INFORMATION AND RESOURCES ON APPLICATION REVIEW PROGRAMS

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Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

AGENDA

- Regulatory Information
  - Guidance and regulations
  - Documents available for public comment
- Marketing Orders
  - Technical Project Lead (TPL) Reviews & Order letters
  - Environmental Assessments/Finding Of No Significant Impact
- Training
  - Webinars, presentations, workshops
  - Connect with CTP

REGULATORY INFORMATION

Navigate the Tobacco Products Section

Products, Guidance & Regulations
Learn about FDA's regulation of tobacco products, including product review and requirements for marketing and labeling.

Compliance, Enforcement & Training
FDA enforces the Tobacco Control Act by giving industry education and training, monitoring industry's compliance with the law, and taking action when necessary.

Newsroom
Stay up to date on the latest news and events from FDA's Center for Tobacco Products through the CTP Newsroom.

Public Health Education
Learn about the FDA's public campaigns to educate about the dangers of tobacco products and find quit smoking resources.

Science & Research
Learn how FDA's support of science and research helps us better understand tobacco use and associated risks, ultimately aiming to reduce the public health burden of tobacco.

About CTP
CTP protects America's youth from tobacco, educates consumers, ensures industry complies with the law, reviews products, and conducts research.

Guidance Documents (click arrows to sort)

Title	Type	Date
Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco	Guidance	08/09/18
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule **(Revised*)**	Guidance	08/09/18
Compliance Policy for Required Warning Statements on Small-Packaged Cigars **(Revised*)**	Guidance	08/09/18
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*)**	Guidance	08/09/18
Submission of Warning Plans for Cigars **(*Revised)**	Guidance	08/09/18
Tobacco Retailer Training Programs **(*Revised)**	Guidance	08/09/18
Listing of Ingredients in Tobacco Products **(*Revised)**	Guidance	04/13/18
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments **(Revised*)**	Guidance	12/07/17
Health Document Submission Requirements for Tobacco Products **(*Revised)**	Guidance	10/18/17
Prohibition of Distributing Free Samples of Tobacco Products	Guidance	10/11/17
Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers **(Revised*)**	Guidance	12/15/16
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions **(Revised*)**	Guidance	12/15/16

regulations.gov

TIPS FOR SUBMITTING EFFECTIVE COMMENTS*

Overview

A comment can express simple support or dissent for a regulatory action. However, a constructive, information-rich comment that clearly communicates and supports its claims is more likely to have an impact on regulatory decision making.

These tips are meant to help the public submit comments that have an impact and help agency policy makers improve federal regulations.

Summary

- ✓ Read and understand the regulatory document you are commenting on
- ✓ Feel free to reach out to the agency with questions
- ✓ Be concise but support your claims
- ✓ Base your justification on sound reasoning, scientific evidence, and/or how you will be impacted
- ✓ Address trade-offs and opposing views in your comment
- ✓ There is no minimum or maximum length for an effective comment
- ✓ The comment process is not a vote – one well supported comment is often more influential than a thousand form letters

Products, Guidance & Regulations

- Submit Comments on Tobacco Products
- Importing and Exporting
- Products, Ingredients & Components
- Rules, Regulations & Guidance
- Review & Evaluation Process
- Labeling
- Advertising & Promotion

Submit Comments on Tobacco Products

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Make your voice heard and be part of our ongoing effort to improve public health in the United States.

We solicit information and comments, announced in the *Federal Register* and posted in dockets on Regulations.gov, from concerned citizens, industry, and organizations on a wide range of issues related to implementation of the Tobacco Control Act.

Submit Comments

Tobacco Product Application Review; Public Meeting; Request for Comments

Docket No: FDA-2018-N-3504

Date: December 7, 2018

Summary: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Tobacco Product Application Review." This meeting is intended to improve public understanding and provide FDA feedback on the policies and processes for submitting and reviewing tobacco product marketing applications, including the general scientific principles relevant to various application pathways, to assist those considering submitting marketing applications for tobacco products under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

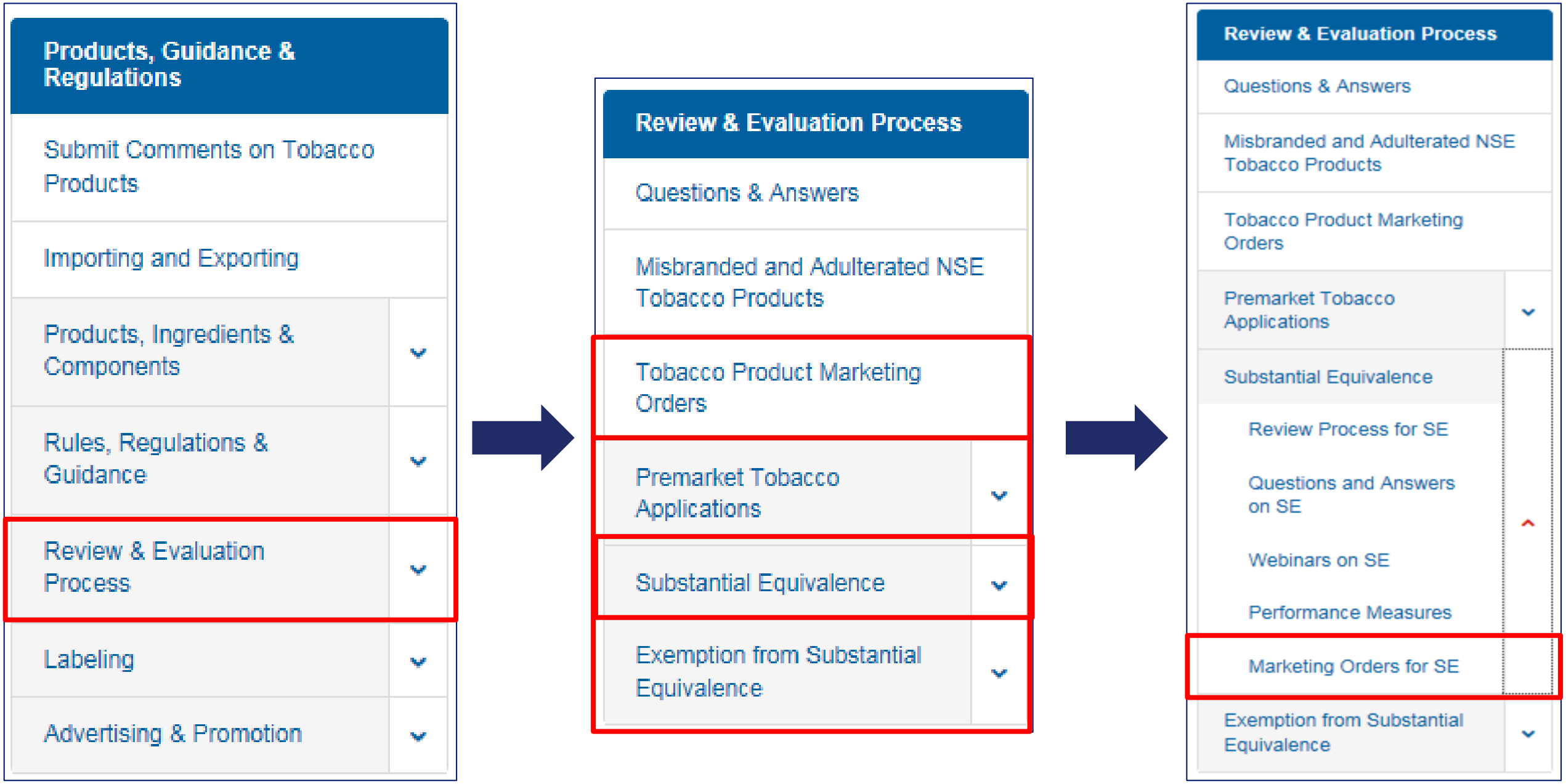
Modified Risk Tobacco Product Applications: Application for Copenhagen Snuff Fine Cut submitted by U.S. Smokeless Tobacco Company; Availability

Docket No: FDA-2018-N-3261

Date: Currently no deadline for public comments

Summary: The FDA is announcing the availability for public comment of a modified risk tobacco product (MRTP) application for Copenhagen Snuff Fine Cut, a loose moist snuff tobacco product submitted by U.S. Smokeless Tobacco Co. LLC. FDA will post the application materials on a rolling basis as they are redacted in accordance with applicable laws.

MARKETING ORDERS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Review & Evaluation Process
Questions & Answers
Misbranded and Adulterated NSE Tobacco Products
Tobacco Product Marketing Orders
Premarket Tobacco Applications
Substantial Equivalence
Exemption from Substantial Equivalence
Review & Evaluation Process
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Misbranded and Adulterated NSE Tobacco Products
Tobacco Product Marketing Orders
Premarket Tobacco Applications
Substantial Equivalence
Review Process for SE
Questions and Answers on SE
Webinars on SE
Performance Measures
Marketing Orders for SE
Exemption from Substantial Equivalence

February 2018

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
Republic Tobacco, LP	OCB Xpert Blue	Roll-Your-Own Tobacco	2/2/2018	SE0013974	EA0013974	FONSI0013974
Republic Tobacco, LP	OCB Xpert Double	Roll-Your-Own Tobacco	2/2/2018	SE0013975	EA0013975	FONSI0013975
Republic Tobacco, LP	OCB Xpert XXL	Roll-Your-Own Tobacco	2/2/2018	SE0013976	EA0013976	FONSI0013976

CTP TRAINING

Product-specific tools

E-liquids

If you are a manufacturer of e-liquids, with a large number of products that require ingredient listing submissions, consider using:

Webinars for Ingredient Listing Submissions

Examples of Ingredient Listing Spreadsheets by Product Category (33:23)

Using a TPMF for Ingredient Listing Submissions (12:01)

Using FDA Tools to Submit Ingredient Listings Electronically (9:05)

If you are a manufacturer of any tobacco product and are preparing to submit ingredient listings for your products, consider using:

- Alternative format spreadsheet for any tobacco product (also available in eSubmitter) (XLS)
- Points to consider and step-by-step instructions for using the any tobacco product spreadsheet (PDF)

Navigate the Tobacco Products Section

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Newsroom
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2018 Webinars

Retailer Requirements: New Warning Statement Requirements For Certain Tobacco Products (8:40)
Download Slides

FDA Tobacco Compliance Webinars Tips for Retailers: Preventing Sales to Minors (21:24)
Download Slides

Importing Tobacco Products: Updates for Importers (13:52)
Download Slides

Tobacco Product Listing Updates (7:07)
Download Slides

Standalone Grandfathered Submissions (25:31)
Download Slides

2017 Webinars

Small Tobacco Product Manufacturers, Domestic Establishment Inspections (19:01)
Download Slides

A Retailer's Guide to 'Covered' Tobacco Products Webinar (15:29)

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Tobacco Product Application Review - A Public Meeting

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October 22-23, 2018
8:30 a.m. to 4:30 p.m. on October 22, and 8:30 to 3 p.m. on October 23

New location
Hilton Washington DC/Rockville Hotel & Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852

Meeting Objective:

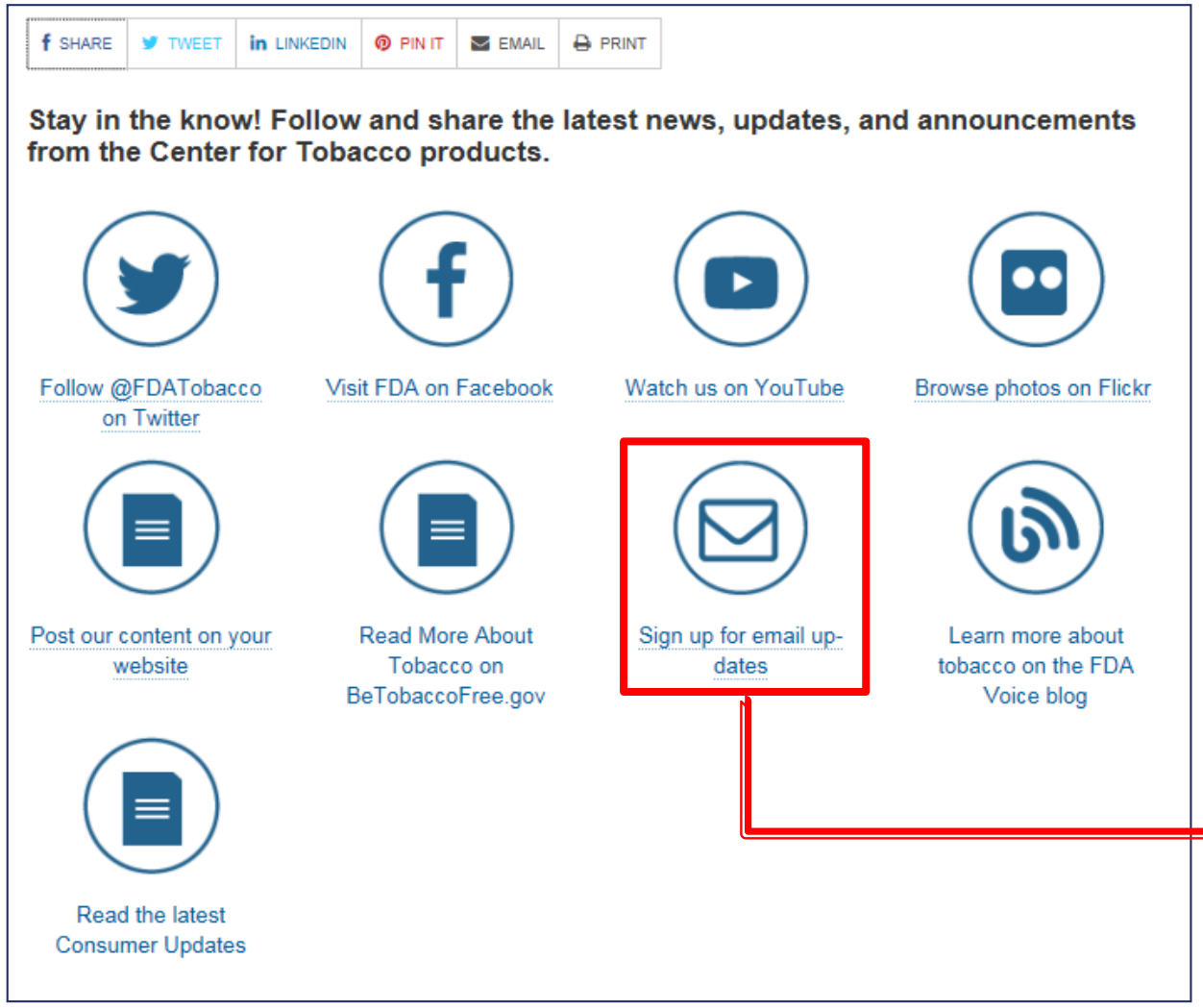
This meeting is intended to improve public understanding and seek feedback on the policies and processes for the submission and review of tobacco product marketing applications, including the general scientific principles relevant to various application pathways, in order to assist persons considering submitting marketing applications for tobacco products under the Federal Food, Drug, and Cosmetic Act (FD&C Act):

- Substantial Equivalence Reports (SE Reports) – Section 905(j)
- Exemption Requests (Ex Reqs) – Section 905(j)
- Premarket Tobacco Product Applications (PMTAs) – Section 910
- Modified Risk Tobacco Product Applications (MRPTAs) – Section 911

Topics to be addressed in the meeting include:

- Overview of the tobacco product marketing applications types
- Information that should be included in a tobacco product marketing application
- Administrative processes involved in the submission and review of a tobacco product marketing application
- Other topics relevant to the submission of tobacco product marketing applications, including Tobacco Product Master Files, meeting requests, Grandfathered review, and Environmental Assessments

CONNECT WITH CTP



- CTP News
- CTP*Connect*
- Spotlight on Science
- Modified Risk Tobacco Product Application Updates

Contact FDA

1-877-287-1373
(9am EST-4pm EST)

Tobacco
For General Inquiries:
AskCTP@fda.hhs.gov

Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center
Building 71, Room G335
Silver Spring, MD 20993-002

Courier Deliveries

Email

- General Consumer Inquiries: AskCTP@fda.hhs.gov
- Tobacco Industry: TobaccoIndustryQuestions@fda.hhs.gov
- Small Business (OSBA): SmallBiz.Tobacco@fda.hhs.gov
- Stakeholder Inquiries: CTP-StakeholderRelations@fda.hhs.gov
- Formal Correspondence and Speech & Meeting Requests: CTPexecsec@fda.hhs.gov
  » Meeting Guidance
- Complaints and disputes: CTPombudsman@fda.hhs.gov
  » CTP Ombudsman

To report problems with tobacco products, go to the Safety Reporting Portal

Write

Center for Tobacco Products
Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

Courier Deliveries
Delivery hours are 8 a.m.–4 p.m. Deliveries received after 4 p.m. will be date-stamped the next business day.
For delivery questions (couriers only), call 301-796-9270.

THE END

Thank you!