



*Tobacco Products Regulation and Policy Conference
October 26-27, 2017*

*The Future of the Deeming Regulation:
Policy and Litigation*



Deeming Rule Basics

- Extended FDA's Tobacco Control Act authority to previously unregulated products, including vapor, cigars, pipe tobacco, hookah, etc.
- Effective August 8, 2016
 - Market “freeze” date – no new products without FDA authorization
- Number of lawsuits filed by vapor and cigar industries challenging aspects of the rule under the Administrative Procedure Act, Regulatory Flexibility Act and Constitution, including:
 - Tobacco product definition
 - Grandfather Date
 - Premarket review process
 - MRTP process and free sample ban
 - User fees and warnings (cigars)
 - FDA's cost-benefit analysis



Deeming Rule Basics – Initial Compliance Deadlines

Requirement	Deadline for Large-Scale Manufacturers	Deadline for Small-Scale Manufacturers
New Products Without FDA premarket authorization	August 8, 2016	
Registration of U.S. manufacturing establishments and submission of List of Products manufactured in such establishments; does NOT apply to foreign establishments	December 31, 2016	
Submission of Health Document Notification	February 8, 2017	August 8, 2017
Submission of Ingredients Listing Reports	February 8, 2017	August 8, 2017
Submission of Harmful and Potentially Harmful Constituents (HPHCs) Reports	August 8, 2019	
SE Reports for deemed products on market on August 8, 2016	February 8, 2018	
PMTAs for deemed products (e.g., vapor products) on market on August 8, 2016	August 8, 2018	

Deeming Rule Basics – Current Compliance Deadlines*

Requirement	Deadline for Large-Scale Manufacturers	Deadline for Small-Scale Manufacturers
New Products Without FDA premarket authorization	August 8, 2016	
Registration of U.S. manufacturing establishments and <u>submission of List of Products manufactured in such establishments; does NOT apply to foreign establishments</u>	October 12, 2017	
Submission of Health Document Notification	February 8, 2017	November 8, 2017
Submission of Ingredients Listing Reports	November 8, 2017	May 8, 2018
Submission of Harmful and Potentially Harmful Constituents (HPHCs) Reports	November 8, 2019	
PMTA or SE Report for deemed combustible products (e.g. cigars or hookah) on market on August 8, 2016	August 8, 2021	
PMTA or SE Report for deemed non-combustible products (e.g., vapor products) on market on August 8, 2016	August 8, 2022	

*Manufacturers in areas affected by recent natural disasters (e.g., Caribbean Islands and certain counties in Florida, Texas and California) have an additional 6 months for upcoming requirements



Deeming Rule Basics

- Some of the issues
 - Despite various extensions, FDA's approach is still “one-size-fits-all”
 - Innovation at a standstill; safer products effectively prevented from coming to the market
 - But is August 8, 2016 market-freeze being enforced?
 - New policy announcement hints potential FDA consideration of Continuum of Risk and Tobacco Harm Reduction
 - New rulemakings from FDA on flavors, premarket and modified risk processes?
 - **Keep in mind:** Smoking and tobacco use rates continue to fall