



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-2834]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of a guidance for industry entitled “Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule,” which was issued in 2017. The guidance was intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, roll-your-own (RYO) tobacco, and cigarette tobacco in complying with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and FDA regulations. FDA is withdrawing the guidance because the compliance deadlines contained therein have passed, have been vacated or stayed, or are otherwise described in other guidance.

DATES: The withdrawal is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Eric C. Mandle, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002; 1-877-287-1373, [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: FDA is withdrawing the guidance for industry entitled “Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule,” which was issued in 2017 (see 82 FR 37459 (August 10, 2017)) and which has been revised several times since then. The guidance was intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, RYO tobacco, and cigarette tobacco in complying with the FD&C Act, as amended by the Tobacco Control Act, and FDA regulations.

The Tobacco Control Act (Pub. L. 111-31) granted FDA the authority to immediately regulate the manufacture, marketing, and distribution of cigarettes, cigarette 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 a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA’s tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, 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 28974 at 28976) (“the final deeming rule”).

In May 2017, FDA published the first edition of this guidance, under which it provided a 3-month extension of all future compliance deadlines under the final deeming rule. The second edition of the guidance, published in August 2017, revised and updated the first edition by further extending certain of the future compliance dates.

On May 15, 2019, the U.S. District Court for the District of Maryland issued an order vacating the extended compliance dates for premarket review in the guidance.<sup>1</sup> On July 12, 2019, the court issued an order directing FDA to require that premarket authorization applications for all new--i.e., not “grandfathered”<sup>2</sup>--deemed tobacco products to be submitted to the Agency within 10 months, by May 12, 2020, and providing for a 1-year period during which products with timely filed applications might remain on the market pending FDA review.<sup>3</sup> As required by the court’s order, deemed new tobacco products on the market as of August 8, 2016, for which premarket authorization applications are not filed by May 12, 2020, are subject to FDA enforcement actions, in the Agency’s discretion. The court subsequently clarified that its order did not restrict FDA’s authority to enforce the premarket review provisions against deemed products, prior to May 12, 2020, or during the 1-year review period.<sup>4</sup> On April 22, 2020, the court, upon FDA’s motion, extended the premarket application deadline set out in its order by 120 days (until September 9, 2020) in light of the global outbreak of respiratory illness caused by a new coronavirus.<sup>5</sup>

FDA is withdrawing the guidance because the compliance deadlines contained therein have passed, have been vacated, or are stayed, with the exception of those for reporting

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<sup>1</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, 379 F.Supp.3d 461 (D. Md. 2019).

<sup>2</sup> A “grandfathered” product is one that was on the market as of February 15, 2007. “Guidance for Industry, Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007,” dated September 2014, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007>.

<sup>3</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, 399 F.Supp.3d 479 (D. Md. 2019). The court has granted intervention to vapor industry trade associations for purposes of appealing the court’s decision and remedies order. See *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), Dkt. No. 154 (October 2, 2019). An appeal is pending. See *American Academy of Pediatrics v. Cigar Ass’n of America*, Nos. 19-2130, -2132, -2198 (4th Cir.).

<sup>4</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, Case No. 8:18-cv-883 (PWG), (D. Md. August 12, 2019), Dkt. No. 132.

<sup>5</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, Case No. 8:18-cv-883 (PWG), (D. Md. April 22, 2020), Dkt. No. 182.

requirements for harmful or potentially harmful constituents (HPHC). FDA has published and described these deadlines in the Small Entity Compliance Guide for the final deeming rule;<sup>6</sup> they are also listed on the Center for Tobacco Products' HPHC website.<sup>7</sup>

Dated: April 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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<sup>6</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-deems-certain-tobacco-products-subject-fda-authority-sales-and-distribution-restrictions-and>

<sup>7</sup> For more information, please see <https://www.fda.gov/tobacco-products/products-ingredients-components/harmful-and-potentially-harmful-constituents-hphcs>.

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