

Useful Links for PMTA

- **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**
<https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>
- **Section 910 of the Federal Food, Drug, and Cosmetic Act - Application for Review of Certain Tobacco Products**
<https://www.gpo.gov/fdsys/search/pagedetails.action?packageId=USCODE-2010-title21&granuleId=USCODE-2010-title21-chap9-subchapIX-sec387j>
- **Pre-market Tobacco Applications homepage**
<http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm304506.htm>
- **Swedish Match North America PMTA Review**
<http://www.fda.gov/downloads/tobaccoproducts/labeling/tobaccoproductreviewevaluation/ucm472123.pdf>

CTP EVENTS

- **The Premarket Tobacco Product Application for Electronic Nicotine Delivery Systems (ENDS): A Public Seminar** - the archived webcast, with closed captioning, will be available at this site in November, 2016.
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm517650.htm>
- **Risk Assessment: A Public Workshop (November 15-16, 2016)**
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm515442.htm>
- **CTP Workshop: Biomarkers of Potential Harm (April 2016)**
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm481513.htm>
- **CTP Workshop: Biomarkers of Exposure (August 2015)**
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm447723.htm>
- **FDA Electronic Cigarette Workshop Series (2014/2015)**
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>

SAFETY REPORTING PORTAL

<https://www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=C1EB51>

INFORMATION ON ELECTRONIC SUBMISSIONS

- **FDA Electronic Submission Gateway (ESG):** <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway>
- **SaS transport file:** <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>
- **eSubmitter:** <http://www.fda.gov/forindustry/fdaesubmitter/ucm108165.htm>
- **CTP Portal:** <https://ctportal.fda.gov/ctportal/login.jsp>

SMALL BUSINESS ASSISTANCE

CTP Office of Small Business Assistance (SmallBiz.Tobacco@fda.hhs.gov)

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm>

QUESTIONS?

Center for Tobacco Products Contact Center

Phone: 877-287-1373

E-mail: AskCTP@fda.hhs.gov

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GUIDANCES

- **Draft Guidance: Applications for Premarket Review of New Tobacco Products**
<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm273388.htm>
- **Draft Guidance: Premarket Tobacco Product Application for Electronic Nicotine Delivery Systems (ENDS)**
<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499351.htm>
- **Draft Guidance: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act :**
<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm297752.htm>
- **Draft Guidance: Use of Investigational Tobacco Products:**
<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM463953.pdf>
- **Guidance: Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016, During the Deeming Compliance Periods**
<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm524908.htm>
- **Guidance: National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions – Small Entity Compliance Guide**
<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM469194.pdf>
- **Final Guidance: Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised*)**
<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm305279.htm>
- **Final Guidance: “Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act (Revised*)**
<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm>
- **Final Guidance: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products:**
<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm436462.htm>
- **Final Guidance: Listing of Ingredients in Tobacco Products:**
<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm191982.htm>
- **Final Guidance: Tobacco Product Master Files:**
<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499350.pdf>
- **Guidance: Label Comprehension Studies for Nonprescription Drugs**
<http://www.fda.gov/downloads/drugs/guidancecomplianceinformation/guidances/ucm143834.pdf>
- **Guidance: Self-Selection Studies for Nonprescription Drugs**
<http://www.fda.gov/downloads/drugs/guidancecomplianceinformation/guidances/ucm272122.pdf>
- **Guidance: Applying Human Factors and Usability Engineering to Medical Devices**
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259760.pdf>

ENVIRONMENTAL ASSESSMENTS

- **Examples of Environmental Assessments in applications posted on the CTP website**
<http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm339928.htm#2>
- **Webinar “Environmental Considerations for Tobacco Product Applications Submitted to CTP”, 2016**
<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm220111.htm>

NATIONAL ESTIMATES OF TOBACCO USE

- NATIONAL YOUTH TOBACCO SURVEY: http://www.cdc.gov/tobacco/data_statistics/surveys/nyts/
- MONITORING THE FUTURE: <http://www.icpsr.umich.edu/icpsrweb/NAHDAP/series/35>
- YOUTH RISK BEHAVIOR SURVEY: <http://www.cdc.gov/healthyyouth/data/yrbs/index.htm>
- NATIONAL HEALTH INTERVIEW SURVEY: <http://www.cdc.gov/nchs/nhis/>
- NATIONAL ADULT TOBACCO SURVEY: http://www.cdc.gov/tobacco/data_statistics/surveys/nats/
- NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY: <http://www.cdc.gov/nchs/nhanes/>
- TOBACCO USE SUPPLEMENT–CURRENT POPULATION SURVEY:
http://thedataweb.rm.census.gov/ftp/cps_ftp.html#cpssupps
- POPULATION ASSESSMENT OF TOBACCO AND HEALTH:
<http://www.icpsr.umich.edu/icpsrweb/NAHDAP/studies/36231>

TOXICOLOGY RESOURCES

- ToxLearn: www.toxlearn.nlm.nih.gov
- Toxicology Tutorials: sis.nlm.nih.gov/enviro/toxtutor.html
- Toxicology Curriculum for Communities Trainer's Manual: www.atsdr.cdc.gov/training/toxmanual/index.html
- Resources for Toxicologists Website: www.actox.org/goodstuff/resources.asp
- Information Resources in Toxicology (4th Edition): www.sciencedirect.com/science/book/9780123735935
- ToxNet: www.toxnet.nlm.nih.gov

SURGEON GENERAL REPORTS (recent examples):

- The Health Consequences of Smoking – 50 Years of Progress (2014)
<http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>
- Preventing Tobacco Use Among Youth and Adults (2012)
<http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>
- How Tobacco Smoke Causes Disease: the Biology and Behavioral Basis for Smoking-Attributable Disease (2010) <http://www.ncbi.nlm.nih.gov/books/NBK53017/>
- The Health Consequences of Involuntary Exposure to Tobacco Smoke (2006)
<http://www.surgeongeneral.gov/library/reports/secondhandsmoke/fullreport.pdf>

OTHER RESOURCES

- National Cancer Institute (NCI) Tobacco Monograph Series
<http://cancercontrol.cancer.gov/brp/tcrb/monographs/>
- Tobacco Atlas
<http://www.cancer.org/aboutus/globalhealth/cancerandtobaccocontrolresources/the-tobacco-atlas>
- International Agency for Research on Cancer (IARC) Handbooks
<https://www.iarc.fr/en/publications/pdfs-online/prev/handbook14/handbook14.pdf>
- International Institute for Qualitative Methodology
<https://www.ualberta.ca/international-institute-for-qualitative-methodology/>
- NIH Mixed Methods Report
https://obsr.od.nih.gov/wp-content/uploads/2016/02/Best_Practices_for_Mixed_Methods_Research.pdf