Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Newly Deemed Tobacco Products

Quick Facts

- Retailers that mix and prepare e-liquids or create or modify vaporizers will be regulated as both retailers and manufacturers.
- Importers of tobacco products must ensure that the tobacco products they import are in compliance with the law.

The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On May 10, 2016, FDA issued a final rule extending its tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), including electronic nicotine delivery systems (ENDS)—such as e-cigarettes and vape pens—all cigars, hookah (waterpipe) tobacco, pipe tobacco, nicotine gels, and certain dissolvables.

On the following chart, we have identified the primary party for complying with the requirements. However, we note that failure to comply with these requirements may render a tobacco product adulterated, misbranded, or both, and it is unlawful for any entity to sell or distribute an adulterated and/or misbranded product in interstate commerce.

Regulations to Prevent Youth Access to Tobacco Products (Found at 21 CFR 1140)

Certain provisions of the deeming regulation only apply to "covered tobacco products."

A "covered tobacco product" is any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to §1100.2, but excludes any component or part that is not made or derived from tobacco. Examples include: e-cigarettes, e-liquid, cigars, hookah (waterpipe) tobacco, pipe tobacco, and dissolvables. Examples of components or parts that are not covered tobacco products include: a pipe or an ENDS atomizer sold without liquid nicotine.

Provision	Newly Deemed Products	Effective Date	Retailers	Manufacturers	Importers	Distributors
Only sell to customers age 18 or older and check photo ID of everyone under age 27	All covered tobacco products	August 8, 2016	X			
Do not give away free samples	All	August 8, 2016	X	X	X	X
Do not sell products in a vending machine Vending machine sales are allowed if in a facility where those under 18 years of age are neither present nor permitted at any time	All covered tobacco products	August 8, 2016	X			

Required Warning Statements

Provision	Newly Deemed Products	Effective Date	Retailers	Manufacturers	Importers	Distributors
Product packages and ads must contain the addictiveness warning statement • "WARNING: This product contains nicotine. Nicotine is an addictive chemical." • The warning must follow size and format requirements	Cigarette tobacco, roll-your-own tobacco, and covered tobacco products (other than cigars and those covered tobacco products that do not contain nicotine)	Manufacturers, importers, distributors, and retailers who direct their own advertising: Advertisements must bear the addictiveness warning beginning August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages beginning August 10, 2018, and cannot distribute such products beginning Setpember 11, 2018, irrespective of the date of manufacture Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages beginning August 10, 2018, unless the retailer falls within the retailer safe harbor[1]	X	X	X	X
Product packages and ads of covered tobacco products <u>that do not contain nicotine</u> may bear an alternative warning statement: • "This product is made from tobacco." • Manufacturers must submit to FDA a self-certification • For more information, visit FDA.gov and search for "extending authorities"	Covered tobacco products that do not contain nicotine	Manufacturers, importers, distributors, and retailers who direct their own advertising: Advertisements must bear the alternative warning beginning August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages beginning August 10, 2018, and cannot distribute such products beginning Setpember 11, 2018, irrespective of the date of manufacture Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages beginning August 10, 2018, unless the retailer falls within the safe harbor[2]	X	X	X	X

1. A retailer of any cigarette tobacco, roll-your-own tobacco, or covered tobacco products (other than cigars) will not be in violation of this section for packaging that: (i) Contains a health warning; (ii) 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; and (iii) Is not altered by the retailer in a way that is material to the requirements of this section.
2. A retailer of any covered tobacco products that do not contain nicotine and may bear the alternative warning statement will not be in violation of this section for packaging that: (i) Contains a health warning; (ii) 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; and (iii) Is not altered by the retailer in a way that is material to the requirements of this section.

Required Warning Statements (Continued)

Provision	Newly Deemed Products	Effective Date	Retailers	Manufacturers	Importers	Distributors
Rotational cigar warning statements on product packages and ads • Cigar product packages and ads must contain warnings that follow size format, rotational, and distribution requirements • For cigars sold individually without product packaging, retailers post the warnings at the point-of-sale instead of directly on the product packages • For more information, visit FDA.gov and search for "extending authorities"	Cigars	Manufacturers, importers, distributors, and retailers who direct their own advertising: Advertisements must bear one of the required warnings beginning August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages beginning August 10, 2018, and cannot distribute such products beginning Setpember 11, 2018, irrespective of the date of manufacture Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages beginning August 10, 2018, unless the retailer falls within the safe harbor[3]	X	X	X	X
Point-of-sale warning statement requirement for cigars sold individually without packaging • Specific placement and formatting requirements • Sign must bear all six required warnings • For more information, visit FDA.gov and search for "extending authorities"	Cigars sold individually without packaging	August 10, 2018	X			
Cigar warning plans on how warnings will be randomly displayed and distributed on packages and rotated on advertisements must be submitted to and approved by FDA For more information, visit FDA.gov and search for "extending authorities"	Cigars	Warning plans must be submitted by August 10, 2017	X[4]	X	X	X

3. A cigar retailer will not be in violation of this section for packaging that: (i) Contains a health warning; (ii) 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; and (iii) Is not altered by the retailer in a way that is material to the requirements of this section.
4. This applies to retailers that materially alter the health warning supplied by a tobacco product manufacturer, importer, or distributor. It also applies to retailers who direct their own advertisements for the tobacco product.

Premarket Review Requirements

Finished Tobacco Product – A tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits). Note that this definition is different from "covered tobacco product."

New, newly deemed tobacco products are subject to the premarket review requirements of the FD&C Act. For such newly deemed products that were on the market as of August 8, 2016, FDA is providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted by the applicable compliance date identified below will be subject to a continued compliance period for 12 months after the initial compliance period. Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement. Products entering the market after August 8, 2016, are not covered by the foregoing compliance policy and will be subject to enforcement if marketed without authorization after August 8, 2016.

Compliance Period	Newly Deemed Products	Compliance Date	Retailers	Manufacturers	Importers	Distributors
Compliance period for manufacturers to submit a substantial equivalence exemption request For more information, visit FDA.gov and search for "substantial equivalence"	New,[5] newly deemed finished tobacco products[6] that were on the market as of August 8, 2016	November 8, 2017		X	X	
Compliance period for manufacturers to submit a substantial equivalence application For more information, visit FDA.gov and search for "substantial equivalence"	New, newly deemed finished tobacco products[7] that were on the market as of August 8, 2016	May 8, 2018		X	X	
Compliance period for manufacturers to submit a premarket tobacco product application For more information, visit FDA.gov and search for "premarket tobacco product applications"	New, newly deemed finished tobacco products[8] that were on the market as of August 8, 2016	November 8, 2018		X	X	

5. A "new tobacco product" is any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or 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.
6. Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the premarket authorization requirements to newly regulated finished tobacco products at this time.
7. Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the premarket authorization requirements to newly regulated finished tobacco products at this time.
8. Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the premarket authorization requirements to newly regulated finished tobacco products at this time.

Other Provisions

Provision	Newly Deemed Products	Effective/Compliance Date	Retailers	Manufacturers	Importers	Distributors
Cigar and pipe tobacco user fees • Data must be reported to calculate fees and payments must be made • For more information, visit FDA.gov and search for "tobacco user fees"	Cigars and pipe tobacco	Domestic manufacturers and importers of cigars and pipe tobacco must report data no later than August 20, 2016		X	X	
Registration of establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product and product listings	Finished tobacco products[9]	For entities engaged in the manufacture, preparation, compounding, or processing of tobacco products in the United States prior to August 8, 2016, and continuing operations after August 8, 2016: September 30, 2017 For entities first engaging in the manufacture, preparation, compounding, or processing of tobacco products in the United States on or after August 8, 2016: **Immediately upon first engaging in the manufacturing of a tobacco product**		X	X[10]	
Ingredient listing For more information, visit FDA.gov and search for "tobacco ingredients"	Finished tobacco products[11]	For products on the market on August 8, 2016: **November 8, 2017**, or **May 8, 2018**, for small-scale tobacco product manufacturers[12] For products entering the market after **August 8, 2016:** 90 days prior to marketing		X	X	

9. Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the registration and product listing requirements to newly regulated finished tobacco products at this time.
10. Only to the extent the importer repackages or otherwise changes the container, wrapper, or labeling of any tobacco product package.
11. Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the ingredient listing requirements to newly regulated finished tobacco products at this time.
12. FDA considers "small-scale tobacco product manufacturers" to be a manufacturer of any regulated tobacco product with 150 employees or fewer and annual total revenues of $5,000,000 or less.

Other Provisions (Continued)

Provision	Newly Deemed Products	Effective/Compliance Date	Retailers	Manufacturers	Importers	Distributors
Harmful and potentially harmful constituents (HPHCs) For more information, visit FDA.gov and search for "HPHC"	Finished tobacco products[13]	November 8, 2019 or For products entering the market after November 8, 2019: 90 days prior to marketing		X	X	
Tobacco health documents For more information, visit FDA.gov and search for "tobacco health documents"	Finished tobacco products[14]	February 8, 2017 or November 8, 2017, for small-scale tobacco product manufacturers[15]		X	X	
Prohibition on the introduction into interstate commerce of products that contain "light," "low," "mild," or other similar descriptors in the label, labeling, or advertising of such products without a modified risk tobacco product order in effect For more information, visit FDA.gov and search for "modified risk"	All	Stop manufacturing: November 8, 2017 Stop distribution into interstate commerce: December 8, 2017	X	X	X	X
Prohibition on the introduction into interstate commerce of modified risk tobacco products (other than those described above) without a modified risk tobacco product order in effect For more information, visit FDA.gov and search for "modified risk"	All	August 8, 2016	X	X	X	X

13. Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the HPHC reporting requirements to newly regulated finished tobacco products at this time.
14. Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the tobacco health document submission requirements to newly regulated finished tobacco products at this time.
15. FDA considers "small-scale tobacco product manufacturers" to be a manufacturer of any regulated tobacco product with 150 employees or fewer and annual total revenues of $5,000,000 or less.

Other Provisions (Continued)

Provision	Newly Deemed Products	Effective/Compliance Date	Retailers	Manufacturers	Importers	Distributors
Tobacco products will be considered misbranded unless they bear a label containing the following information: • The name and place of business • Quantity of the contents • Percentage of domestic and foreign-grown tobacco[16] • The statement: "Sale only allowed in the United States" on labels, packaging, and shipping containers of tobacco products	All products in package form	August 10, 2018		X	X	
All required label and labeling statements must be prominent and in such terms that render it likely to be read and understood	All	November 8, 2017		X	X	

16. In the draft guidance, entitled *Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops*, FDA indicated that it intends to use enforcement discretion regarding section 903(a)(2)(C) of the FD&C Act for those products that are made or derived from tobacco. When the guidance is finalized it will represent FDA's current thinking on the issues contained within.

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