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.
• Regulatory Information
  o Guidance and regulations
  o Documents available for public comment

• Marketing Orders
  o Technical Project Lead (TPL) Reviews & Order letters
  o Environmental Assessments/Finding Of No Significant Impact

• Training
  o Webinars, presentations, workshops
  o 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.

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

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.

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.

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

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

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

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 docketson 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.
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name and Order Letter</th>
<th>Product Category</th>
<th>Date Issued</th>
<th>Decision Summary</th>
<th>EA/Catex/NEPA Memo</th>
<th>Finding of No Significant Impact (FONSi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Republic Tobacco, LP</td>
<td>OCB Xpert Blue</td>
<td>Roll-Your-Own Tobacco</td>
<td>2/2/2018</td>
<td>SE0013974</td>
<td>EA0013974</td>
<td>FONSI0013974</td>
</tr>
<tr>
<td>Republic Tobacco, LP</td>
<td>OCB Xpert Double</td>
<td>Roll-Your-Own Tobacco</td>
<td>2/2/2018</td>
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<td>EA0013975</td>
<td>FONSI0013975</td>
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<tr>
<td>Republic Tobacco, LP</td>
<td>OCB Xpert XXL</td>
<td>Roll-Your-Own Tobacco</td>
<td>2/2/2018</td>
<td>SE0013976</td>
<td>EA0013976</td>
<td>FONSI0013976</td>
</tr>
</tbody>
</table>
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)
Tobacco Product Application Review - A Public Meeting

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
- CTPConnect
- Spotlight on Science
- Modified Risk Tobacco Product Application Updates
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

Write

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

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.
Thank you!