

# Published Regulations and Guidances as of 5-1-18



## FINAL RULES

Title	Pub Date	FR Citation
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents	3/19/2010	75 FR 13225
Amendments to General Regulations of the Food and Drug Administration	11/30/2010	75 FR 73951
Required Warnings for Cigarette Packages and Advertisements	6/22/2011	76 FR 36628
Tobacco Products, Exemptions From Substantial Equivalence Requirements	7/5/2011	76 FR 38961
Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products	2/2/2012	77 FR 5171
Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	7/10/2014	79 FR 39302
National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions	9/24/2015	80 FR 57531
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	5/10/2016	81 FR 28973
Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco	5/10/2016	81 FR 28707
Refuse to Accept Procedures for Premarket Tobacco Product Submissions	12/29/2016	81 FR 95863
Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”	1/9/2017	82 FR 2193

## PROPOSED RULES

Title	Pub Date	FR Citation
Amendments to General Regulations of the Food and Drug Administration	11/30/2010	75 FR 73984

Administration		
Required Warnings for Cigarette Packages and Advertisements	11/12/2010	75 FR 69524
Tobacco Products, Exemptions From Substantial Equivalence Requirements	1/6/2011	76 FR 737
Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products	4/14/2011	76 FR 20901
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	11/17/2011	76 FR 71281
Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	5/31/2013	78 FR 32581
National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions	1/23/2014	79 FR 3742
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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products	4/25/2014	79 FR 23142
Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”	9/25/2015	80 FR 57756
Refuse to Accept Procedures for Premarket Tobacco Product Submissions	8/8/16	81 FR 52329
Tobacco Product Standard for N-nitrosornicotine Level in Finished Smokeless Tobacco Products	1/23/17	82 FR 8004

## **ADVANCE NOTICE OF PROPOSED RULEMAKING**

Title	Pub Date	FR Citation
Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act	3/19/2010	75 FR 13241
Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products	9/9/2011	76 FR 55835
Menthol in Cigarettes, Tobacco Products	7/24/2013	78 FR 44484
Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products	7/1/2015	80 FR 37555
Tobacco Product Standard for Nicotine Level of Combusted Cigarettes	3/16/18	83 FR 11818
Regulation of Flavors in Tobacco Products	3/21/18	83 FR 12294
Regulation of Premium Cigars	3/26/18	83 FR 12901

## **FINAL GUIDANCES**

Title	Pub Date	FR Citation
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product	11/12/2009	74 FR 58298
Listing of Ingredients in Tobacco Products	12/1/2009	74 FR 62795
Timeframe for Submission of Tobacco Health Documents	12/21/2009	74 FR 67877

General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)*	12/23/2009	*No FR
Tobacco Health Document Submission	4/20/2010	75 FR 20606
Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco	5/7/2010	75 FR 25271
Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco	6/8/2010	75 FR 32481
Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products	6/10/2010	75 FR 32953
Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products	1/6/2011	76 FR 789
Harmful and Potentially Harmful Constituents’ in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act”	1/31/2011	76 FR 5387
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers	4/25/2011	76 FR 22905
Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements	10/25/2011	76 FR 66074
Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products	3/28/2012	77 FR 18830
Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products	5/25/2012	77 FR 31368
Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents	8/22/2013	78 FR 52203
Tobacco Retailer Training Programs	9/5/2013	78 FR 54657
Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions	12/4/2013	78 FR 72900
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments	4/7/2014	No FR
Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	7/16/2014	79 FR 41585
Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	9/29/2014	79 FR 58358
Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order	8/28/2015	80 FR 52299
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second Edition)	9/8/2015	80 FR 53810
Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent	9/14/2015	80 FR 55124
Small Entity Compliance Guide: National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions	10/26/15	80 FR 65229
Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	5/10/2016	81 FR 28783

Small Entity Compliance Guide: The Food and Drug Administration Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements	5/10/2016	81 FR 28780
Tobacco Product Master Files	5/10/2016	81 FR 28778
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised)	7/15/16	81 FR 46087
'Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act (Revised)	8/31/2016	No FR
Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016 During the Deeming Compliance Periods	10/12/16	No FR
Health Document Submission Requirements for Tobacco Products	12/5/2016	81 FR 87565
Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)	12/8/2016	No FR
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)	12/12/2016	No FR
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments	12/13/2016	81 FR 89950
Listing of Ingredients in Tobacco Products (Revised)	12/29/2016	81 FR 96003
Submission of Warning Plans for Cigars	12/29/2016	81 FR 96017
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule	05/15/2017	No FR
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised*)	08/10/2017	82 FR 37459
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*)	09/19/2017	82 FR 43768
Compliance Policy for Required Warning Statements on Small-Packaged Cigars	09/25/2017	82 FR 44628
Prohibition of Distributing Free Samples of Tobacco Products	10/12/2017	82 FR 47534
Health Document Submission Requirements for Tobacco Products (*Revised)	10/18/2017	No FR
Listing of Ingredients in Tobacco Products (*Revised)	10/18/2017	No FR
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised*)	10/18/2017	No FR
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments	12/8/2017	82 FR 57993
Listing of Ingredients in Tobacco Products	4/17/2018	83 FR 16866

## **DRAFT GUIDANCES**

Title	Pub Date	FR Citation
The Scope of the Prohibition Against Marketing a Tobacco Product in Combination With Another Article or Product Regulated Under the Federal Food, Drug, and Cosmetic Act	10/5/2009	74 FR 51160
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments	10/21/2009	74 FR 54052

Listing of Ingredients in Tobacco Products	11/3/2009	74 FR 56842
Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products Under the Federal Food, Drug, and Cosmetic Act	11/27/2009	74 FR 62329
Tobacco Health Document Submission	12/28/2009	74 FR 68629
Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	6/9/2010	75 FR 32791
'Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act	6/10/2010	75 FR 32952
Tobacco Retailer Training Programs	7/16/2010	75 FR 41498
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers	8/31/2010	75 FR 53316
Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	3/23/2011	76 FR 16424
Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	4/25/2011	76 FR 22903
Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products	9/9/2011	76 FR 55923
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions	9/9/2011	76 FR 55927
Applications for Premarket Review of New Tobacco Products	9/28/2011	76 FR 60055
Modified Risk Tobacco Product Applications	4/3/2012	77 FR 20026
Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act	4/3/2012	77 FR 20030
Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions	2/8/2013	78 FR 9396
Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent	2/25/2014	79 FR 10534
Draft Guidance for Industry on Substantial Equivalence Reports; Manufacturer Requests for Extensions or To Change the Predicate Tobacco Product	7/15/2014	79 FR 41292
Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order	5/13/2015	80 FR 27318
Use of Investigational Tobacco Products	9/24/2015	80 FR 57623
Premarket Tobacco Product Application for Electronic Nicotine Delivery Systems	5/10/2016	81 FR 28781
Submission of Warning Plans for Cigars	8/31/2016	81 FR 60004
Health Document Submission Requirements for Tobacco Products (Revised)	9/9/2016	81 FR 62505
Listing of Ingredients in Tobacco Products (Revised)	10/28/2016	81 FR 75136
Compliance Policy for Required Warning Statements on Small-Packaged Cigars	1/17/17	82 FR 4892
Interpretation of and Compliance Policy for Certain Label Requirements; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops	1/17/17	82 FR 4893

