# Published Regulations and Guidances as of 2-19-21



#### **FINAL RULES**

Title	Pub Date	FR Citation
Regulations Restricting the Sale and Distribution of Cigarettes and	3/19/2010	75 FR 13225
Smokeless Tobacco To Protect Children and Adolescents		
Amendments to General Regulations of the Food and Drug	11/30/2010	75 FR 73951
Administration		
Required Warnings for Cigarette Packages and Advertisements	6/22/2011	76 FR 36628
Tobacco Products, Exemptions From Substantial Equivalence	7/5/2011	76 FR 38961
Requirements		
Further Amendments to General Regulations of the Food and Drug	2/2/2012	77 FR 5171
Administration to Incorporate Tobacco Products		
Tobacco Products, User Fees, Requirements for the Submission of	7/10/2014	79 FR 39302
Data Needed To Calculate User Fees for Domestic Manufacturers		
and Importers of Tobacco Products		
National Environmental Policy Act; Environmental Assessments	9/24/2015	80 FR 57531
for Tobacco Products; Categorical Exclusions		
Deeming Tobacco Products To Be Subject to the Federal Food,	5/10/2016	81 FR 28973
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		
Requirements for the Submission of Data Needed to Calculate	5/10/2016	81 FR 28707
User Fees for Domestic Manufacturers and Importers of Cigars		
and Pipe Tobacco		
Refuse to Accept Procedures for Premarket Tobacco Product	12/29/2016	81 FR 95863
Submissions		
Clarification of When Products Made or Derived from Tobacco	1/9/2017	82 FR 2193
Are Regulated as Drugs, Devices, or Combination Products;		
Amendments to Regulations Regarding "Intended Uses"		
Tobacco Products: Required Warnings for Cigarette Packages and	3/18/2020	85 FR 15638
Advertisements – Final Rule	- /a a /a a a a	0.7.777.000.00
Tobacco Products; Required Warnings for Cigarette Packages and	5/29/2020	85 FR 32293
Advertisements; Delayed Effective Date	1 /1 7 /0 0 5 1	0.5 FD 0.753
Tobacco Products; Required Warnings for Cigarette Packages and	1/15/2021	86 FR 3793
Advertisements; Delayed Effective Date		

#### PROPOSED RULES

Title	Pub Date	FR Citation
Amendments to General Regulations of the Food and Drug	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	1/6/2011	76 FR 737
Requirements		
Further Amendments to General Regulations of the Food and Drug	4/14/2011	76 FR 20901
Administration to Incorporate Tobacco Products		
Regulations Restricting the Sale and Distribution of Cigarettes and	11/17/2011	76 FR 71281
Smokeless Tobacco to Protect Children and Adolescents		
Tobacco Products, User Fees, Requirements for the Submission of	5/31/2013	78 FR 32581
Data Needed To Calculate User Fees for Domestic Manufacturers		
and Importers of Tobacco Products		
National Environmental Policy Act; Environmental Assessments	1/23/2014	79 FR 3742
for Tobacco Products; Categorical Exclusions		
Deeming Tobacco Products To Be Subject to the Federal Food,	4/25/2014	79 FR 23142
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		
Clarification of When Products Made or Derived From Tobacco	9/25/2015	80 FR 57756
Are Regulated as Drugs, Devices, or Combination Products;		
Amendments to Regulations Regarding "Intended Uses"		
Refuse to Accept Procedures for Premarket Tobacco Product	8/8/2016	81 FR 52329
Submissions		
Tobacco Product Standard for N-nitrosonornicotine Level in	1/23/2017	82 FR 8004
Finished Smokeless Tobacco Products		
Content and Format of Substantial Equivalence Reports	4/2/2019	84 FR 12740
Required Warnings for Cigarette Packages and Advertisements	8/15/2019	84 FR 42754
Premarket Tobacco Product Applications and Recordkeeping	9/25/2019	84 FR 50566
Requirements		

### ADVANCE NOTICE OF PROPOSED RULEMAKING

Title	Pub Date	FR Citation
Request for Comment on Implementation of the Family Smoking	3/19/2010	75 FR 13241
Prevention and Tobacco Control Act		
Non-Face-to-Face Sale and Distribution of Tobacco Products and	9/9/2011	76 FR 55835
Advertising, Promotion, and Marketing of Tobacco Products		
Menthol in Cigarettes, Tobacco Products	7/24/2013	78 FR 44484
Nicotine Exposure Warnings and Child-Resistant Packaging for	7/1/2015	80 FR 37555
Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other		
Tobacco Products		
Tobacco Product Standard for Nicotine Level of Combusted	3/16/2018	83 FR 11818
Cigarettes		
Regulation of Flavors in Tobacco Products	3/21/2018	83 FR 12294

3/26/2018	83 FR 12901
3/20/2010	05 110 12/01

# Regulation of Premium Cigars

FINAL GUIDANCES

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product   Listing of Ingredients in Tobacco Products   Listing of Ingredients in Tobacco Products   Listing of Ingredients in Tobacco Products   Listing of Ingredients in Tobacco Health Documents   Listing of Ingredients in Tobacco   Listing of Cartesian Regulations Restricting   Listing of Listing   Listing   Listing of Listing	Title	Pub Date	FR Citation
Listing of Ingredients in Tobacco Products Timeframe for Submission of Tobacco Health Documents Tobacco Health Documents 12/21/2009 74 FR 62795 77 FR 777 78 FR 62795 78 FR 777 78 FR 62795 78 FR 78 F	Registration and Product Listing for Owners and Operators of	11/12/2009	74 FR 58298
Timeframe for Submission of Tobacco Health Documents    12/21/2009   74 FR 67877	Domestic Tobacco Product		
General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)*  Tobacco Health Document Submission  Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco  Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco  Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products  Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products  Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act"  Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers  Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements  Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Civil Money Penalties for Tobacco Products  Guidance on Meetings With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Product  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  **No FR**  12/2/2015  **No FR**  12	Listing of Ingredients in Tobacco Products	12/1/2009	74 FR 62795
Contain Certain Characterizing Flavors (Edition 2)*  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  Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco  Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products  Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products  Harmful and Potentially Harmful Constituents' in Tobacco  Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act"  Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco  Regulations of the Food and Drug Administration To Incorporate Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Registration and Product Listing for Owners and Operators of Domestic Tobacco Retailers: Responses to Prequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Setsablishments  Small Entity Compliance Guide: Requirements for the Submission of Tof-2011 Tobacco Retailers: Responses to Product Setsablishments  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Setsablishments  Small Entity Compliance Guide: Requirements for the Submission of Tof-2014 Tobacco Product Setsablishments  Small Entity Compliance Guide: Requirements for the Submission of Tof-2014 Tobacco Product Setsablishments  Small Entity Compliance Guide: Requirements for the Submission of Tof-2014 Tobacco Product Setsablishments  Frequently Asked Questions Responses to Product Setsablishments  Regist		12/21/2009	
Tobacco Health Document Submission	General Questions and Answers on the Ban of Cigarettes that	12/23/2009	*No FR
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Smokeless Tobacco   Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products   Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products   1/6/2011   76 FR 789			
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Tobacco Products  Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act'  Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers  Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements  Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Pobacco Retailer Training Programs  Prequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Product Statellishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  Product: Responses to Frequently Asked Questions (Second)			
Tobacco Products  Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act'  Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers  Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements  Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  7/8 FR 52203  Tobacco Retailer Training Programs  9/5/2013  7/8 FR 72900  Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Product  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Product Statablishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)		1/6/2011	76 FR 789
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Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers  Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Givil Money Penalties for Tobacco Retailers: Responses to Prequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  76 FR 66074  76 FR 66074  77 FR 18830  77 FR 18830  77 FR 18830  78 FR 52201  78 FR 52203  78 FR 52203  78 FR 52203  78 FR 52203  78 FR 72200  78 FR 72200  78 FR 72900  79 FR 41585  79 FR 41585  70 Determination of the Period Covered by a No-Tobacco-Sale Order Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)			
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Packages and Advertisements  Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Givil Money Penalties for Tobacco Retailers: Responses to 12/4/2013  Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Product Sestablishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  77 FR 18830  78 FR 52203  78 FR 52203  78 FR 54657  78 FR 54657  78 FR 72900  79 FR 72900  79 FR 41585  716/2014  79 FR 41585  716/2014  79 FR 41585  79 FR 58358  716/2014  79 FR 58358  70 FR 52299  70 FR 58310			
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Regulations of the Food and Drug Administration To Incorporate Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  77 FR 31368  8/22/2013  78 FR 52203  78 FR 54657  78 FR 72900  78 FR 72900  79 FR 41585  79 FR 41585  80 FR 53858  80 FR 52299  80 FR 53810			
Tobacco Products  Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  77 FR 31368  78 FR 52203  78 FR 54657  78 FR 72900  78 FR 72900  79 FR 72900  79 FR 41585  77 FR 41585  80 FR 52299  80 FR 58358  80 FR 52299  80 FR 52299  80 FR 53810	Small Entity Compliance Guide: Further Amendments to General	3/28/2012	77 FR 18830
Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  77 FR 31368  78 FR 52203  78 FR 52203  78 FR 54657  78 FR 72900  78 FR 72900  78 FR 72900  79 FR 41585  79 FR 41585  79 FR 41585  80 FR 53858  80 FR 52299  80 FR 52299  80 FR 53810	Regulations of the Food and Drug Administration To Incorporate		
Research and Development of Tobacco Products  Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  78 FR 52203  78 FR 54657  78 FR 72900  78 FR 72900  78 FR 72900  78 FR 72900  79 FR 41585  7/16/2014  79 FR 41585  80 FR 53858  80 FR 52299  80 FR 53810	Tobacco Products		
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Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents  Tobacco Retailer Training Programs  Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  78 FR 54657  78 FR 72900  102/4/2014  No FR 79 FR 41585  7/16/2014  79 FR 58358  80 FR 58358  80 FR 52299  80 FR 53810	Research and Development of Tobacco Products		
Children and Adolescents  Tobacco Retailer Training Programs  Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  78 FR 54657  78 FR 72900  79 FR 70 F	Compliance With Regulations Restricting the Sale and	8/22/2013	78 FR 52203
Tobacco Retailer Training Programs  Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions  Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  78 FR 54657  78 FR 72900  79 FR 41585  79 FR 41585  79 FR 41585  80 FR 58358  80 FR 52299  80 FR 52299  80 FR 53810	Distribution of Cigarettes and Smokeless Tobacco To Protect		
Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second)  12/4/2013 78 FR 72900  12/4/2014 No FR 79 FR 41585 79 FR 41585 80 FR 58358 80 FR 58358 80 FR 58358 80 FR 52299 80 FR 52299 80 FR 53810	Children and Adolescents		
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second	Tobacco Retailer Training Programs	9/5/2013	78 FR 54657
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second	Civil Money Penalties for Tobacco Retailers: Responses to	12/4/2013	78 FR 72900
Domestic Tobacco Product Establishments  Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic  Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco  Product: Responses to Frequently Asked Questions (Second  7/16/2014  79 FR 41585  79 FR 58358  80 FR 58358  80 FR 52299  80 FR 53810	Frequently Asked Questions		
Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic  Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco  Product: Responses to Frequently Asked Questions (Second  7/16/2014  79 FR 41585  79 FR 41585  80 FR 58358  80 FR 52299  80 FR 52299	Registration and Product Listing for Owners and Operators of	4/7/2014	No FR
of Data Needed To Calculate User Fees for Domestic  Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco  Product: Responses to Frequently Asked Questions (Second  79 FR 58358  80 FR 52299  80 FR 53810	Domestic Tobacco Product Establishments		
Manufacturers and Importers of Tobacco Products  Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  79 FR 58358  80 FR 52299  80 FR 53810	Small Entity Compliance Guide: Requirements for the Submission	7/16/2014	79 FR 41585
Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second 79 FR 58358 80 FR 52299 80 FR 52299 80 FR 53810 80 FR 53810 80 FR 53810 80 FR 53810	of Data Needed To Calculate User Fees for Domestic		
in the United States as of February 15, 2007  Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  8/28/2015  80 FR 52299  80 FR 53810			
Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  8/28/2015  80 FR 52299  80 FR 53810	Establishing That a Tobacco Product Was Commercially Marketed	9/29/2014	79 FR 58358
and Compliance With an Order  Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  80 FR 53810	·		
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Second  80 FR 53810	Determination of the Period Covered by a No-Tobacco-Sale Order	8/28/2015	80 FR 52299
Product: Responses to Frequently Asked Questions (Second			
Product: Responses to Frequently Asked Questions (Second		9/8/2015	80 FR 53810
Edition)	Product: Responses to Frequently Asked Questions (Second		
l l	Edition)		

Enforcement Policy for Certain (Provisional) Tobacco Products	9/14/2015	80 FR 55124
That the Food and Drug Administration Finds Not Substantially		
Equivalent		
Small Entity Compliance Guide: National Environmental Policy	10/26/15	80 FR 65229
Act; Environmental Assessments for Tobacco Products;		
Categorical Exclusions		
Small Entity Compliance Guide: Requirements for the Submission	5/10/2016	81 FR 28783
of Data Needed To Calculate User Fees for Domestic	0,10,2010	0111120700
Manufacturers and Importers of Tobacco Products		
Small Entity Compliance Guide: The Food and Drug	5/10/2016	81 FR 28780
Administration Deems Certain Tobacco Products Subject to FDA	3/10/2010	0111120700
Authority, Sales and Distribution Restrictions, and Health Warning		
Requirements for Packages and Advertisements		
Tobacco Product Master Files	5/10/2016	81 FR 28778
	7/15/2016	81 FR 46087
Registration and Product Listing for Owners and Operators of	//13/2010	81 FK 40087
Domestic Tobacco Product Establishments (Revised)	0/21/2017	N. ED
'Harmful and Potentially Harmful Constituents' in Tobacco	8/31/2016	No FR
Products as Used in Section 904(e) of the Federal Food, Drug, and		
Cosmetic Act (Revised)		
Investigational Use of Deemed, Finished Tobacco Products That	10/12/2016	No FR
Were on the U.S. Market on August 8, 2016 During the Deeming		
Compliance Periods		
Health Document Submission Requirements for Tobacco Products	12/5/2016	81 FR 87565
Small Entity Compliance Guide: FDA Deems Certain Tobacco	12/8/2016	No FR
Products Subject to FDA Authority, Sales and Distribution		
Restrictions, and Health Warning Requirements for Packages and		
Advertisements (Revised)		
Demonstrating the Substantial Equivalence of a New Tobacco	12/12/2016	No FR
Product: Responses to Frequently Asked Questions (Edition 3)		
Registration and Product Listing for Owners and Operators of	12/13/2016	81 FR 89950
Domestic Tobacco Product Establishments		
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	5/15/2017	No FR
Related to the Final Deeming Rule	0,10,201,	1,0111
Extension of Certain Tobacco Product Compliance Deadlines	8/10/2017	82 FR 37459
Related to the Final Deeming Rule (Revised*)	0/10/2017	0211(37.13)
Registration and Product Listing for Owners and Operators of	9/19/2017	82 FR 43768
Domestic Tobacco Product Establishments (Revised*)	7/17/2017	02 I K +3700
Compliance Policy for Required Warning Statements on Small-	9/25/2017	82 FR 44628
Packaged Cigars	9/23/2017	82 FK 44028
	10/12/2017	92 ED 47524
Prohibition of Distributing Free Samples of Tobacco Products  Health December Submission Requirements for Tobacco Products	10/12/2017	82 FR 47534 No FR
Health Document Submission Requirements for Tobacco Products	10/18/2017	NUFK
(*Revised)	10/10/2017	N. ED
Listing of Ingredients in Tobacco Products (*Revised)	10/18/2017	No FR
Extension of Certain Tobacco Product Compliance Deadlines	10/18/2017	No FR
Related to the Final Deeming Rule (Revised*)	10/0/50:5	0.0
Registration and Product Listing for Owners and Operators of	12/8/2017	82 FR 57993
Domestic Tobacco Product Establishments Listing of Ingredients in Tobacco Products		
	4/17/2018	83 FR 16866

Extension of Certain Tobacco Product Compliance Deadlines	3/8/2019	No FR
Related to the Final Deeming Rule (*Revised)		
FDA Deems Certain Tobacco Products Subject to FDA Authority,	3/8/2019	No FR
Sales and Distribution Restrictions, and Health Warning		
Requirements for Packages and Advertisements (*Revised)		
Interpretation of and Compliance Policy for Certain Label	3/25/2019	84 FR 11108
Requirement; Applicability of Certain Federal Food, Drug, and		
Cosmetic Act Requirements to Vape Shops		
Premarket Tobacco Product Applications for Electronic Nicotine	6/12/19	84 FR 27200
Delivery Systems		
Compliance Policy for Limited Modifications to Certain Marketed	11/26/2019	84 FR 65160
Tobacco Products		
Enforcement Priorities for Electronic Nicotine Delivery Systems	01/07/2020	85 FR 720
and Other Deemed Products on the Market Without Premarket		
Authorization		
Required Warnings for Cigarette Packages and Advertisements:	3/18/2020	85 FR 15710
Small Entity Compliance Guide		
Submission of Plans for Cigarette Packages and Cigarette	3/20/2020	85 FR 16103
Advertisements		
Enforcement Priorities for Electronic Nicotine Delivery Systems	4/30/2020	85 FR 23973
and Other Deemed Products on the Market Without Premarket		
Authorization (Revised)		
Submission of Plans for Cigarette Packages and Cigarette	5/29/2020	85 FR 32401
Advertisements (Revised)		
Submission of Plans for Cigarette Packages and Cigarette	2/16/2021	86 FR 9508
Advertisements (Revised)		

## **DRAFT GUIDANCES**

Title	Pub Date	FR Citation
The Scope of the Prohibition Against Marketing a Tobacco	10/5/2009	74 FR 51160
Product in Combination With Another Article or Product		
Regulated Under the Federal Food, Drug, and Cosmetic Act		
Registration and Product Listing for Owners and Operators of	10/21/2009	74 FR 54052
Domestic Tobacco Product Establishments		
Listing of Ingredients in Tobacco Products	11/3/2009	74 FR 56842
Preliminary Timetable for the Review of Applications for	11/27/2009	74 FR 62329
Modified Risk Tobacco Products Under the Federal Food, Drug,		
and Cosmetic Act		
Tobacco Health Document Submission	12/28/2009	74 FR 68629
Compliance With Regulations Restricting the Sale and	6/9/2010	75 FR 32791
Distribution of Cigarettes and Smokeless Tobacco to Protect		
Children and Adolescents		
'Harmful and Potentially Harmful Constituents' in Tobacco	6/10/2010	75 FR 32952
Products as Used in Section 904(e) of the Federal Food, Drug, and		
Cosmetic Act		
Tobacco Retailer Training Programs	7/16/2010	75 FR 41498
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco	8/31/2010	75 FR 53316
Retailers		

Compliance With Decayletions Destricting the Cole and	2/22/2011	76 ED 16424
Compliance With Regulations Restricting the Sale and	3/23/2011	76 FR 16424
Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents		
Establishing That a Tobacco Product Was Commercially Marketed	4/25/2011	76 FR 22903
in the United States as of February 15, 2007	4/23/2011	70 FR 22903
Submission of Warning Plans for Cigarettes and Smokeless	9/9/2011	76 FR 55923
Tobacco Products	9/9/2011	70 FK 33923
Demonstrating the Substantial Equivalence of a New Tobacco	9/9/2011	76 FR 55927
Product: Responses to Frequently Asked Questions	9/9/2011	70 FR 33927
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	4/3/2012	77 FR 20030
Tobacco Products and Tobacco Smoke Under the Federal Food,	4/3/2012	// 1 K 20030
Drug, and Cosmetic Act		
Civil Money Penalties for Tobacco Retailers: Responses to	2/8/2013	78 FR 9396
Frequently Asked Questions	2/0/2013	701103300
Enforcement Policy for Certain (Provisional) Tobacco Products	2/25/2014	79 FR 10534
That the Food and Drug Administration Finds Not Substantially	2/25/2011	7,5 110 1005 1
Equivalent		
Draft Guidance for Industry on Substantial Equivalence Reports;	7/15/2014	79 FR 41292
Manufacturer Requests for Extensions or To Change the Predicate	,,,10,201.	// 111 112/2
Tobacco Product		
Determination of the Period Covered by a No-Tobacco-Sale Order	5/13/2015	80 FR 27318
and Compliance With an Order		
Use of Investigational Tobacco Products	9/24/2015	80 FR 57623
Premarket Tobacco Product Application for Electronic Nicotine	5/10/2016	81 FR 28781
Delivery Systems		
Submission of Warning Plans for Cigars	8/31/2016	81 FR 60004
Health Document Submission Requirements for Tobacco Products	9/9/2016	81 FR 62505
(Revised)		
Listing of Ingredients in Tobacco Products (Revised)	10/28/2016	81 FR 75136
Compliance Policy for Required Warning Statements on Small-	1/17/2017	82 FR 4892
Packaged Cigars		
Interpretation of and Compliance Policy for Certain Label	1/17/2017	82 FR 4893
Requirements; Applicability of Certain Federal Food, Drug, and		
Cosmetic Act Requirements to Vape Shops		
The Prohibition of Distributing Free Samples of Tobacco Products	1/18/2019	82 FR 5583
Use of Investigational Tobacco Products (*Revised)	2/21/2019	84 FR 5448
Enforcement Policy for Certain Marketed Tobacco Products	3/1/2019	84 FR 7084
Modifications to Compliance Policy for Certain Deemed Tobacco	3/14/2019	84 FR 9345
Products		
Submission of Plans for Cigarette Packages and Cigarette	12/30/2019	84 FR 71957
Advertisements		
Tobacco Products: Principles for Designing and Conducting	10/28/2020	85 FR 68341
Tobacco Product Perception and Intention Studies		