemed combustible tobacco products, such as most cigars, pipe tobacco and hookah tobacco, and August 8, 2022 for SE Exemption requests, SE reports, and PMTAs for deemed noncombustible tobacco products, such as most ENDS or e-cigarettes.

FDA intends to provide a continued compliance period pending review of those applications (SE exemption requests, SE reports, and PMTAs). FDA intends for this compliance period to continue until the agency renders a decision on an application (i.e., issuance of: a Marketing Order; a No Marketing Order; a Refuse to File; or Refuse to Accept) or the application is withdrawn.

New products for which no application has been submitted by August 8, 2021, for deemed combustible tobacco products, or August 8, 2022, for deemed non-combustible tobacco products months from the effective date of the Deeming Rule will no longer be subject to this compliance policy, and will be subject to enforcement.

### **11. How does FDA intend to enforce the premarket requirements for newly deemed products that were not marketed on or before the effective date of the Deeming Rule?**

Newly deemed tobacco products that are grandfathered (on the market as of February 15, 2007) are not subject to premarket review. Newly deemed products that are not grandfathered and were not on the market as of the effective date of the Deeming Rule, are subject to the premarket review requirements and must obtain a marketing order from FDA specific to the product under the PMTA pathway, the SE application pathway, or the SE exemption request pathway. Any new tobacco product not on the market as of the effective date of the Deeming Rule is not

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<sup>10</sup> <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm557714.htm>.

<sup>11</sup> An application is considered submitted on the date it is delivered and received electronically, through the mail, or through a courier to the CTP Document Control Center. See 81 FR at 28990. All regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or mailed to: Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

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covered by the compliance policy set forth above and will be subject to enforcement if it is marketed without premarket authorization.

### **12. Will the newly deemed tobacco products be subject to good manufacturing practices (GMPs)?**

FDA must first promulgate through rulemaking good manufacturing practice requirements applicable to tobacco products (or Tobacco Product Manufacturing Practices). Once these requirements are in effect, they will apply to newly deemed tobacco products. However, manufacturers must comply with any applicable adulteration and misbranding provisions pertaining to tobacco products of chapter IX of the FD&C Act.

### **13. Are the newly deemed tobacco products subject to user fees?**

Certain classes of tobacco products, including cigars and pipe tobacco, are subject to user fees. For additional information, please reference the User Fee Final Rule, codified at 21 CFR part 1150.

### **14. When do the additional provisions (parts 1140 and 1143) become effective?**

- The additional provisions in part 1140 took effect on August 8, 2016, which was 90 days after the publication of the Deeming Rule. These provisions include the minimum age and identification provisions, the vending machine provision, and the prohibition on free sample distribution.
- The health warning requirements in part 1143 took effect on May 10, 2018<sup>12</sup>, which is 24 months after the publication of the Deeming Rule. On July 5, 2018, the United States District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 CFR §§ 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted.<sup>13</sup>
- The requirement to submit a warning plan to FDA took effect on May 10, 2017<sup>14</sup>, which was 12 months after the publication of the Deeming Rule.

### **15. Are there any additional extensions for small-scale tobacco product manufacturers?**

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<sup>12</sup> The effective date is May 10, 2018. FDA issued a guidance on May 10, 2017, which, among other things, provided a compliance date of August 10, 2018. See <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf>.

<sup>13</sup> In addition, the agency does not intend to enforce the labeling requirements under sections 903(a)(2) and 920(a) for cigars and pipe tobacco while the injunction remains in effect. See Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco (August 2018).

<sup>14</sup> The effective date for this requirement is May 10, 2017. FDA issued a guidance on May 10, 2017, which, among other things, provided a compliance date of August 10, 2017.

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FDA is including targeted relief to “small-scale tobacco product manufacturers.” For purposes of such relief, FDA considers a “small-scale tobacco product manufacturer” to be 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. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with. To help make FDA’s individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues.

The additional time to comply afforded to the small-scale tobacco product manufacturer included:

- **SE Extension Request** – For the first 30 months following the effective date of the Deeming Rule, FDA presently intends to grant extensions on a case-by-case basis, for SE applicants that need additional time to respond to SE deficiency letters.
- **Tobacco Health Document Submission** – FDA presently intends not to bring enforcement action against small-scale tobacco product manufacturers who submit the required information within 12 months of the effective date of the Deeming Rule.<sup>15</sup>
- **Ingredient Listing Submission** – FDA presently intends not to bring enforcement action against those small-scale tobacco product manufacturers who submit the information required in section 904(a)(1) of the FD&C Act within 12 months of the effective date of the Deeming Rule.<sup>16</sup>

Small-scale tobacco product manufacturers will also benefit from additional assistance, including:

- **Assistance with Marketing Applications** – Like all manufacturers, small-scale tobacco manufacturers will benefit from additional assistance with their marketing applications, including the designation of a Regulatory Health Project Manager, access to an appeals process in the event that FDA denies their marketing applications, and assistance from CTP’s Office of Compliance and Enforcement (OCE) staff with identifying the types of documents that may be used to establish that their products were on the market on February 15, 2007.
- **Assistance in Navigating Other Regulatory Requirements** – Small-scale tobacco product manufacturers may obtain assistance from OCE staff with submission of rotational warning plans for FDA approval. CTP also has an extension system to assist small businesses in navigating the regulatory requirements of FDA. For example, the

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<sup>15</sup> FDA issued a guidance in October 2017, which, among other things, extended the compliance date to November 8, 2017 for small-scale tobacco product manufacturers and to May 8, 2018 for small-scale tobacco product manufacturers in areas impacted by 2017 natural disasters or at least 90 days prior to the delivery for introduction into interstate commerce of the tobacco products to which the health documents relate, whichever is later. See, <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm>.

<sup>16</sup> FDA has previously extended the compliance date for small-scale tobacco product manufacturers. Most recently, FDA issued a revised guidance on November 6, 2018, which extended the compliance date to May 8, 2019 for small-scale tobacco product manufacturers impacted by recent natural disasters. See, <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm>.

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CTP Call Center receives calls received from regulated industry and sends them to the appropriate CTP office.

- **Office of Small Business Assistance (OSBA)**- CTP has established the Office of Small Business Assistance (OSBA), which responds to hundreds of calls, emails, and correspondence from small businesses every year and assists in answering specific questions about the requirements that apply to small businesses and how to comply with the law. OSBA can be reached by email at [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov) or by phone at 1-877-CTP-1373 (1-877-287-1373) Monday – Friday, 9:00 a.m. – 4:00 p.m. EDT.

### **B. Age and Identification Restrictions**

#### **1. Where can I find the regulation containing age and identification restrictions and any explanation?**

The final regulation can be found in chapter 21 of the Code of Federal Regulations, part 1140. In addition, the full preamble to the Deeming Rule, which discusses these restrictions and comments received, can be found in the *Federal Register*.

#### **2. What products are subject to the new age and identification restriction?**

Covered tobacco products are subject to the age and identification requirements that prohibit the sale of the products to people under the age of 18 and require verification of age with photo identification (except for any person over the age of 26). Cigarettes and smokeless tobacco products remain subject to the age and identification requirements (§ 1140.14(a)(1) and (a)(2)).

#### **3. What is a “covered tobacco product”?**

***Covered tobacco product*** means any tobacco product deemed to be subject to the FD&C Act pursuant to § 1100.2 of this chapter (i.e., subchapter K), but excludes any component or part that is not made or derived from tobacco. Covered tobacco products include ENDS, cigars, pipe tobacco, waterpipe tobacco, dissolvable nicotine products, to name a few, as well as parts and components made or derived from tobacco, e.g., an e-cigarette cartridge containing e-liquid made or derived from tobacco.

For example:

- An e-liquid with nicotine made or derived from tobacco is a covered tobacco product.
- A nicotine-free e-liquid that is not made or derived from tobacco is not a covered tobacco product (and not subject to the minimum age and identification requirements and the vending machine restrictions), but it is nevertheless subject to FDA’s tobacco control authorities if it satisfies the definition of “component or part.”

#### **4. How are cigars defined in this regulation?**

The Deeming Rule defines ***cigar*** as 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 (§ 1143.1).

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### **5. How are manufacturers and retailers defined in this regulation?**

**Manufacturer**<sup>17</sup> means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product (§ 1140.3).

**Retailer** means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under part 1140 (§ 1140.3).

### **6. What are the requirements for retailers of newly deemed products?**

In addition to other requirements, retailers may not sell covered tobacco products to anyone under the age of 18. Except for those people over the age of 26, retailers must verify a purchaser's age through photographic identification containing the bearer's date of birth (§ 1140.14(b)).

### **7. Am I required to verify a purchaser's birth date if he or she is older than 26 years of age?**

No, verification is not required for sale to a person over the age of 26 (§ 1140.14(b)).

### **8. Does this regulation change the current age and identification requirements for the sale and distribution of cigarettes and smokeless tobacco?**

No, the current age and identification requirements for the sale and distribution of cigarettes and tobacco remain the same. As before, these products cannot be sold to anyone under the age of 18<sup>18</sup> according to federal law, and verification is necessary for those people 26 years of age and under (§ 1140.14(a)(1) and (a)(2)).

### **9. Can I sell covered tobacco products in vending machines?**

No, with one exception. Covered tobacco products must not be sold with the assistance of any electronic or mechanical device (such as a vending machine) unless it is in a facility where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time (§ 1140.14(b)(3)).

### **10. When do the age and identification restrictions become effective?**

The age and identification requirements took effect on August 8, 2016, which was 90 days after the publication of the Deeming rule.

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<sup>17</sup> For purposes of parts 1140 and 1143, the term *manufacturer* does not include importer. *Importer* is separately defined and means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States (§ 1140.3).

<sup>18</sup> State laws may have a higher minimum age for sale.

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### **C. Health Warning Requirements**

#### **1. Where can I find information about the new health warning requirements?**

The health warning requirements are codified in Title 21 of the Code of Federal Regulations, part 1143. You can also find additional information about the required warnings in the preamble to the Deeming Rule. The preamble can be found in the *Federal Register* or at CTP's Deeming Rule webpage:

<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm388395.htm>.

#### **2. What products are subject to the new health warning requirements?**

The new warning label requirements apply to all covered tobacco products<sup>19</sup> as well as cigarette tobacco and RYO tobacco. The warning label requirements for all covered tobacco products (except cigars), cigarette tobacco, and RYO tobacco are codified in § 1143.3 and the warning label requirements for cigars are codified in § 1143.5.

#### **3. Who must comply with the health warning requirements?**

*Manufacturers, distributors, importers, and certain retailers* of cigarette tobacco, RYO tobacco, or covered tobacco products must comply with the health warning requirements on packages and advertisements for sale or distribution of these products in the United States. For purposes of the Deeming Rule, the terms manufacturer, distributor, importer, and retailer are defined as follows:

***Manufacturer*** means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product.

***Distributor*** means any person who furthers the distribution of tobacco products at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of part 1140.

***Importer*** means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States.

***Retailer*** means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under part 1140.

For example, if you make cigars, you are a manufacturer under these regulations. You are also a manufacturer, however, if you obtain cigars originally made by another manufacturer, remove them from the original manufacturer's packaging (if any), and repackage or relabel them for sale

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<sup>19</sup> As defined above, the term *covered tobacco product* means any tobacco product deemed to be subject to the FD&C Act pursuant to § 1100.2, but excludes any component or part of a tobacco product that is not made or derived from tobacco.

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under another name — even though you did not roll the cigars themselves. As a second example, if you own a trucking firm and are contracted to transport cigars from a warehouse to a retailer (only), you are a common carrier, not a distributor, for the purposes of the Deeming Rule (§ 1140.3).

### **4. Do the warning requirements apply to small businesses that meet the definition of manufacturer, distributor, importer, or retailer?**

The required warning statement(s) must be on all covered tobacco products, cigarette tobacco, and RYO tobacco packages and advertisements, regardless of who manufacturers, distributes, imports, sells, or offers to sell the product.

### **5. What are the consequences if a product is found to not be in compliance with the health warning requirements?**

Covered tobacco products, cigarette tobacco, and RYO tobacco packages that are not in compliance with the health warning provisions are misbranded under section 903(a)(7)(B) of the FD&C Act (21 U.S.C. 387c(a)(7)(b)). Sale or distribution in interstate commerce of misbranded tobacco products may result in warning letters, criminal prosecution, civil money penalties, injunction, seizure, and/or no-tobacco-sale orders.

### **6. Are retailers subject to enforcement if they sell a product in packaging that does not comply with the health warning requirements?**

A retailer will not be in violation of the Deeming Rule for the sale of covered tobacco products, cigarette tobacco, or RYO tobacco, where the packaging:

1. Contains a health warning.
2. Is supplied by a license- or permit-holding tobacco product 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.
3. Is not altered by the retailer in a way that is material to the requirements of these sections.

(§§ 1143.3(a)(3) and 1143.5(a)(4).))

### **7. Are retailers subject to enforcement if they display an advertisement that does not comply with the health warning requirements?**

Requirements relating to health warnings on advertisements only apply to a retailer if the retailer is responsible for or directs the warning statement. However, this does not relieve the retailer of liability if the retailer publicly displays an advertisement for a covered tobacco product, cigarette tobacco, or RYO tobacco that does not contain a health warning, or if the retailer alters the

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warning on the advertisement in a manner that is material to the health warning requirements (for example, if the retailer tears the warning off a printed advertisement) (§§ 1143.3(b)(3) and 1143.5(b)(3)).

### **8. Can FDA enforce the health warning requirements against other entities, aside from the retailer?**

Yes. Whether or not the above exceptions for retailers apply, FDA can enforce the health warning provisions against the manufacturer, importer, or distributor of the product, and, potentially, the product itself (e.g., through seizure).

### **9. When does this part of the Deeming Rule become effective?**

The health warning requirements will become effective 24 months after final publication of the Deeming Rule (“the new warning date”) (§ 1143.13).<sup>20</sup> As stated above, On July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 §§ CFR 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs’ appeal in the case: *Cigar Ass’n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass’n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted.

### **10. After the effective date for the health warnings, can manufacturers continue to sell and distribute their remaining stock of covered tobacco products, cigarette tobacco, and RYO tobacco if the packaging does not comply with the health warning requirements?**

Yes, for 30 days after the effective date only,<sup>21</sup> manufacturers may continue to introduce into interstate commerce covered tobacco products, cigarette tobacco, and RYO tobacco manufactured before the effective date of the new warning requirements with packaging that do not comply with the new health warning requirements. This sell-off period only applies to products manufactured before the effective date of the new warning requirements (§ 1143.13). As stated above, On July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 §§ CFR 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs’ appeal in the case: *Cigar Ass’n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass’n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted.

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<sup>20</sup> The effective date is May 10, 2018. FDA issued a guidance on May 10, 2017, which, among other things, provided a compliance date of August 10, 2018. See <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf>.

<sup>21</sup> See note above.



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### **11. After the effective date for the health warnings, can distributors and retailers sell-off their remaining stock of covered tobacco products, cigarette tobacco, and RYO tobacco if the packaging does not comply with the new health warning requirements?**

Yes. Distributors and retailers may continue to sell and distribute the tobacco product packages after the effective date,<sup>22</sup> but only if the products were manufactured before the effective date of the new required warning statement for covered tobacco products, cigarette tobacco, and RYO tobacco. As stated above, On July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 §§ CFR 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted.

### **12. When must I submit my cigar warning plan to FDA?**

Warning plans should be submitted to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later (§ 1143.5(c)(3)). On May 10, 2017, FDA issued a guidance, which, among other things, provided a compliance date of August 10, 2017 for the warning plan requirement. Therefore, warning plans for tobacco products on the market as of August 8, 2016 that are subject to these requirements were expected to be submitted to FDA by August 10, 2017. This will provide industry with sufficient time to submit proposed warning plans to FDA for review and approval.

The warning plans should describe the random display of the warning statements required for packaging, the random distribution of the products in areas of the United States where the product is marketed, and the quarterly rotation of the warnings on advertisements for each brand of cigar (§ 1143.5). FDA intends to work with the responsible manufacturer, importer, distributor, or retailer to ensure warning plans contain sufficient information required for approval.

Cigar manufacturers, importers, distributors, and affected retailers may wish to contact FDA for assistance or questions regarding warning plan submission requirements. FDA may be contacted at 1-877-CTP-1373 or at the following address:

Food and Drug Administration  
Center for Tobacco Products  
Office of Compliance and Enforcement  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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<sup>22</sup> See note above.

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### **13. What if my tobacco product does not contain nicotine?**

A tobacco product that does not contain nicotine<sup>23</sup> is not required to bear the addictiveness warning if the manufacturer submits to FDA a statement certifying that the tobacco product does not contain nicotine and that the tobacco product manufacturer has data to support that assertion (§ 1143.3(c)). These products are required to bear the alternative statement “This product is made from tobacco” on all packages and advertisements in place of the addictiveness warning (§ 1143.3(c)). FDA may be contacted at 1-877-CTP-1373 or at the following address:

Food and Drug Administration  
Center for Tobacco Products  
Office of Compliance and Enforcement  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

### **14. In what language must the required warnings appear on covered tobacco products (including cigars), cigarette tobacco, and RYO tobacco packages and advertisements?**

The required warning statement must be in the English language on all covered tobacco products, cigarette tobacco, and RYO tobacco packages. The required warning statement also must be in English in all covered tobacco product advertisements except in the following cases:

1. If an advertisement appears in a foreign language publication (e.g., newspaper, magazine, periodical), the required warning statement must be in the predominant language of the publication, even if the advertisement is presented in a different language. The predominant language is the primary language used in the content in the publication (e.g., stories or articles featured in newspapers, magazines, periodicals).
2. If an advertisement appears in an English language publication, but the advertisement is not presented in English, the textual portion of the required warning must be presented in the language principally used in the advertisement.

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<sup>23</sup> As stated in footnote 3, components or parts that are not made or derived from tobacco do not meet the definition of “covered tobacco product,” and would not be required to carry an addiction warning or submit a self-certification.

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**Table A. Compliance With Various Automatic Provisions**

<b>FD&amp;C Act Citation</b>	<b>Provision</b>	<b>Compliance Upon Effective Date</b>
902(1)-(5), (8)	<p>A tobacco product shall be deemed to be adulterated if--</p> <p>(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;</p> <p>(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;</p> <p>(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;</p> <p>(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 919 by the date specified in section 919 or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;</p> <p>(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;</p> <p style="text-align: center;">* * *</p> <p>(8) it is in violation of section 911.</p>	Effective date of part 1100
903(a)(1)	<p>(a) In General- A tobacco product shall be deemed to be misbranded--</p> <p>(1) if its labeling is false or misleading in any particular;</p>	Effective date of part 1100
903(a)(6), (7)	<p>(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;</p>	Effective date of part 1100

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<b>FD&amp;C Act Citation</b>	<b>Provision</b>	<b>Compliance Upon Effective Date</b>
	(7) if, in the case of any tobacco product distributed or offered for sale in any State-- (A) its advertising is false or misleading in any particular; or (B) it is sold or distributed in violation of regulations prescribed under section 906(d);	
904(c)(2), (3)	(2) DISCLOSURE OF ADDITIVE- If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing. (3) DISCLOSURE OF OTHER ACTIONS- If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.	Effective date of part 1100
905(i)(3)	(3) BIENNIAL REPORT OF ANY CHANGE IN PRODUCT LIST- Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following: (A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1). (B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance,	Effective date of part 1100

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<b>FD&amp;C Act Citation</b>	<b>Provision</b>	<b>Compliance Upon Effective Date</b>
	<p>the date of such discontinuance, and the identity of its established name.</p> <p>(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.</p> <p>(D) Any material change in any information previously submitted under this paragraph or paragraph (1).</p>	
<p>911(a), 911(b)</p> <p>[with the exception of products sold or distributed using the descriptors set forth in 911(b)(2)(A)(ii)]</p>	<p><b>MODIFIED RISK TOBACCO PRODUCTS</b></p> <p>(a) In General- No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.</p> <p>(b) Definitions- In this section:</p> <p>(1) <b>MODIFIED RISK TOBACCO PRODUCT-</b> The term `modified risk tobacco product' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.</p> <p>(2) <b>SOLD OR DISTRIBUTED-</b></p> <p>(A) <b>IN GENERAL-</b> With respect to a tobacco product, the term `sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' means a tobacco product--</p> <p>(i) the label, labeling, or advertising of which represents explicitly or implicitly that--</p> <p>(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;</p>	<p>Effective date of part 1100</p>

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	<p>(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or</p> <p>(III) the tobacco product or its smoke does not contain or is free of a substance;</p> <p>***</p> <p>(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.</p>	
919(a)	919(a) Establishment of Quarterly Fee- Beginning on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this chapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).	See FDA's final rule revising the current user fee regulations published concurrently with the Deeming Rule.

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**Table B. Compliance Periods for Other Provisions**

FD&C Act Citation	Provision	Compliance Period <sup>24</sup>
903(a)(2)	A tobacco product shall be deemed misbranded if in package form unless it bears a label containing-- (A) the name and place of business of the tobacco product manufacturer, packer, or distributor; (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; (C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and (D) the statement required under section 920(a), except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.	24 months after the publication of this final regulation
903(a)(3)	A tobacco product is misbranded--if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.	Effective date of part 1100 PLUS 1 year
903(a)(4)	A tobacco product is misbranded--(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation.	24 months after the publication of this final regulation
903(a)(8)	A tobacco product is misbranded--(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product--(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently;	24 months after the publication of this final regulation

<sup>24</sup> For information on any revised or updated compliance periods, please refer to the document, Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Newly Deeming Tobacco Products, <https://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM501016.pdf>

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<b>FD&amp;C Act Citation</b>	<b>Provision</b>	<b>Compliance Period<sup>24</sup></b>
	<p>and (B) a brief statement of--(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and (ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.</p>	
<p>904(a)(1) and 904(c)(1)</p>	<p>(a)(1) REQUIREMENT.--Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information: (1) Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.</p> <p>-----</p> <p>(c) TIME FOR SUBMISSION.--</p> <p>(1) IN GENERAL.--At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).</p>	<p>Effective date of part 1100 PLUS 6 months (products on the market as of the effective date) or 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date).</p>
<p>904(a)(3)</p>	<p>REQUIREMENT.--Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information: (3) Beginning 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand.</p> <p>-----</p> <p>(c) TIME FOR SUBMISSION.--</p>	<p>Effective date of part 1100 PLUS 3 years or, for products delivered for introduction into interstate commerce later than 3 years after the effective date, 90 days before delivery for introduction into</p>



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<b>FD&amp;C Act Citation</b>	<b>Provision</b>	<b>Compliance Period<sup>24</sup></b>
	(1) IN GENERAL.--At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).	interstate commerce (products entering the market after the effective date).
904(a)(4)	REQUIREMENT.--Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information: (4) Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.	Effective date of part 1100 PLUS 6 months
905(b), (c), (d), and (h)	<p>905(b)--REGISTRATION BY OWNERS AND OPERATORS.--On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. If enactment of the Family Smoking Prevention and Tobacco Control Act occurs in the second half of the calendar year, the Secretary shall designate a date no later than 6 months into the subsequent calendar year by which registration under this subsection shall occur.</p> <p>905(c)--REGISTRATION BY NEW OWNERS AND OPERATORS.--Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall</p>	If the final rule publishes in the second half of the calendar year, FDA intends to issue a compliance policy with a compliance period for registration that is no later than 6 months into the subsequent calendar year.

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<b>FD&amp;C Act Citation</b>	<b>Provision</b>	<b>Compliance Period<sup>24</sup></b>
	<p>immediately register with the Secretary that person's name, place of business, and such establishment.</p> <p>905(d)--REGISTRATION OF ADDED ESTABLISHMENTS.--Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco.</p>	
905(i)(1)	<p>PRODUCT LIST.--Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by--</p> <p>(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;</p> <p>(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and</p> <p>(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the</p>	Same compliance period as that for initial registration, see date specified for 905(b).

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FD&C Act Citation	Provision	Compliance Period <sup>24</sup>
	Secretary requests such a statement with respect to that particular tobacco product.	
907(a)(1)(B)	(B) ADDITIONAL SPECIAL RULE.--Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.	Effective date of part 1100 PLUS 2 years
911(b)(2)(A)(ii)	<p>911(a)--IN GENERAL.--No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued under subsection (g) is effective with respect to such product.</p> <p>911(b)(1)--MODIFIED RISK TOBACCO PRODUCT.--The term 'modified risk tobacco product' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.</p> <p>(2) SOLD OR DISTRIBUTED.--</p> <p>(A) IN GENERAL.--With respect to a tobacco product, the term 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' means a tobacco product--</p> <p>* * *</p> <p>(ii) the label, labeling, or advertising of which uses the descriptors light, mild, or low or similar descriptors; or</p> <p>* * *</p> <p>(3) EFFECTIVE DATE.--The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act for those products whose label, labeling, or advertising contains the terms described in such paragraph on such date of enactment. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any</p>	Use of “light,” “low,” and “mild” descriptors: Effective date of part 1100 PLUS 1 year (stop manufacture); Effective date of part 1100 PLUS 13 months (stop distribution)

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FD&C Act Citation	Provision	Compliance Period <sup>24</sup>
	product, irrespective of the date of manufacture, that is not in conformance with paragraph (2)(A)(ii).	
920(a)(1)	(1) REQUIREMENT.--Beginning 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of tobacco products other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'Sale only allowed in the United States.'	24 months after the publication of this final regulation

**DOCUMENT HISTORY**

**May 2016** — First edition of guidance issued.

**December 2016** — Clarifying and corrective edits made throughout the document. Information regarding prohibition on free samples added.

**August 2018** — Section III.A.10 and A.15 are revised to reflect changes to certain compliance dates, including the premarket review compliance policy for deemed products on the market as of August 8, 2016. Section III.A.14 and C.9-11 of guidance are revised to reflect a stay of enforcement of the warning requirements for cigars and pipe tobacco (21 CFR §§ 1143.3 and 1143.5) after the United States District Court for the District of Columbia granted plaintiffs' motion for an injunction pending appeal. *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal) as well as FDA's intention to not enforce the requirements under sections 903(a)(2) and 920(a) of the FD&C Act for cigars and pipe tobacco while the injunction remains in effect.

— Clarifying and corrective edits made throughout the document.

**November 2018** — Revised compliance date for "Ingredient listing" to provide a six-month extension for small-scale tobacco product manufacturers and importers impacted by recent natural disasters.