Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule

Guidance for Industry (Revised)*

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 FDA-2017- D-2834.

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/Labeling/RulesRegulationsGuidance/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

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

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* This is the fourth edition of this guidance, which originally issued in May 2017. Revisions are noted by date at the end of the guidance.

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Guidance for Industry[1]

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 guidance document is intended to assist any person who manufactures, packages, sells, offers to sell, distributes, or imports for sale and distribution within the United States newly regulated tobacco products, roll-your-own tobacco, and cigarette tobacco. This guidance document discusses:

- FDA's extension of future compliance deadlines for certain provisions under the May 2016 final Deeming rule.[2]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance was prepared by the Office of Regulations and the Office of Compliance and Enforcement in the Center for Tobacco Products at FDA.

[2] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016).

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (section 901(b) of the FD&C Act).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of a tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority. This included electronic nicotine delivery systems (ENDS), cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28976).

Chapter IX of the FD&C Act now applies to newly regulated products, including sections 904(a)(1) and (4) (ingredient listing and health document submissions), 903(a)(4) and 903(a)(8) (labeling requirements), 904(c)(1) (timing of submissions), 905(b), (c), (d), and (h) (establishment registration), 905(i)(1) (product listing), 907(a)(1)(B) (additional special rules), 911 (modified risk claims), 904(a)(3) and 915 (harmful and potentially harmful constituent reporting), 920 (labeling, recordkeeping, and records inspection), and 905 and 910 (premarket review requirements). The final rule also included several requirements that apply to a subgroup of products referred to "covered tobacco products."[3]

In May 2017, FDA published the first edition of this guidance document, under which it provided a three-month extension of all future compliance deadlines for requirements under the final deeming rule. The May 2017 guidance applied to all categories of newly regulated products, including ENDS (e.g., e-cigarettes and e-cigars), hookah, pipe tobacco, and cigars, as well as the addictiveness warning requirement for RYO and cigarette tobacco. The guidance noted that the three-month extension did not apply to requirements under the final deeming rule where compliance deadlines already had passed, such as mandatory age and photo-ID checks to prevent illegal sales to minors. It explained that FDA would continue to enforce such requirements.

[3] The final deeming rule defines covered tobacco product to include any tobacco product deemed to be subject to Chapter IX of the FD&C Act under 21 C.F.R. 1100.2, but "excludes any component or part that is not made or derived from tobacco" (21 C.F.R. § 1140.3).

III. DISCUSSION

A. FDA's Extension of Certain Future Compliance Deadlines Related to the Final Deeming Rule

FDA is providing a further extension of certain future compliance deadlines for requirements under the final deeming rule. This further extension applies only to compliance deadlines relating to premarket review requirements, specifically for substantial equivalence exemption requests (SE EX requests), substantial equivalence reports (SE reports), and premarket tobacco product applications (PMTAs). No compliance deadlines relating to other provisions in the final deeming rule are being further extended, either those that have already passed and are being enforced, or those scheduled for a future date that were extended in the May 2017 guidance.

The further extension of premarket review compliance deadlines covered by this guidance applies to all categories of newly regulated products that were on the market on August 8, 2016, including ENDS (e.g. e-cigarettes and e-cigars), hookah, pipe tobacco, and cigars. The compliance dates are being extended from November 8, 2017 (SE EX requests), May 8, 2018 (SE reports), and November 8, 2018 (PMTAs) to August 8, 2021 (SE EX requests, SE reports, and PMTAs for newly regulated combustible tobacco products, such as most cigars, pipe tobacco and hookah tobacco) and August 8, 2022 (SE EX requests, SE reports, and PMTAs for newly regulated noncombustible tobacco products, such as most ENDS or e-cigarettes). These new compliance dates are reflected in the chart in Section III.B., along with the compliance dates from the May 2017 guidance that are not being further extended.

The preamble to the May 10, 2016, final deeming rule explained that FDA was providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. It explained that under the latter compliance period:

> Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period.

81 Fed. Reg. 29,011 (May 10, 2016). The preamble further explained that this compliance policy did not apply to any new tobacco product that was not on the market on August 8, 2016. *Id*. FDA is revising the compliance policy relating to the period after FDA receipt of SE EX requests, SE reports, and PMTAs for newly regulated products that were on the market on August 8, 2016. Under this new compliance policy, there will be a continued compliance period pending review of those applications (SE EX requests, SE reports, and PMTAs). This compliance period will 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. The chart in Section III.B has been revised from the first edition of this guidance, issued in May 2017, to reflect this revised compliance policy.

For purposes of this guidance, FDA is using "future compliance deadlines" to refer to dates in the future on which it intends to begin enforcement of certain requirements under the deeming rule. Such dates include both (1) the effective date a particular requirement will become effective as a matter of law (e.g., the effective date for the health warning requirements in 21 C.F.R. part 1143) or (2) a compliance date that FDA has set as a matter of enforcement discretion, stating that it does not intend to enforce a particular requirement that is already in effect for a period of time in order to give industry more time to comply (e.g., compliance dates for various provisions of the FD&C Act set forth in the preamble to the final deeming rule, see 81 FR 29006).

This guidance revises and updates the first edition of this guidance, issued in May 2017. As with the May 2017 guidance, the compliance dates announced in this guidance supersede the compliance dates included in any other guidance issued prior to this guidance.

B. Compliance Dates

The compliance dates for requirements under the final deeming rule are detailed in the following chart. Requirements under the final deeming rule where compliance deadlines have already passed are not affected by this guidance and are not listed on the chart.

Required Warning Statements

Provision	Products Affected	Requirement and Compliance Date Under This Guidance
Product packages and ads must contain the addictiveness warning statement (21 C.F.R. § 1143.3(a) and (b)) • "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 August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages August 10, 2018 Manufacturers cannot distribute such products irrespective of the date of manufacture September 11, 2018 Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages unless the retailer falls within the retailer safe harbor[4] August 10, 2018
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 August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages August 10, 2018 Manufacturers cannot distribute such products irrespective of the date of manufacture September 11, 2018

[4] 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. 21 C.F.R §1143(a)(3)(ii).

		Retailers cannot offer for sale, sell, distribute, or import products with non- compliant packages unless the retailer falls within the safe harbor[5] August 10, 2018
Rotational cigar warning statements on product packages and ads (21 C.F.R. § 1143.5) • Cigar product packages and ads must contain warnings that follow size format, rotational, and distribution requirements • 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 August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages August 10, 2018 Manufacturers cannot distribute such products beginning irrespective of the date of manufacture September 11, 2018 Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages unless the retailer falls within the safe harbor[6] August 10, 2018

[5] 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.

[6] 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.

Point-of-sale warning statement requirement for cigars sold individually without packaging (21 C.F.R. § 1143.5(a)(3)) • 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
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 (21 C.F.R. § 1143.5(c)(1)) For more information, visit FDA.gov and search for "extending authorities"	Cigars	August 10, 2017

Premarket Review Requirements

Compliance Period	Products Affected	Compliance Date Under this Guidance
Compliance period for manufacturers to submit a substantial equivalence exemption request (§910 of the FD&C Act) For more information, visit FDA.gov and search for "substantial equivalence"	New,[7] newly deemed finished tobacco products[8 9] that were on the market as of August 8, 2016	August 8, 2021 (combustible tobacco products) August 8, 2022 (noncombustible tobacco products)
Compliance period for manufacturers to submit a substantial equivalence report (§910 of the FD&C Act) For more information, visit FDA.gov and search for "substantial equivalence"	New, newly deemed finished tobacco products[10] that were on the market as of August 8, 2016	August 8, 2021 (combustible tobacco products) August 8, 2022 (noncombustible tobacco products)
Compliance period for manufacturers to submit a premarket tobacco product application (PMTA) (§905 of the FD&C Act) For more information, visit FDA.gov and search for "premarket tobacco product applications"	New, newly deemed finished tobacco products[11] that were on the market as of August 8, 2016	August 8, 2021 (combustible tobacco products) August 8, 2022 (noncombustible tobacco products)

7 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. §910(a)(1) of the FD&C Act.

8 FDA has defined "finished tobacco product" as 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).

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 premarket authorization requirements to newly regulated finished tobacco products at this time.

10 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.

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 premarket authorization requirements to newly regulated finished tobacco products at this time.

Other Provisions

Provision	Products Affected	Compliance Date Under this Guidance
Registration of establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product and product listings (§905(b), (c), (d), (h), and (i)(1) of the FD&C Act)	Newly deemed finished tobacco products[12]	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: October 12, 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**
Ingredient listing (§904(a)(1) of the FD&C Act) For more information, visit FDA.gov and search for "tobacco ingredients"	Newly deemed finished tobacco products[13]	For products on the market on August 8, 2016: **May 8, 2018,** or **November 8, 2018** for small-scale tobacco product manufacturers[14] For products entering the market after **August 8, 2016:** 90 days prior to marketing

[12] 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.

[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 ingredient listing requirements to newly regulated finished tobacco products at this time.

[14] 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.

[15] These compliance dates apply to all firms regardless of whether the manufacturer or importer is in an area impacted by recent natural disasters, as described in the October 2017 edition of this guidance.

Other Provisions (Continued)

Provision	Products Affected	Compliance Date Under this Guidance
Harmful and potentially harmful constituents (HPHCs) (§904 and 915 of the FD&C Act) For more information, visit FDA.gov and search for "HPHC"	Newly deemed finished tobacco products[16]	November 8, 2019 or For products entering the market after November 8, 2019: 90 days prior to marketing
Tobacco health documents (§904(a)(1) and (4) of the FD&C Act) For more information, visit FDA.gov and search for "tobacco health documents"	Newly deemed finished tobacco products[17]	November 8, 2017, for small-scale tobacco product manufacturers[18] or May 8, 2018, for small-scale tobacco product manufacturers in areas impacted by recent natural disasters[19]
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 (§911 of the FD&C Act) For more information, visit FDA.gov and search for "modified risk"	All newly deemed tobacco products	Stop manufacturing: November 8, 2017 Stop distribution into interstate commerce: December 8, 2017

[16] 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.

[17] 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.

[18] 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. The compliance deadline for submission of tobacco health documents for entities other than small-scale tobacco product manufacturers has already passed (February 8, 2017) and is not affected by the extension announced in this guidance.

[19] For a complete list complete list of the areas that have been impacted by recent natural disasters, please visit https://www.fda.gov/TobaccoProducts/NewsEvents/ucm579265.htm.

Tobacco products will be considered foreign-grown tobacco[20]	All newly deemed tobacco	August 10, 2018
All required label and labeling statements must be prominent and in such terms that render it likely to be read and understood (§903(a)(3) of the FD&C Act)	All newly deemed tobacco products	November 8, 2017

[20] FDA issued a Draft Guidance titled "Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Food, Drug, and Cosmetic Act Requirements to Vape Shops," which included a proposed compliance policy relating this requirement (pp. 5-6). This compliance policy would apply to all tobacco products.

DOCUMENT HISTORY

May 2017 – First edition of guidance issued.

August 2017 – *Three-Month Extension of Certain Compliance Deadlines Related to the Final Deeming Rule* is revised to reflect changes to premarket review compliance policy related to "deemed" tobacco products. Specific revisions include the following:

- Title – Removal of "Three-Month" to reflect the inclusion of extended compliance deadlines for premarket review policy.
- Section II – Added explanation of extension of compliance policies included in May 2017 first edition of guidance.
- Section III.A – Added explanation of previous premarket review compliance policy and summary of revised premarket review compliance policy for deemed tobacco products.
- Section III.B – Updated chart to include revised premarket review compliance policy, and third column revised from "new compliance date" to "compliance date under this guidance" to provide additional clarity.

October 2017 — (1) Revised compliance date for "Registration of establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product and product listings" to reflect the date extension found in the "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" guidance issued in September 2017; (2) Revised compliance date for "Ingredient listing" to provide a six-month extension for tobacco product manufacturers and importers impacted by recent natural disasters; and (3) Revised compliance date for "Tobacco health documents" to provide a six-month extension for tobacco product manufacturers and importers in areas impacted by recent natural disasters.

November 2017 --- Revised compliance date for "Ingredient listing" to provide a six-month extension for all tobacco product manufacturers and importers, regardless of whether the manufacturer or importer is in an area impacted by recent natural disasters, as described in the October 2017 edition of this guidance.