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

(Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to https://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 seventh revision to the first edition of this guidance, which issued in May 2017.

Provision	Products Affected	Compliance Date Under This Guidance
		For products entering the market after August 8, 2016: 90 days prior to marketing
Harmful and potentially harmful constituents (HPHCs) (section 904 and 915 of the FD&C Act) For more information, visit FDA.gov and search for "HPHC"	Newly deemed finished tobacco products[17]	6 months from the publication date of a final guidance regarding HPHC reporting under section 904(a)(3)[18] or 9 months from the publication date of a final guidance regarding HPHC reporting under section 904(a)(3), for small tobacco product manufacturers.[19] or For products entering the market after the publication date of a final guidance regarding HPHC reporting under section 904(a)(3): 90 days prior to marketing
Tobacco health documents (section 904(a) (4) of the FD&C Act)	Newly deemed finished tobacco products[20]	November 8, 2017, for small-scale manufacturers[21]

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

[18] In the preamble of the final deeming regulation, FDA indicated that it intends to issue guidance regarding HPHC reporting (and later a testing and reporting regulation under section 915) with enough time for manufacturers to report given the 3-year compliance period. At this time, FDA has not published a final HPHC reporting guidance, and as a result, we are providing a revised compliance date based on when a final HPHC reporting guidance is issued.

[19] For this compliance policy, the term "small tobacco product manufacturer" has the meaning given that term under the statute, i.e., a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

[20] 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.

[21] 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 products manufacturers has already passed (February 8, 2017) and is not affected by the extension announced in this guidance.