THE CTP WEBSITE: WHAT'S NEW

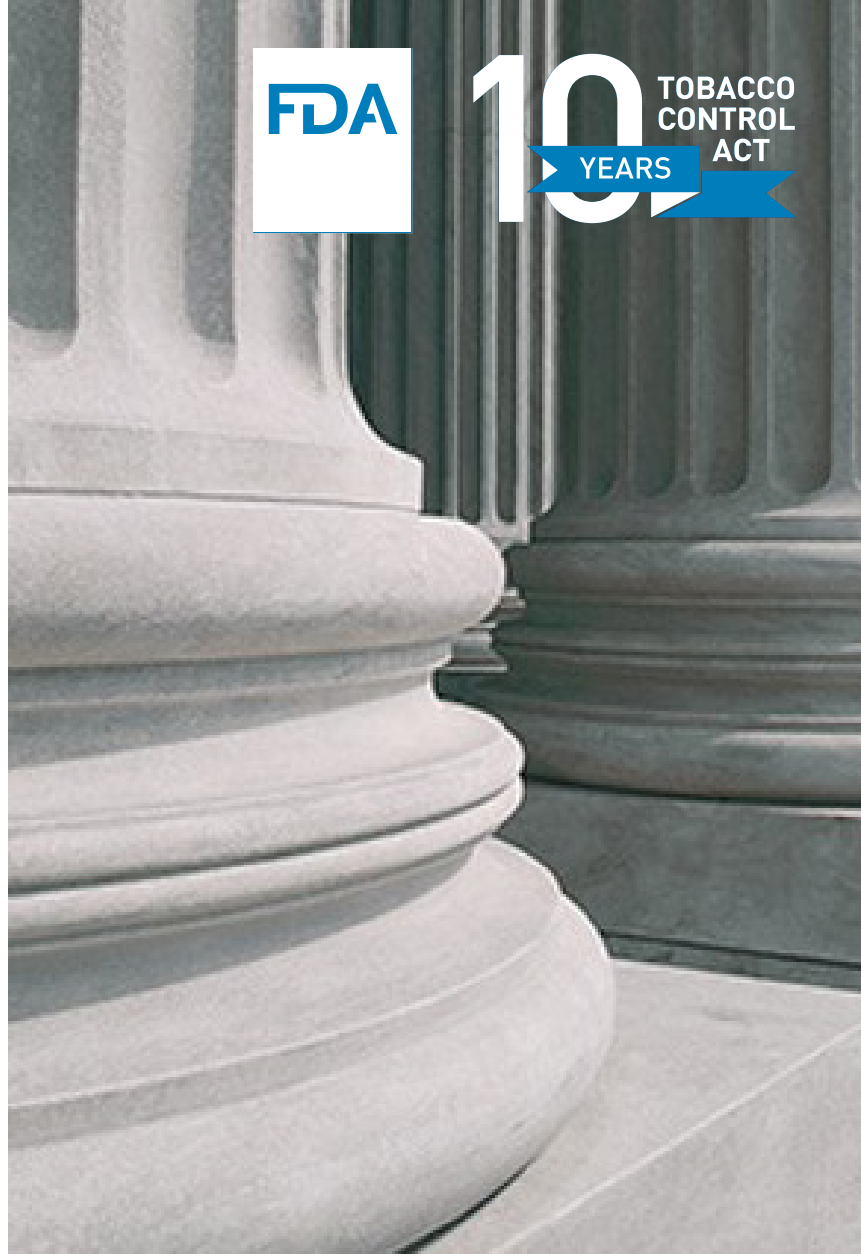
Presented by
Stephanie Redus, M.S.
Senior Regulatory Health Project Manager
Office of Science, DRPM, CTP, FDA

CENTER FOR TOBACCO PRODUCTS

THE CTP WEBSITE: WHAT'S NEW

Presented by
Stephanie Redus, M.S.
Senior Regulatory Health Project Manager
Office of Science, DRPM, CTP, FDA

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



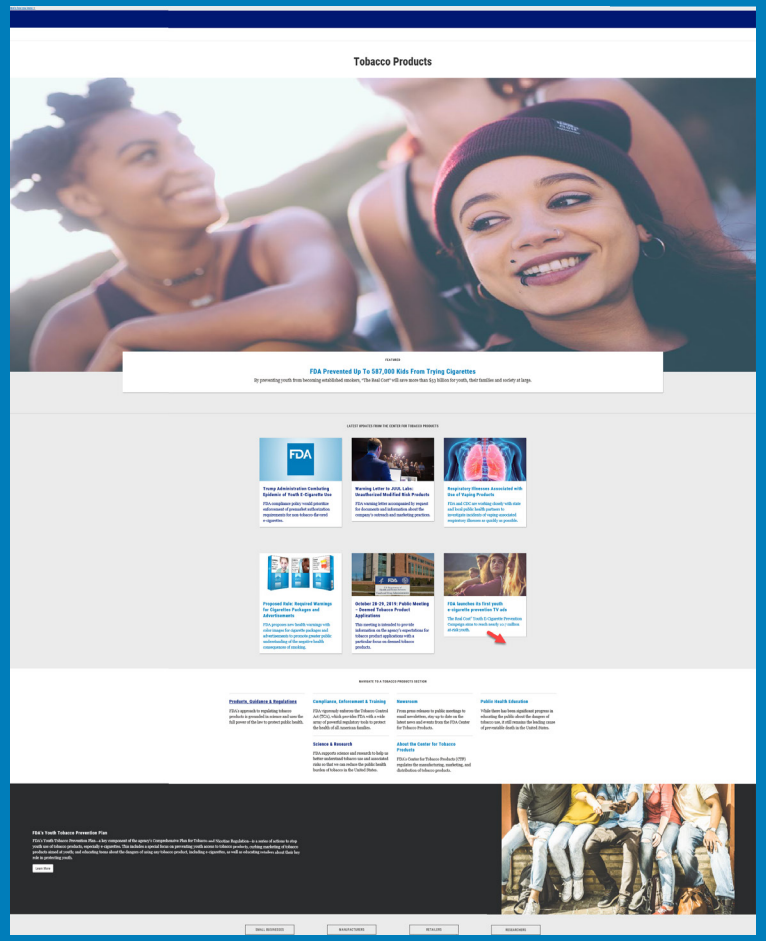
AGENDA

- Changes
- Featured content
- New content and updated site pages
- Contacting CTP

CHANGES

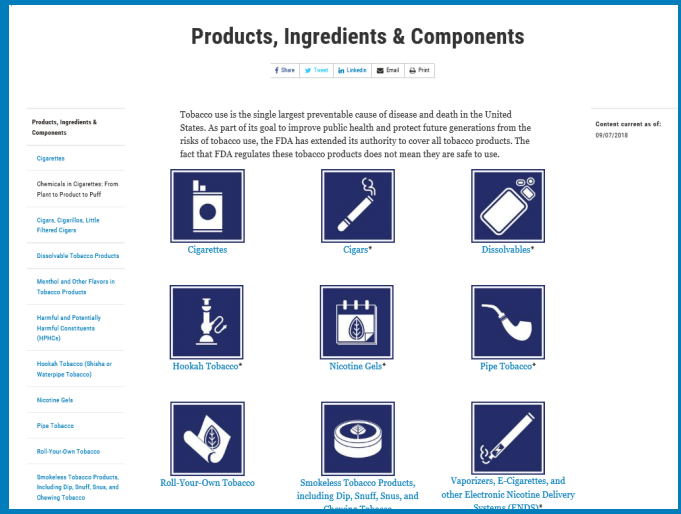
WHAT HAS CHANGED?

- New Platform
  - Handles content in a way that makes it easily accessed and shared in the many platforms that our audiences use (website, social media and applications)
  - Establishes a foundation for future enhancements and meets new federal, HHS, and FDA requirements

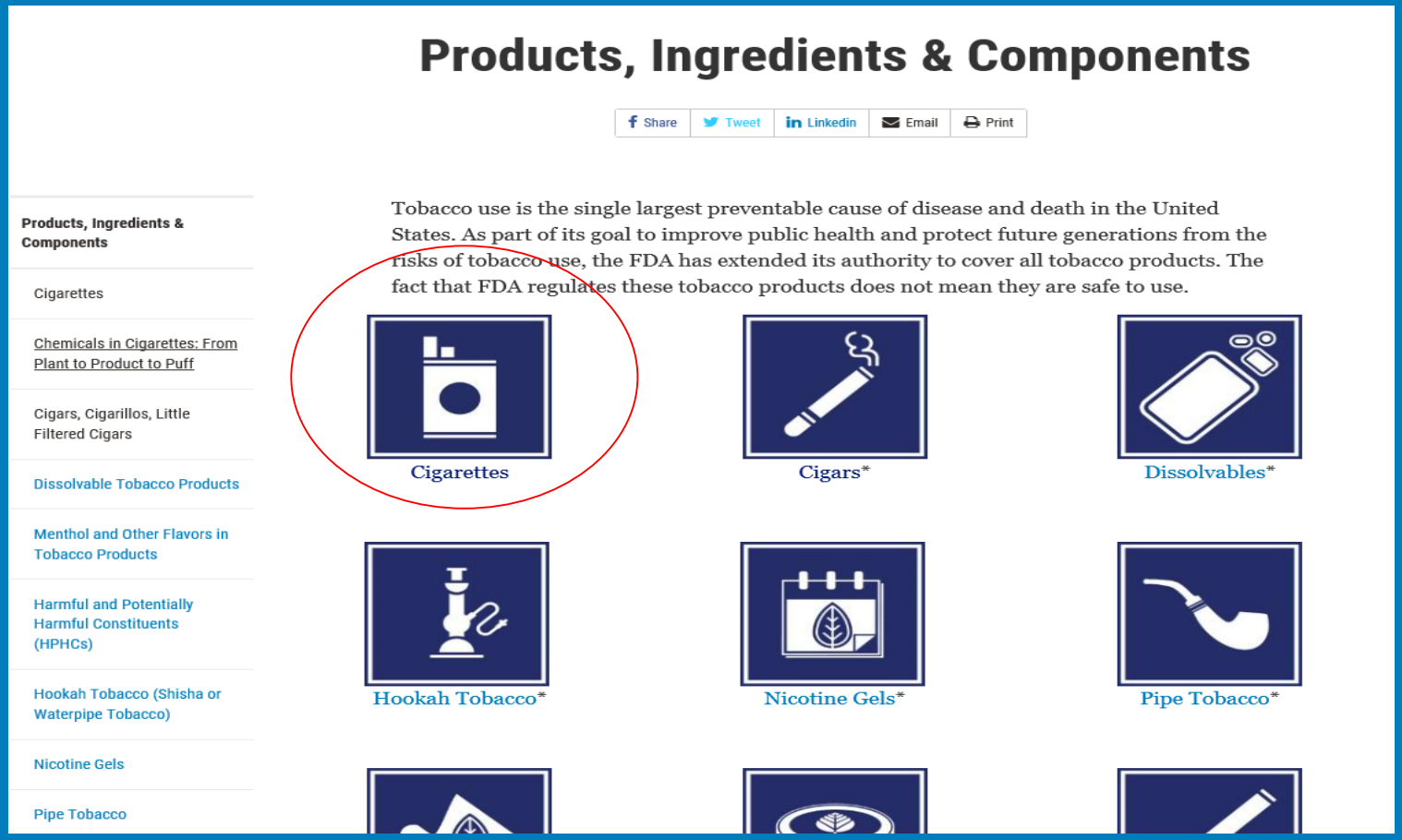


WHAT HAS CHANGED?

- New Design
  - Adopts a “mobile-first/responsive approach” and is focused on helping users complete tasks easily
  - Based on thorough review of web analytics, internal/external user experience (UX) sessions, and current research finding to better understand how visitors interact with our website
  - More User friendly with content discovery to “show and tell”, using more images, visual elements and short description to highlight information



WHAT HAS CHANGED?



Products, Ingredients & Components

Share | Tweet | Linkedin | Email | Print

Products, Ingredients & Components

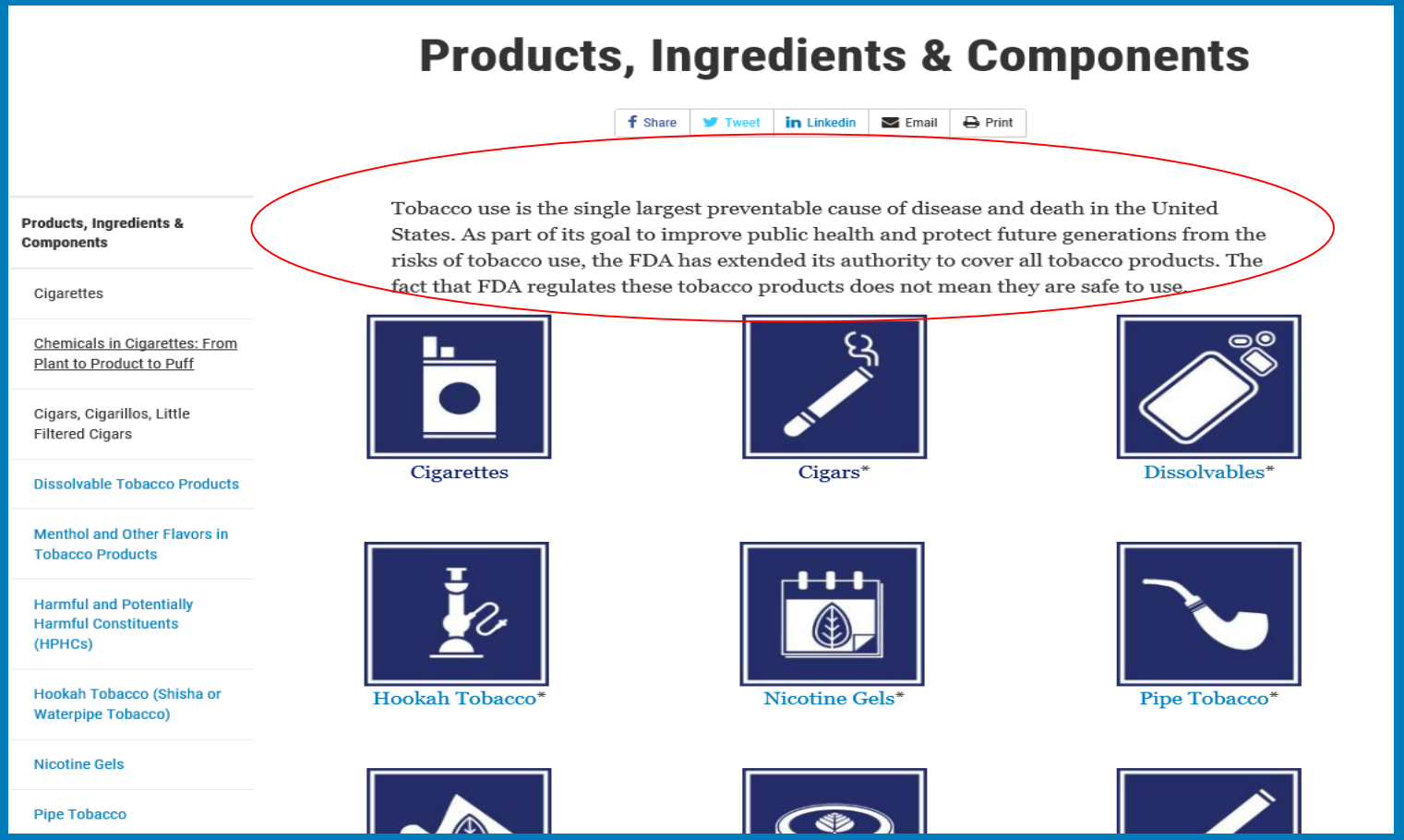
- Cigarettes
- Chemicals in Cigarettes: From Plant to Product to Puff
- Cigars, Cigarillos, Little Filtered Cigars
- Dissolvable Tobacco Products
- Menthol and Other Flavors in Tobacco Products
- Harmful and Potentially Harmful Constituents (HPHCs)
- Hookah Tobacco (Shisha or Waterpipe Tobacco)
- Nicotine Gels
- Pipe Tobacco

Tobacco use is the single largest preventable cause of disease and death in the United States. As part of its goal to improve public health and protect future generations from the risks of tobacco use, the FDA has extended its authority to cover all tobacco products. The fact that FDA regulates these tobacco products does not mean they are safe to use.

Cigarettes | Cigars* | Dissolvables*

Hookah Tobacco* | Nicotine Gels* | Pipe Tobacco*

WHAT HAS CHANGED?



Products, Ingredients & Components

Share | Tweet | Linkedin | Email | Print

Products, Ingredients & Components

- Cigarettes
- Chemicals in Cigarettes: From Plant to Product to Puff
- Cigars, Cigarillos, Little Filtered Cigars
- Dissolvable Tobacco Products
- Menthol and Other Flavors in Tobacco Products
- Harmful and Potentially Harmful Constituents (HPHCs)
- Hookah Tobacco (Shisha or Waterpipe Tobacco)
- Nicotine Gels
- Pipe Tobacco

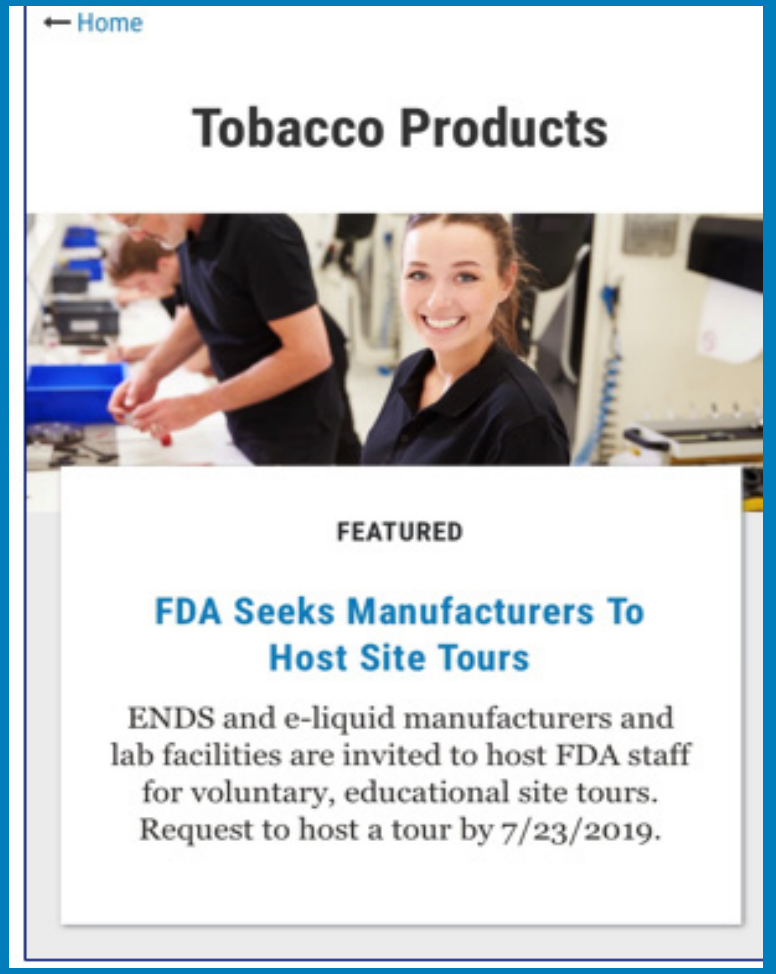
Tobacco use is the single largest preventable cause of disease and death in the United States. As part of its goal to improve public health and protect future generations from the risks of tobacco use, the FDA has extended its authority to cover all tobacco products. The fact that FDA regulates these tobacco products does not mean they are safe to use.

Cigarettes | Cigars* | Dissolvables*

Hookah Tobacco* | Nicotine Gels* | Pipe Tobacco*

WHAT HAS CHANGED?

- Mobile vs. Desktop view
  - Very similar views on both

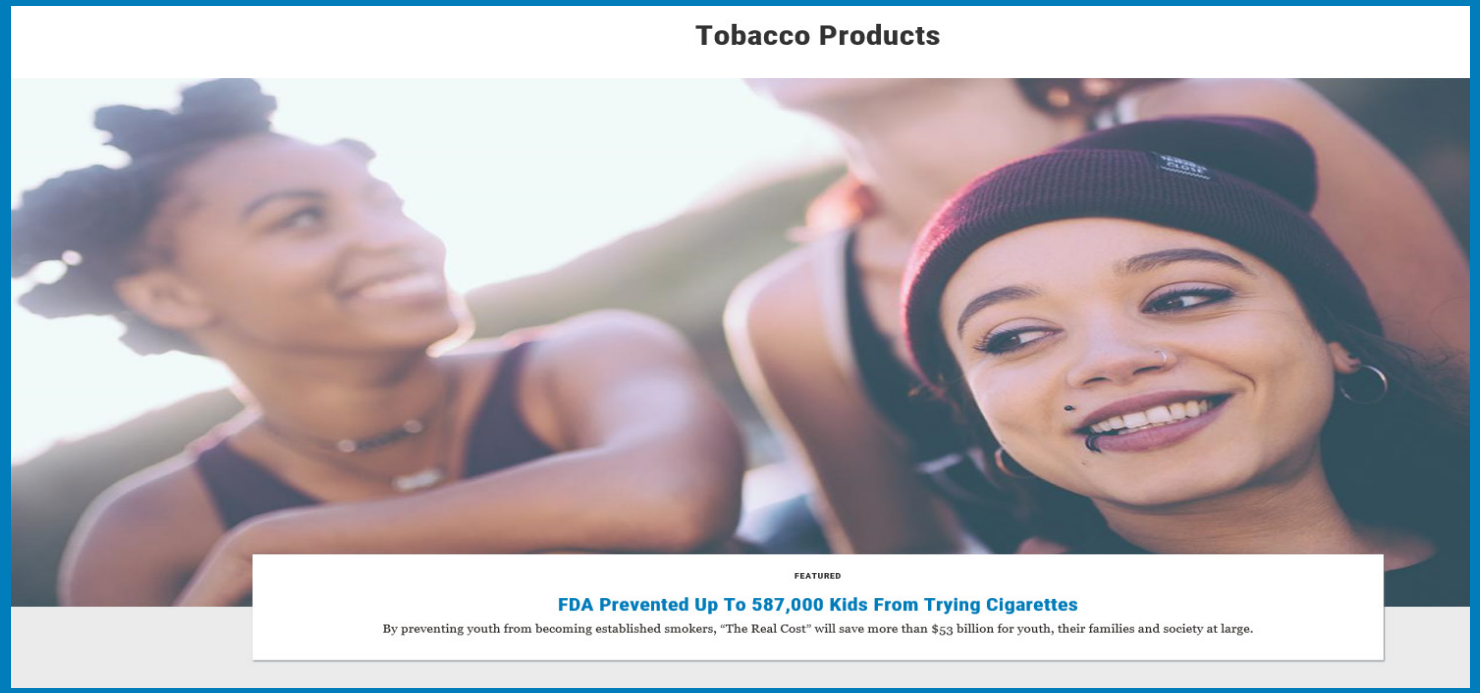


WHAT HAS CHANGED?

- Information layout

WHAT HAS CHANGED?

- Information layout
  - Featured information

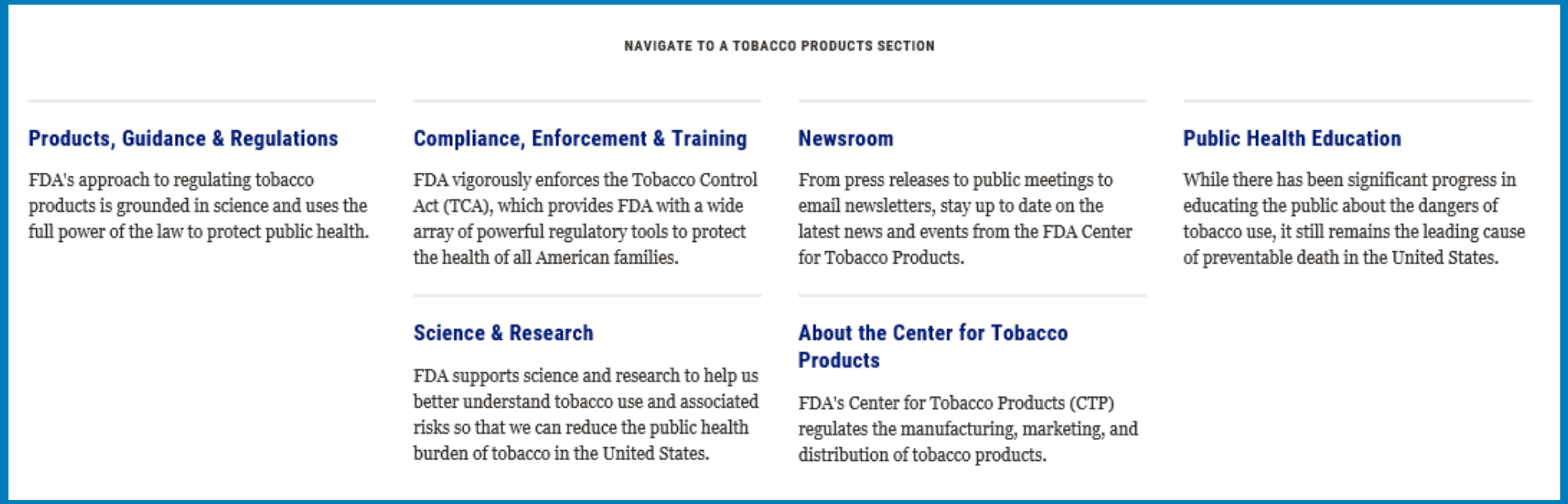


WHAT HAS CHANGED?

- Information layout
  - Featured information
  - Latest updates from the center

WHAT HAS CHANGED?

- Information layout
  - Featured information
  - Latest updates from the center
  - Navigate to a Tobacco Products Section



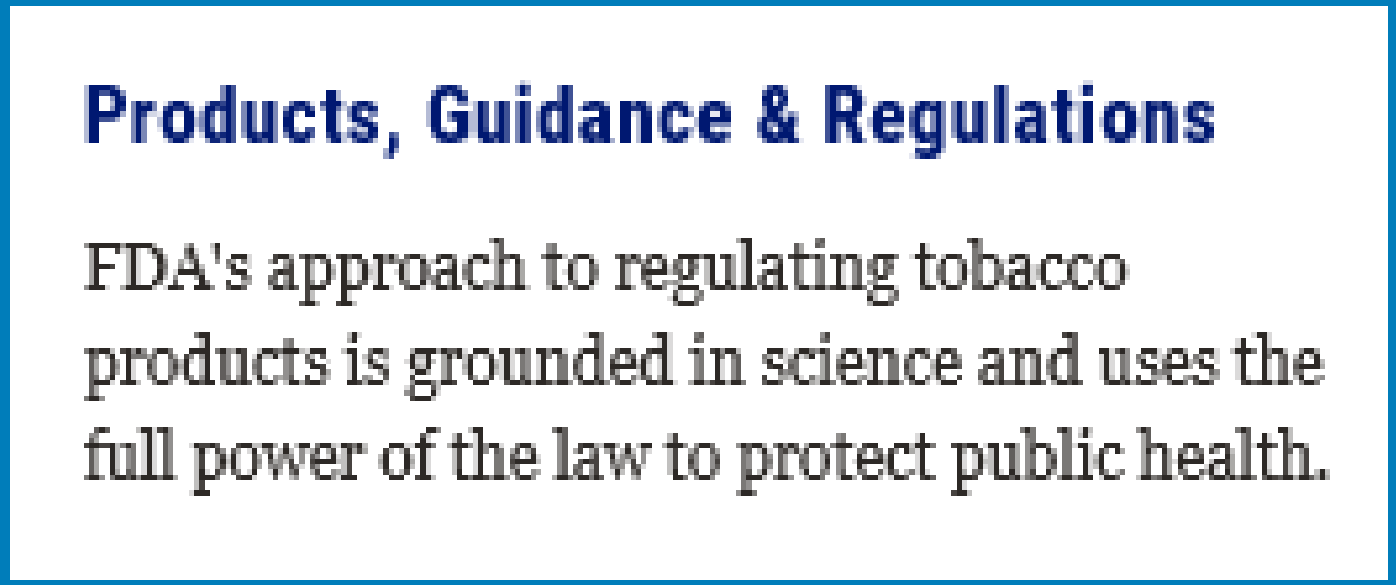
FEATURED CONTENT

CONTENT: TOBACCO PRODUCTS SECTION

- Overall structure and content is the exact same

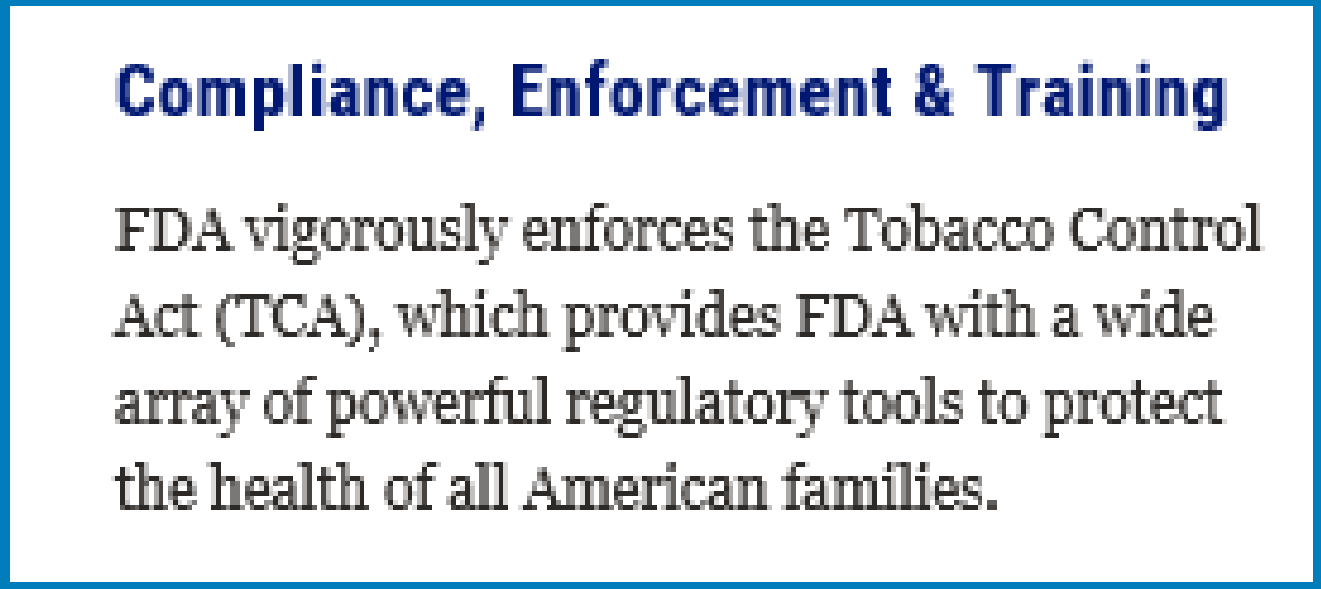
CONTENT: TOBACCO PRODUCTS SECTION

- Overall structure and content is the exact same
  - Products, Guidance & Regulation



CONTENT: TOBACCO PRODUCTS SECTION

- Overall structure and content is the exact same
  - Products, Guidance & Regulation
  - Compliance, Enforcement & Training

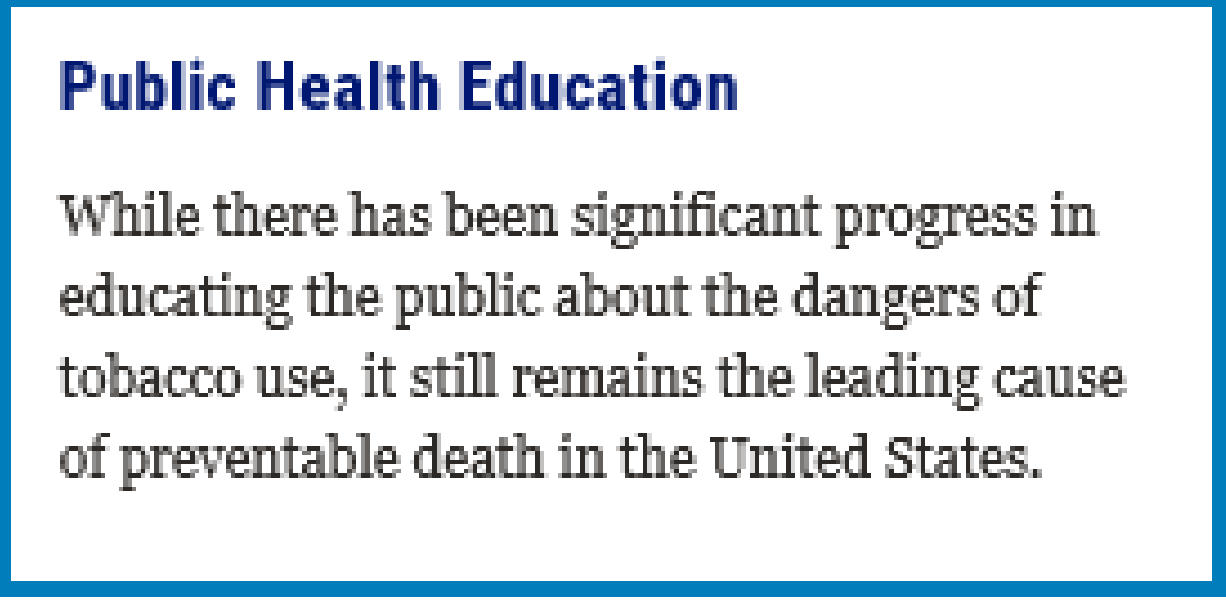


CONTENT: TOBACCO PRODUCTS SECTION

- Overall structure and content is the exact same
  - Products, Guidance & Regulation
  - Compliance, Enforcement & Training
  - Newsroom

CONTENT: TOBACCO PRODUCTS SECTION

- Overall structure and content is the exact same
  - Products, Guidance & Regulation
  - Compliance, Enforcement & Training
  - Newsroom
  - Public Health Education

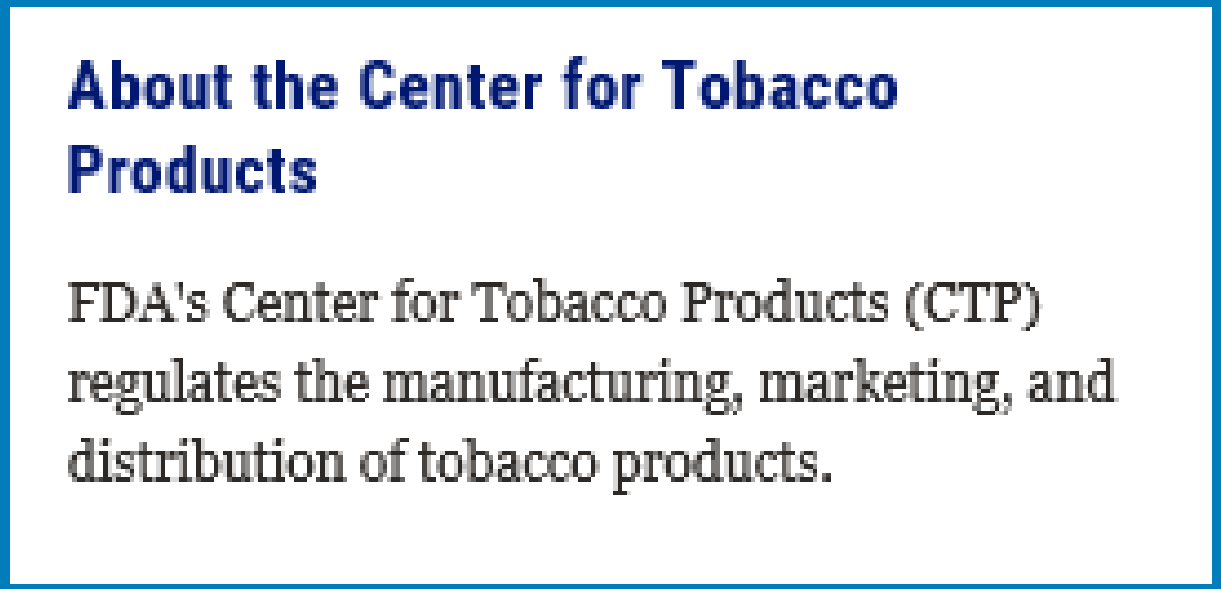


CONTENT: TOBACCO PRODUCTS SECTION

- Overall structure and content is the exact same
  - Products, Guidance & Regulation
  - Compliance, Enforcement & Training
  - Newsroom
  - Public Health Education
  - Science & Research

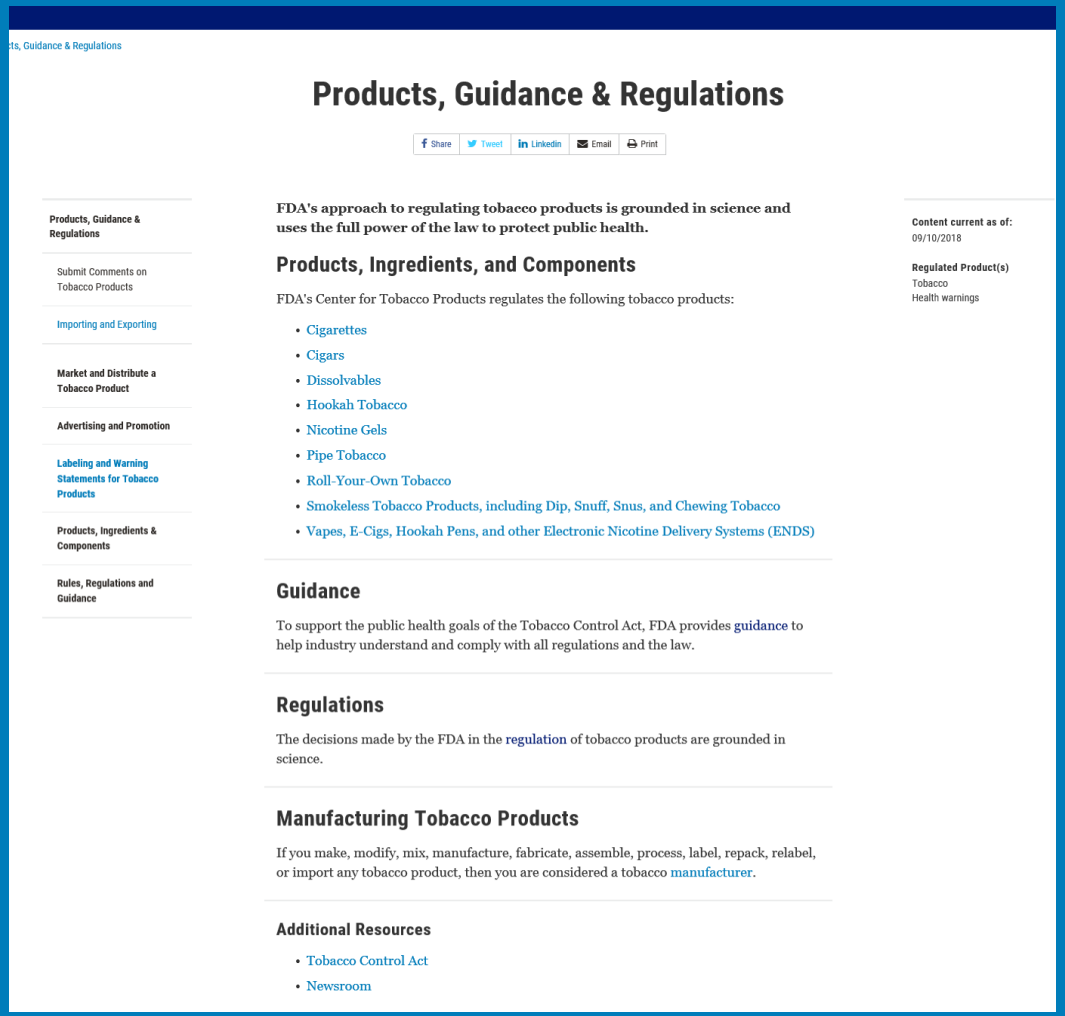
CONTENT: TOBACCO PRODUCTS SECTION

- Overall structure and content is the exact same
  - Products, Guidance & Regulation
  - Compliance, Enforcement & Training
  - Newsroom
  - Public Health Education
  - Science & Research
  - About CTP



CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Guidance & Regulation



ts, Guidance & Regulations

Products, Guidance & Regulations

Share Tweet LinkedIn Email Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

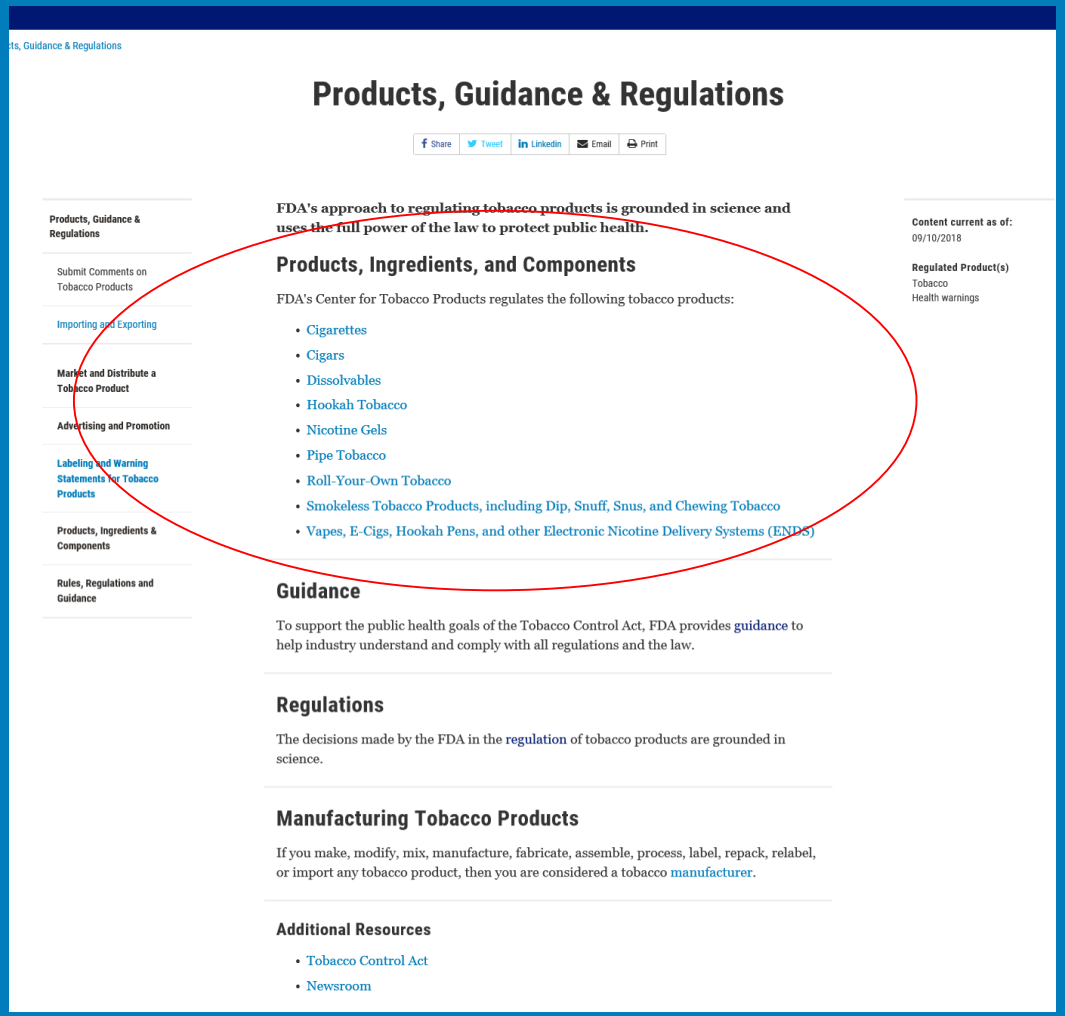
- Tobacco Control Act
- Newsroom

Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Guidance & Regulation
  - Products, Ingredients, and Components



ts, Guidance & Regulations

Products, Guidance & Regulations

Share Tweet Linkedin Email Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

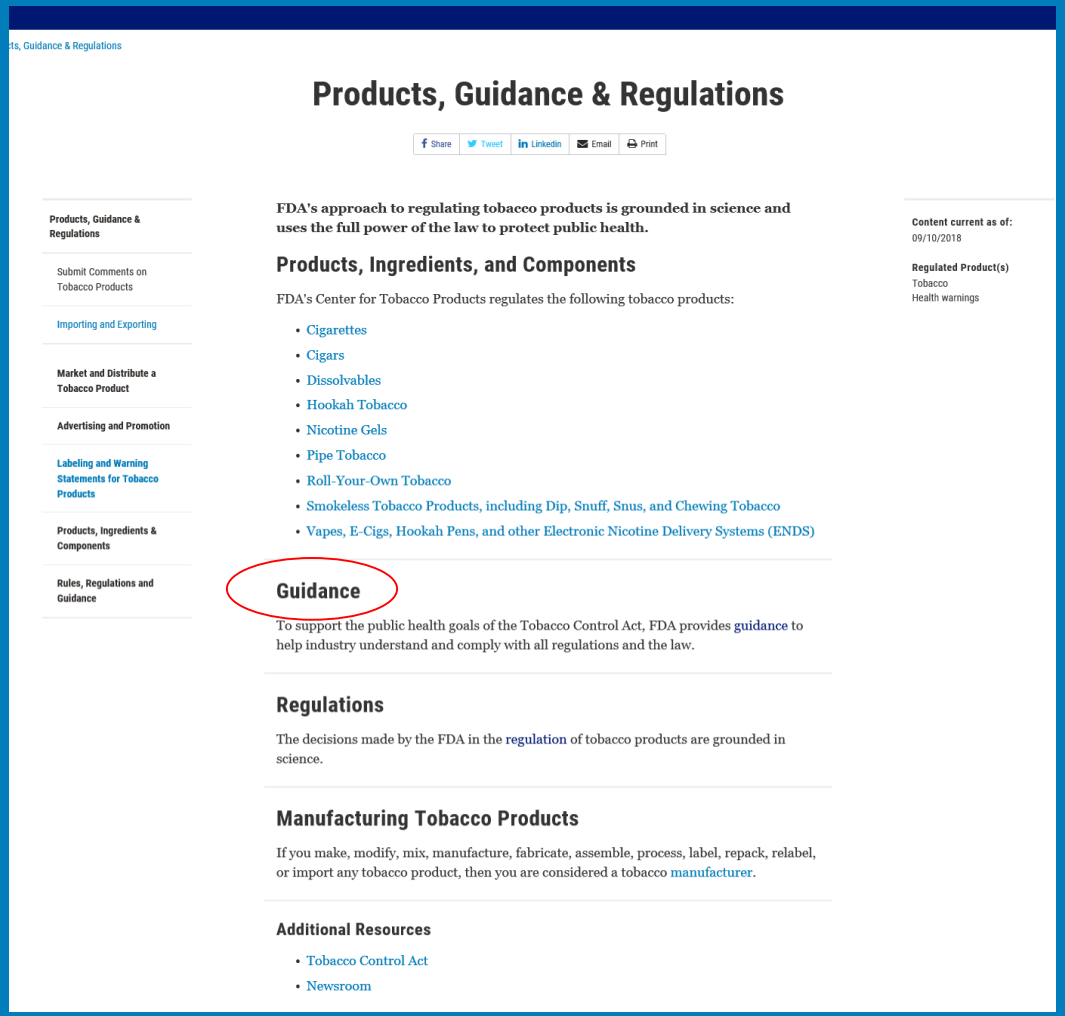
- Tobacco Control Act
- Newsroom

Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Guidance & Regulation
  - Products, Ingredients, and Components
  - Guidance's documents



ts, Guidance & Regulations

Products, Guidance & Regulations

Share | Tweet | LinkedIn | Email | Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

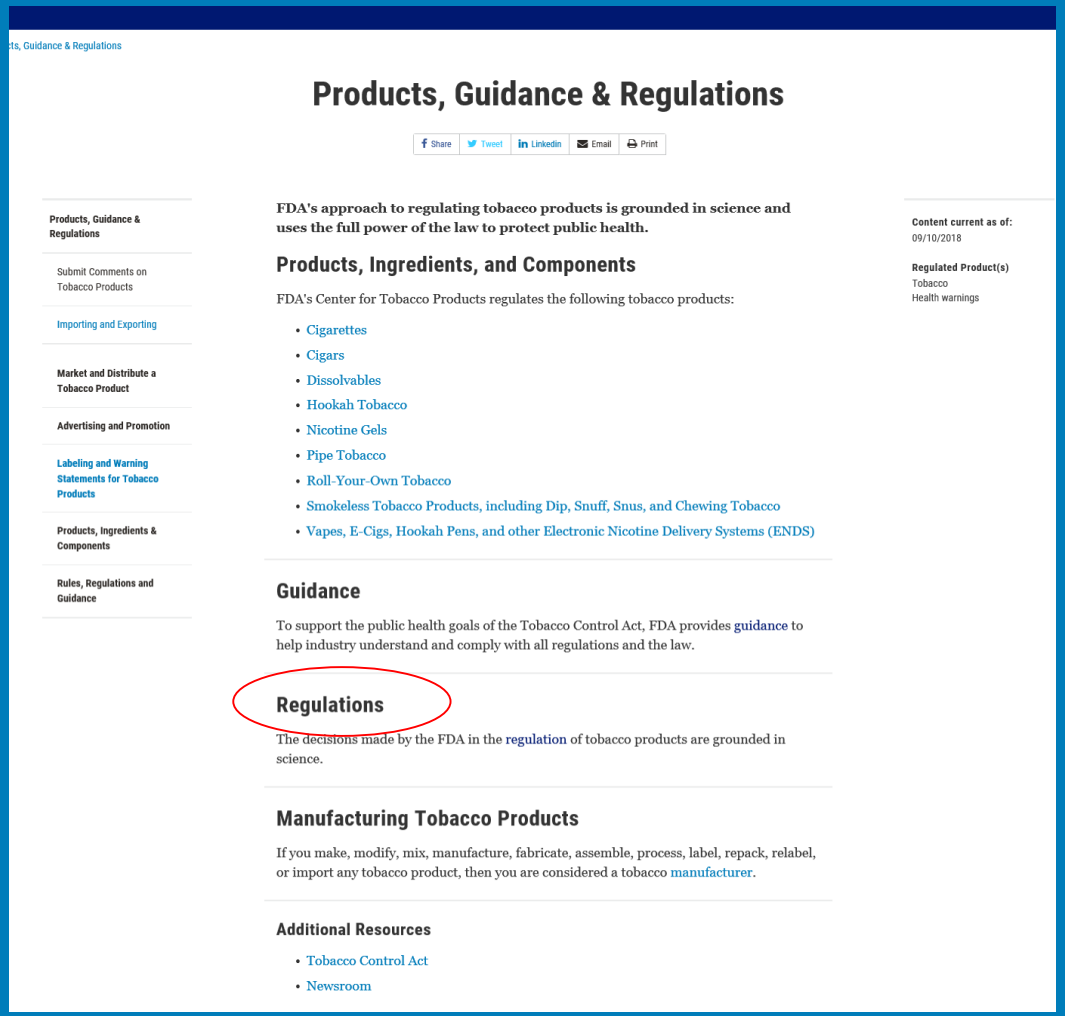
- Tobacco Control Act
- Newsroom

Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Guidance & Regulation
  - Products, Ingredients, and Components
  - Guidance's documents
  - Regulation documents



ts, Guidance & Regulations

Products, Guidance & Regulations

Share | Tweet | LinkedIn | Email | Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

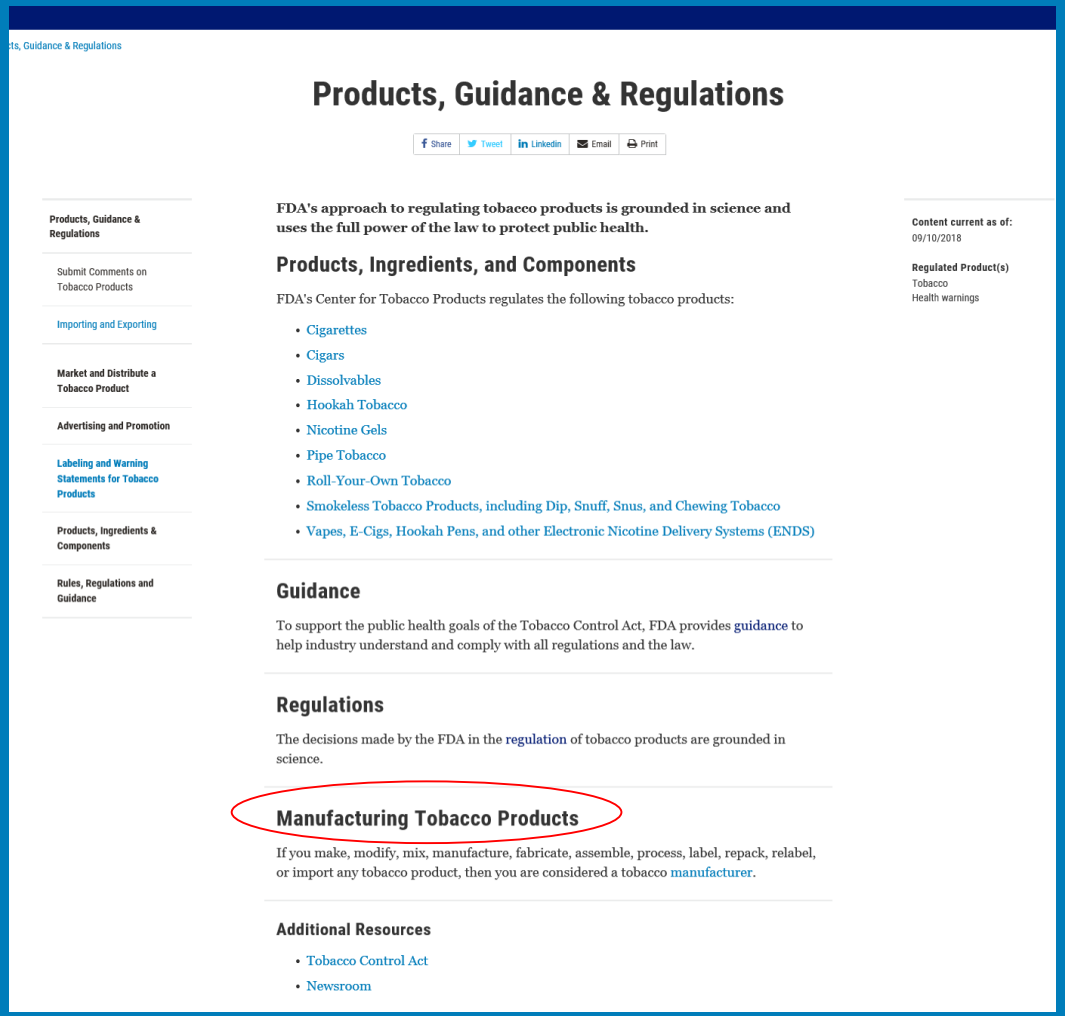
- Tobacco Control Act
- Newsroom

Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Guidance & Regulation
  - Products, Ingredients, and Components
  - Guidance's documents
  - Regulation documents
  - Manufacturing information



ts, Guidance & Regulations

Products, Guidance & Regulations

Share | Tweet | LinkedIn | Email | Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

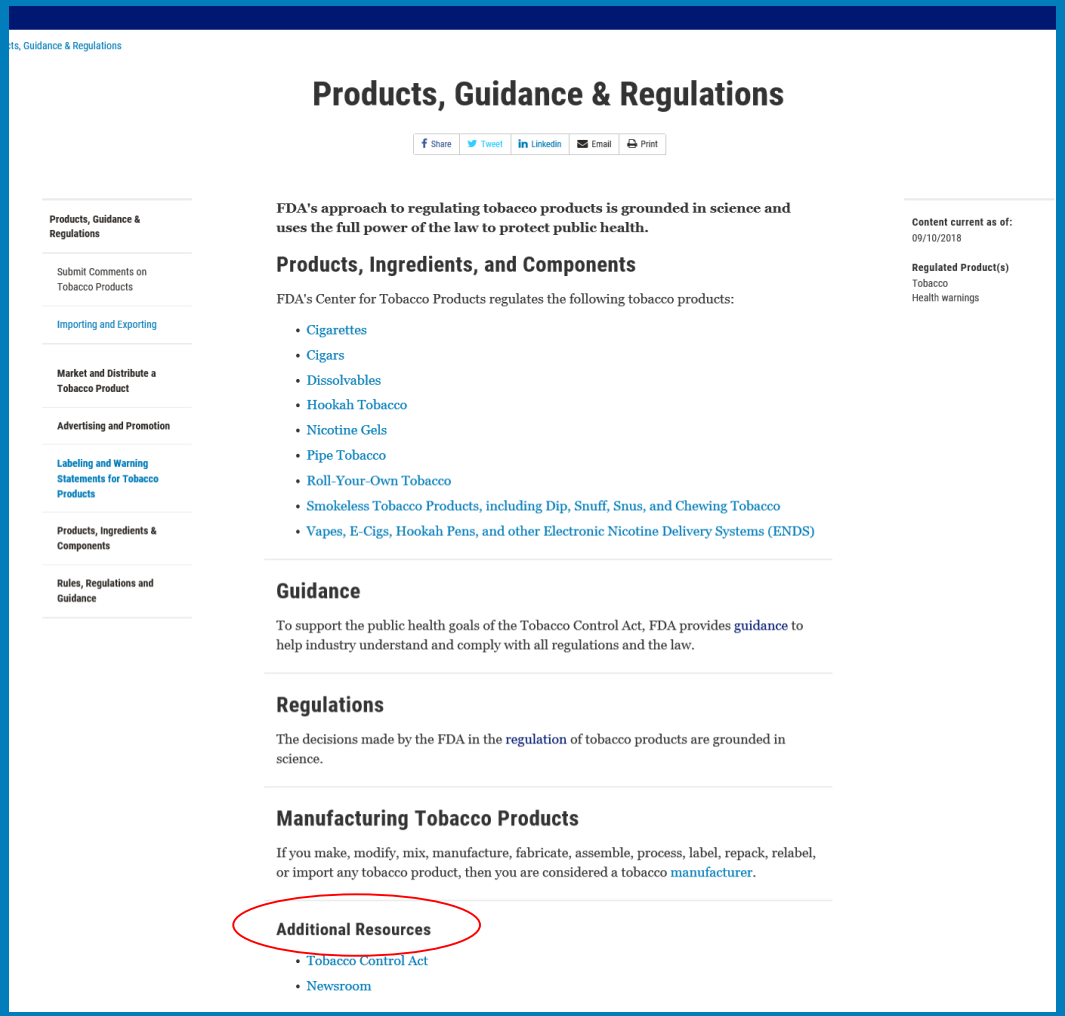
- Tobacco Control Act
- Newsroom

Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Guidance & Regulation
  - Products, Ingredients, and Components
  - Guidance's documents
  - Regulation documents
  - Manufacturing information
  - Additional resources



ts, Guidance & Regulations

Products, Guidance & Regulations

Share | Tweet | Linkedin | Email | Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

- Tobacco Control Act
- Newsroom

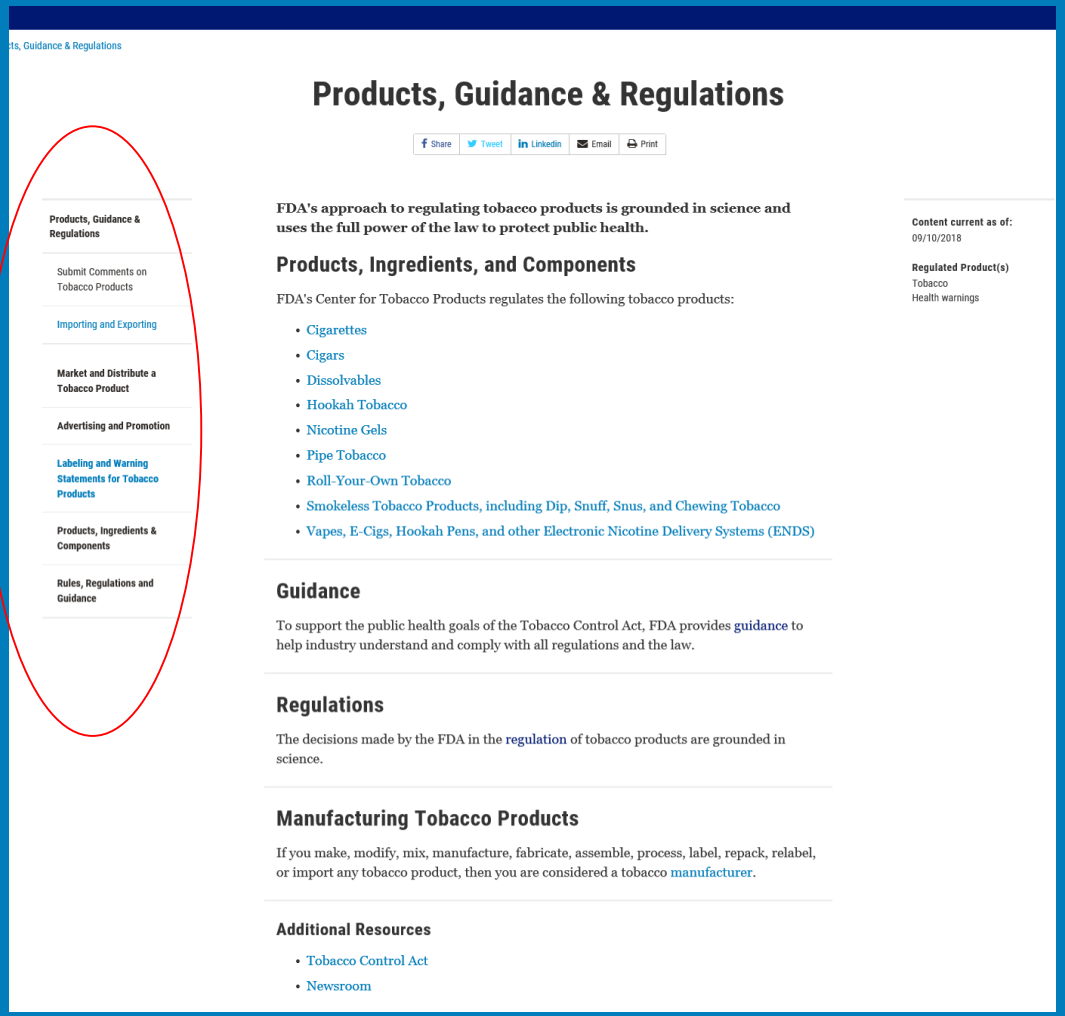
Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Guidance & Regulation
  - Products, Ingredients, and Components
  - Guidance's documents
  - Regulation documents
  - Manufacturing information
  - Additional resources

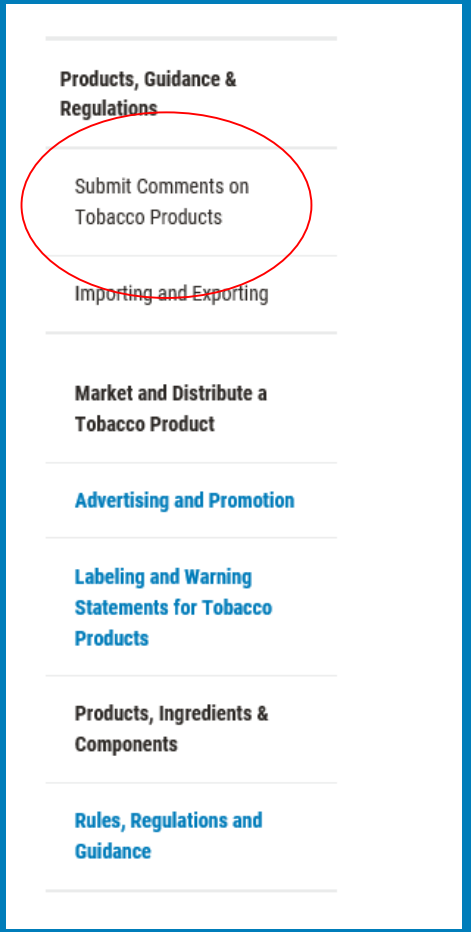
– Side menu



CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

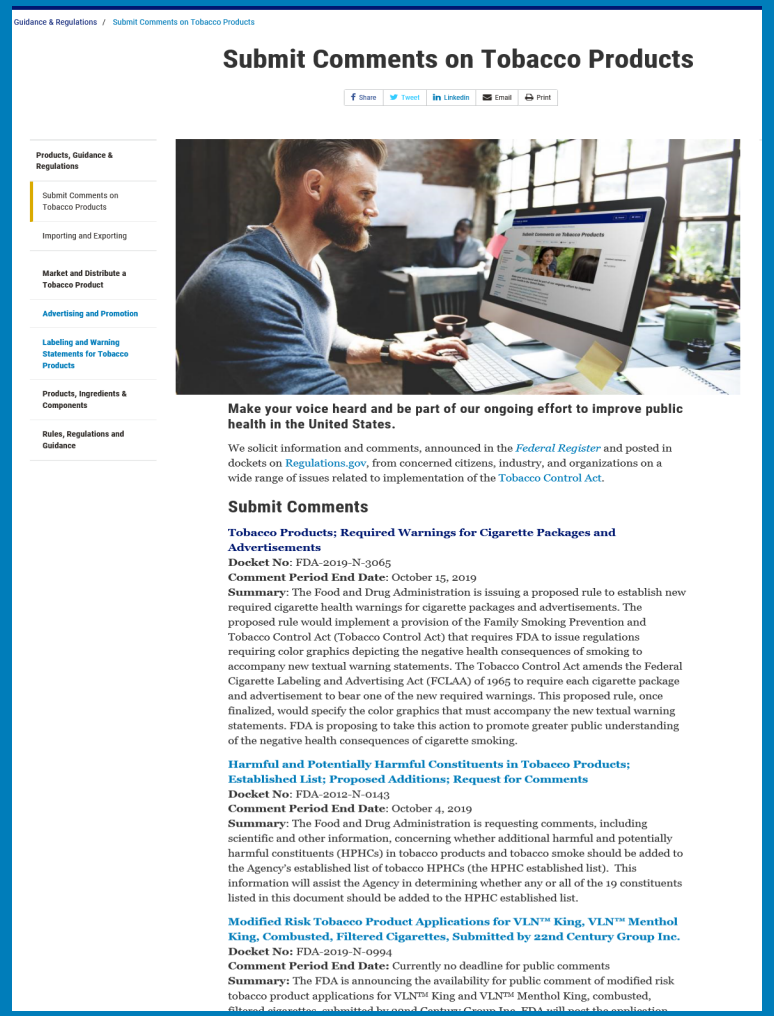
- Products, Guidance & Regulation
  - Products, Ingredients, and Components
  - Guidance's documents
  - Regulation documents
  - Manufacturing information
  - Additional resources

– Side menu



CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments



Guidance & Regulations / Submit Comments on Tobacco Products

Submit Comments on Tobacco Products

Share | Tweet | LinkedIn | Email | Print

Products, Guidance & Regulations

- Submit Comments on Tobacco Products
- Importing and Exporting
- Market and Distribute a Tobacco Product
- Advertising and Promotion
- Labeling and Warning Statements for Tobacco Products
- Products, Ingredients & Components
- Rules, Regulations and Guidance

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 Products; Required Warnings for Cigarette Packages and Advertisements
Docket No: FDA-2019-N-3065
Comment Period End Date: October 15, 2019
Summary: The Food and Drug Administration is issuing a proposed rule to establish new required cigarette health warnings for cigarette packages and advertisements. The proposed rule would implement a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. This proposed rule, once finalized, would specify the color graphics that must accompany the new textual warning statements. FDA is proposing to take this action to promote greater public understanding of the negative health consequences of cigarette smoking.

Harmful and Potentially Harmful Constituents in Tobacco Products; Established List; Proposed Additions; Request for Comments
Docket No: FDA-2012-N-0143
Comment Period End Date: October 4, 2019
Summary: The Food and Drug Administration is requesting comments, including scientific and other information, concerning whether additional harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke should be added to the Agency's established list of tobacco HPHCs (the HPHC established list). This information will assist the Agency in determining whether any or all of the 19 constituents listed in this document should be added to the HPHC established list.

Modified Risk Tobacco Product Applications for VLN™ King, VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group Inc.
Docket No: FDA-2019-N-0994
Comment Period End Date: Currently no deadline for public comments
Summary: The FDA is announcing the availability for public comment of modified risk tobacco product applications for VLN™ King and VLN™ Menthol King, combusted,

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments
  - Proposed rules

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

Docket No: FDA-2019-N-3065

Comment Period End Date: October 15, 2019

Summary: The Food and Drug Administration is issuing a proposed rule to establish new required cigarette health warnings for cigarette packages and advertisements. The proposed rule would implement a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. This proposed rule, once finalized, would specify the color graphics that must accompany the new textual warning statements. FDA is proposing to take this action to promote greater public understanding of the negative health consequences of cigarette smoking.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments
  - Proposed rules
  - MRTPAs

Modified Risk Tobacco Product Applications for VLN™ King, VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group Inc.

Docket No: FDA-2019-N-0994

Comment Period End Date: Currently no deadline for public comments

Summary: The FDA is announcing the availability for public comment of modified risk tobacco product applications for VLN™ King and VLN™ Menthol King, combusted, filtered cigarettes, submitted by 22nd Century Group Inc. FDA will post the application materials on a rolling basis as they are redacted in accordance with applicable laws.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments
  - Proposed rules
  - MRTPAs

What makes an effective and useful comment?

Our decisions are based on science and law. We look for logic, good science, and other evidence in the comments we evaluate.

- Provide a clear statement of whether you support or oppose the proposed rule or guidance.
- Include any of the following that support your position:
  - data
  - research
  - analysis
- Read more tips for submitting effective comments on the regulations.gov website.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments
  - Proposed rules
  - MRTPAs

Your role in shaping tobacco regulation

Our regulatory process generally follows these steps:

1. **Rule/Regulation Proposed**
   We publish a proposed rule in the *Federal Register*.
2. **Public Comments Considered**
   Our proposals generally have a 60-90 day review period.
3. **Final Rule Issued**
   After considering all comments, we issue a final rule.
4. **Compliance with New Rule Enforced**
   We must ensure that retailers and businesses comply with the regulation.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments
  - Proposed rules
  - MRTPAs

Modified Risk Tobacco Product Applications for VLN™ King, VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group Inc.

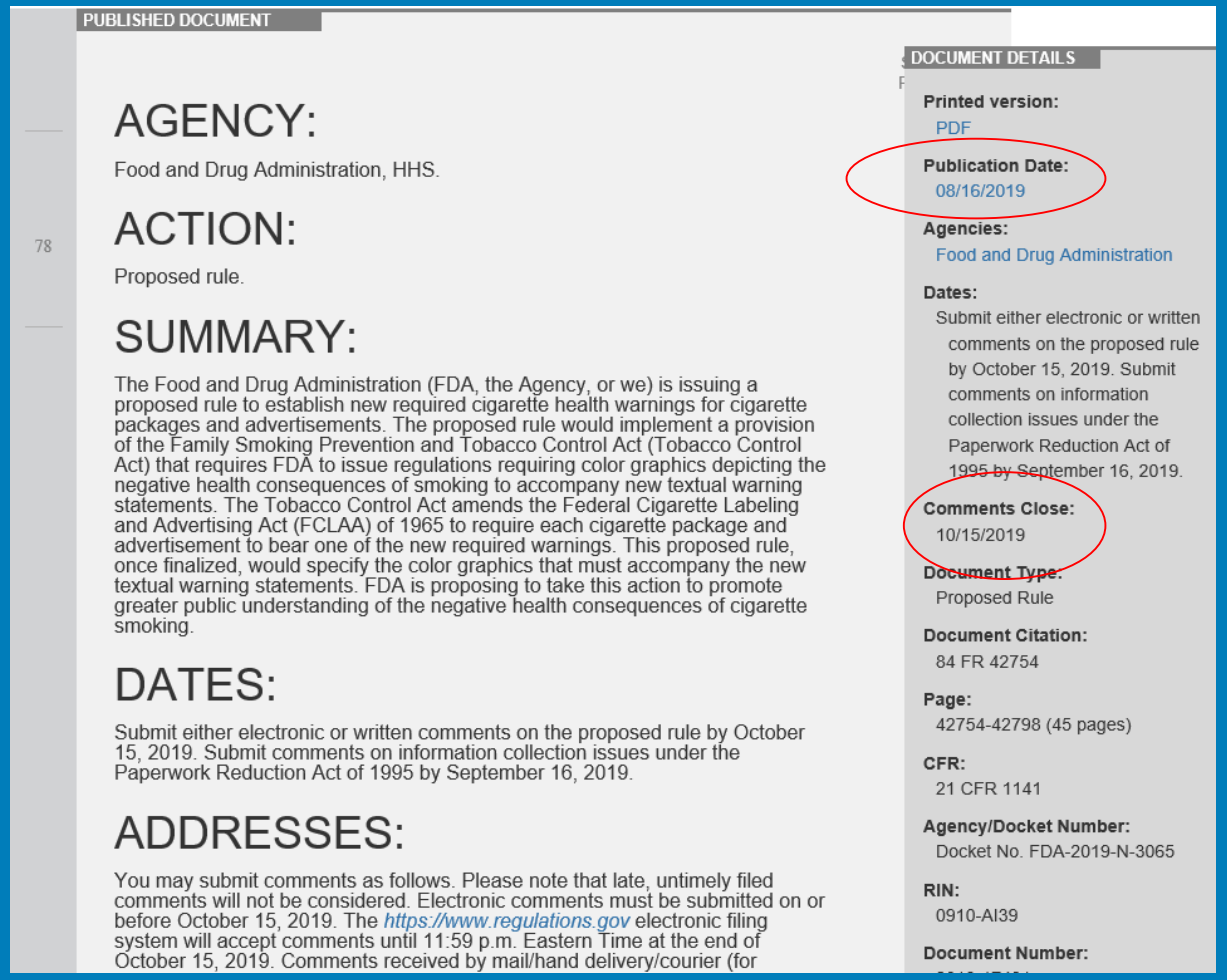
Docket No: FDA-2019-N-0994

Comment Period End Date: Currently no deadline for public comments

Summary: The FDA is announcing the availability for public comment of modified risk tobacco product applications for VLN™ King and VLN™ Menthol King, combusted, filtered cigarettes, submitted by 22nd Century Group Inc. FDA will post the application materials on a rolling basis as they are redacted in accordance with applicable laws.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments
  - Proposed rules
  - MRTPAs



PUBLISHED DOCUMENT

78

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Proposed rule.

SUMMARY:

The Food and Drug Administration (FDA, the Agency, or we) is issuing a proposed rule to establish new required cigarette health warnings for cigarette packages and advertisements. The proposed rule would implement a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. This proposed rule, once finalized, would specify the color graphics that must accompany the new textual warning statements. FDA is proposing to take this action to promote greater public understanding of the negative health consequences of cigarette smoking.

DATES:

Submit either electronic or written comments on the proposed rule by October 15, 2019. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by September 16, 2019.

ADDRESSES:

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 15, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 15, 2019. Comments received by mail/hand delivery/courier (for

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
08/16/2019

Agencies:
Food and Drug Administration

Dates:
Submit either electronic or written comments on the proposed rule by October 15, 2019. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by September 16, 2019.

Comments Close:
10/15/2019

Document Type:
Proposed Rule

Document Citation:
84 FR 42754

Page:
42754-42798 (45 pages)

CFR:
21 CFR 1141

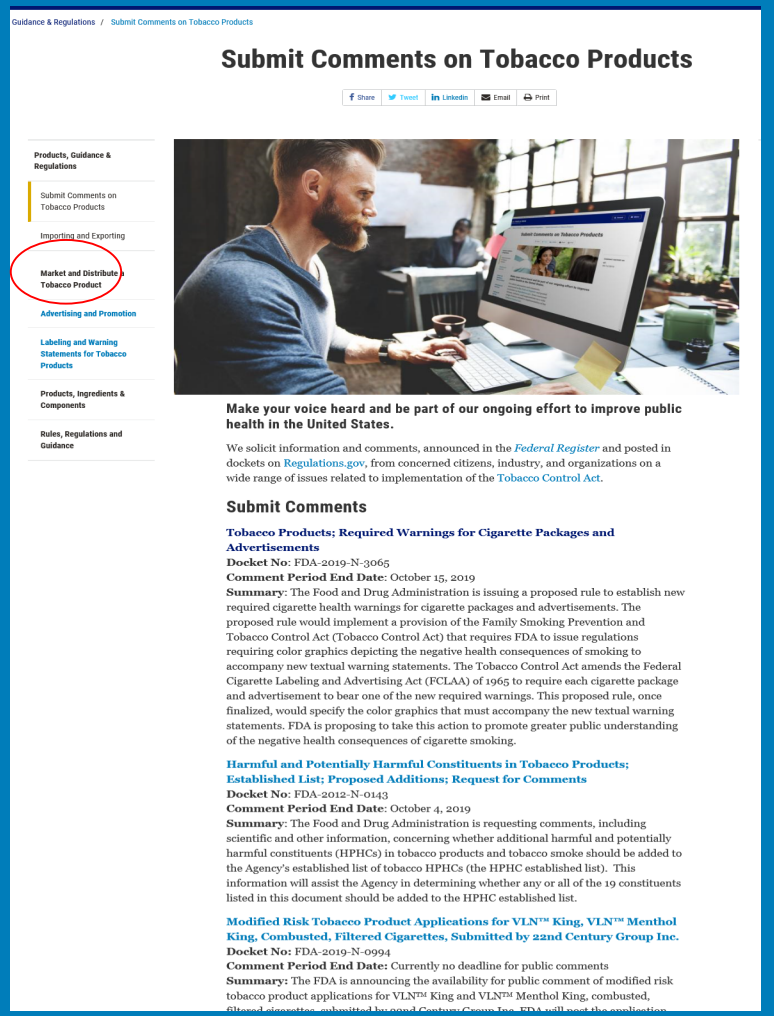
Agency/Docket Number:
Docket No. FDA-2019-N-3065

RIN:
0910-AI39

Document Number:

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Allow for submission of comments
  - Proposed rules
  - MRTPAs



Guidance & Regulations / Submit Comments on Tobacco Products

Submit Comments on Tobacco Products

Share | Tweet | LinkedIn | Email | Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

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 Products; Required Warnings for Cigarette Packages and Advertisements
Docket No: FDA-2019-N-3065
Comment Period End Date: October 15, 2019
Summary: The Food and Drug Administration is issuing a proposed rule to establish new required cigarette health warnings for cigarette packages and advertisements. The proposed rule would implement a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. This proposed rule, once finalized, would specify the color graphics that must accompany the new textual warning statements. FDA is proposing to take this action to promote greater public understanding of the negative health consequences of cigarette smoking.

Harmful and Potentially Harmful Constituents in Tobacco Products; Established List; Proposed Additions; Request for Comments
Docket No: FDA-2012-N-0143
Comment Period End Date: October 4, 2019
Summary: The Food and Drug Administration is requesting comments, including scientific and other information, concerning whether additional harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke should be added to the Agency's established list of tobacco HPHCs (the HPHC established list). This information will assist the Agency in determining whether any or all of the 19 constituents listed in this document should be added to the HPHC established list.

Modified Risk Tobacco Product Applications for VLN™ King, VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group Inc.
Docket No: FDA-2019-N-0994
Comment Period End Date: Currently no deadline for public comments
Summary: The FDA is announcing the availability for public comment of modified risk tobacco product applications for VLN™ King and VLN™ Menthol King, combusted, filtered cigarettes, submitted by 22nd Century Group Inc. FDA will post the application

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Market and Distribute a Tobacco Product

idance & Regulations / Market and Distribute a Tobacco Product

Market and Distribute a Tobacco Product

Share | Tweet | Linkedin | Email | Print

Market and Distribute a Tobacco Product

Questions & Answers

Misbranded and Adulterated NSE Tobacco Products

Tobacco Product Marketing Orders

Scientific Policy Memoranda about FDA Review of Tobacco Product Applications

Substantial Equivalence

Exemption from Substantial Equivalence

Premarket Tobacco Product Applications

Learn about preparing marketing applications for deemed tobacco products

Join the FDA's free, public meeting on Oct. 28-29, 2019, for information about policies, processes, and general scientific principles for tobacco product application review, with a particular focus on deemed tobacco products such as cigars, waterpipes, and electronic nicotine delivery systems (ENDS), including e-liquids and electronic cigarettes.

- Nominate an expert panelist by September 13, 2019
- Register by September 30, 2019

FDA oversees all pathways to legally market and distribute tobacco products in the U.S. Determine an appropriate pathway to market for your tobacco product and learn more about how the FDA reviews and evaluates marketing order applications.

Introduce a new tobacco product to market

A "new tobacco product" is any product not commercially marketed in the United States as of February 15, 2007, or the modification of a tobacco product where the modified product was commercially marketed in the U.S. after February 15, 2007.

Products on the market as of or on February 15, 2007 are considered grandfathered tobacco products.

New tobacco products may not be legally marketed in the United States without a tobacco product marketing order from the FDA.* These products are evaluated based on the product's risks to the population as a whole. There are three pathways to market for new tobacco products:

- Premarket Tobacco Product Applications
  A premarket tobacco product application may be submitted when seeking marketing authorization for any new tobacco product. However, for some products, other pathways may be more applicable.
- Substantial Equivalence
  A new tobacco product may be found "substantially equivalent," to a "predicate" product by demonstrating the product has the same characteristics as that predicate product, or if the product has different characteristics, by demonstrating that the new product does not raise different questions of public health than the predicate product.
- Request Exemption from Demonstrating Substantial Equivalence
  A tobacco product that is modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive may be considered for an exemption from demonstrating substantial equivalence.

**New tobacco products commercially marketed after February 15, 2007 but before March 22, 2011 with an SE Report submitted by March 22, 2011 are known as provisional SE tobacco products— these may continue to be marketed unless FDA issues an order that the new product is not substantially equivalent.*

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Market and Distribute a Tobacco Product
  - What is a new tobacco product
  - What is a grandfathered tobacco products

A "new tobacco product" is any product not commercially marketed in the United States as of February 15, 2007, or the modification of a tobacco product where the modified product was commercially marketed in the U.S. after February 15, 2007.

Products on the market as of or on February 15, 2007 are considered grandfathered tobacco products.

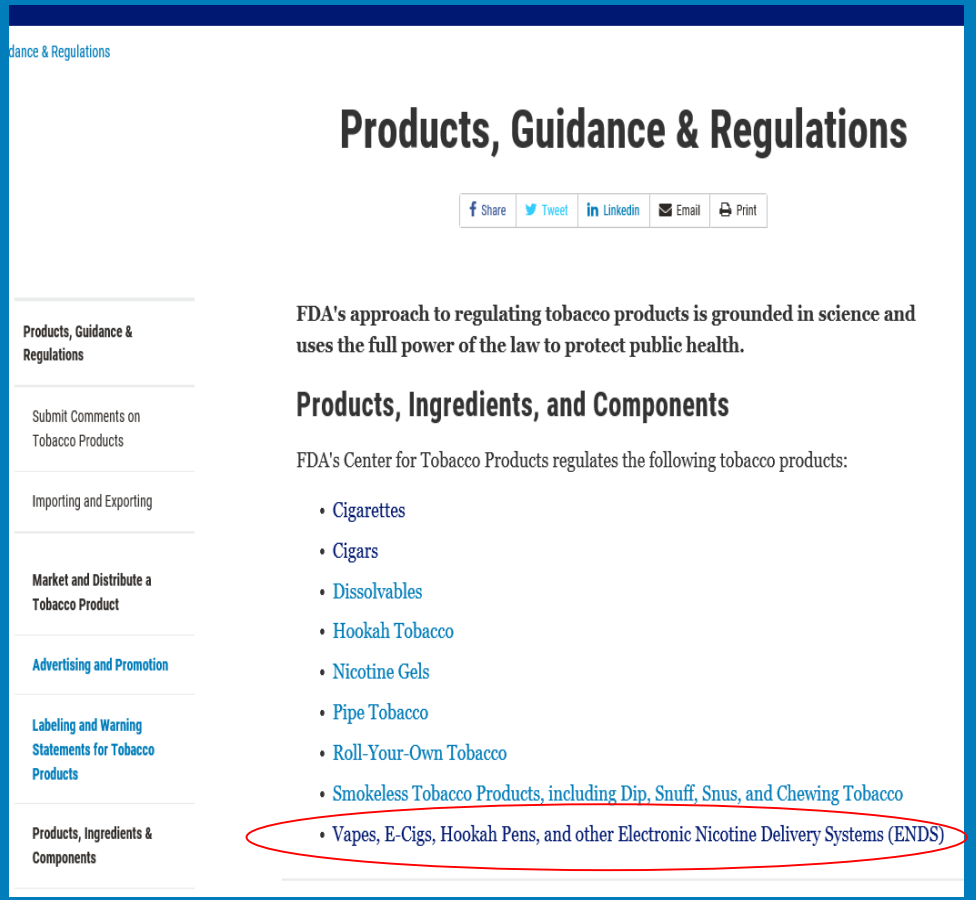
CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Market and Distribute a Tobacco Product
  - What is a new tobacco product
  - What is a grandfathered tobacco products
  - Three pathways to market a new tobacco product
    - Premarket Tobacco Product Applications
    - Substantial Equivalence
    - Request Exemption from Demonstrating Substantial Equivalence

- **Premarket Tobacco Product Applications**
  A premarket tobacco product application may be submitted when seeking marketing authorization for any new tobacco product. However, for some products, other pathways may be more applicable.
- **Substantial Equivalence**
  A new tobacco product may be found "substantially equivalent," to a "predicate" product by demonstrating the product has the same characteristics as that predicate product, or if the product has different characteristics, by demonstrating that the new product does not raise different questions of public health than the predicate product.
- **Request Exemption from Demonstrating Substantial Equivalence**
  A tobacco product that is modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive may be considered for an exemption from demonstrating substantial equivalence.

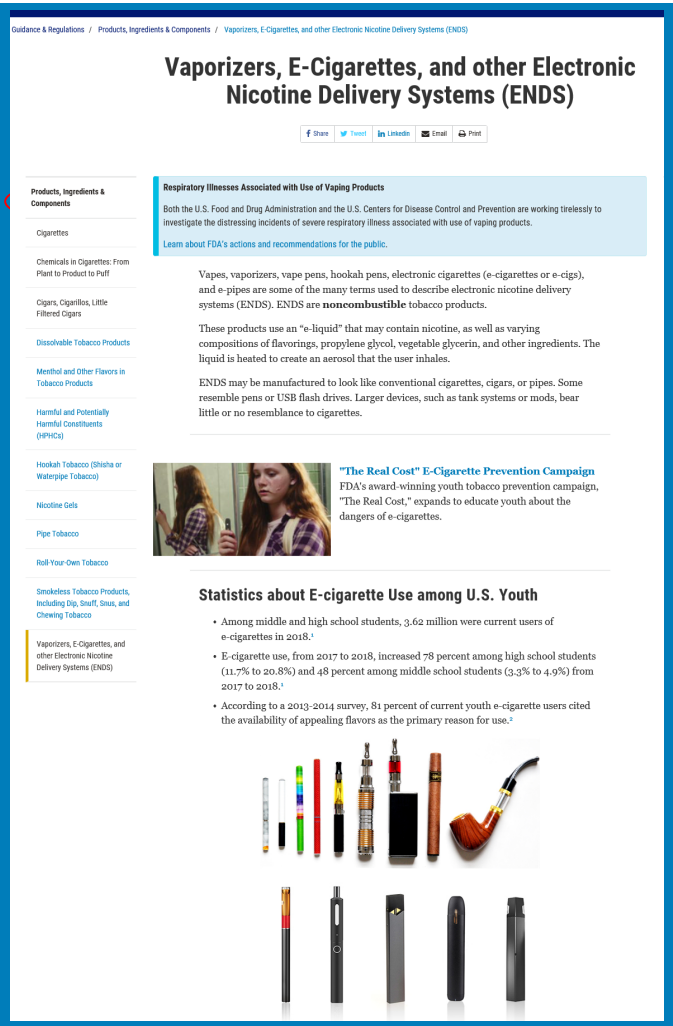
CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)



CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)



Guidance & Regulations / Products, Ingredients & Components / Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)

Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)

Share | Tweet | LinkedIn | Email | Print

Products, Ingredients & Components

- Cigarettes
- Chemicals in Cigarettes: From Plant to Product to Puff
- Cigars, Cigarillos, Little Filtered Cigars
- Dissolvable Tobacco Products
- Menthol and Other Flavors in Tobacco Products
- Harmful and Potentially Harmful Constituents (HPHCs)
- Hookah Tobacco (Shisha or Waterpipe Tobacco)
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, Including Dip, Snuff, Snus, and Chewing Tobacco
- Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)

Respiratory Illnesses Associated with Use of Vaping Products

Both the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention are working tirelessly to investigate the distressing incidents of severe respiratory illness associated with use of vaping products.

Learn about FDA's actions and recommendations for the public.

Vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), and e-pipes are some of the many terms used to describe electronic nicotine delivery systems (ENDS). ENDS are **noncombustible** tobacco products.

These products use an "e-liquid" that may contain nicotine, as well as varying compositions of flavorings, propylene glycol, vegetable glycerin, and other ingredients. The liquid is heated to create an aerosol that the user inhales.

ENDS may be manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble pens or USB flash drives. Larger devices, such as tank systems or mods, bear little or no resemblance to cigarettes.

"The Real Cost" E-Cigarette Prevention Campaign
FDA's award-winning youth tobacco prevention campaign, "The Real Cost," expands to educate youth about the dangers of e-cigarettes.

Statistics about E-cigarette Use among U.S. Youth

- Among middle and high school students, 3.62 million were current users of e-cigarettes in 2018.[1]
- E-cigarette use, from 2017 to 2018, increased 78 percent among high school students (11.7% to 20.8%) and 48 percent among middle school students (3.3% to 4.9%) from 2017 to 2018.[1]
- According to a 2013-2014 survey, 81 percent of current youth e-cigarette users cited the availability of appealing flavors as the primary reason for use.[2]

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)
    - Statistics about E-cigarettes Use among U.S. Youth

Statistics about E-cigarette Use among U.S. Youth

- Among middle and high school students, 3.62 million were current users of e-cigarettes in 2018.[1]
- E-cigarette use, from 2017 to 2018, increased 78 percent among high school students (11.7% to 20.8%) and 48 percent among middle school students (3.3% to 4.9%) from 2017 to 2018.[1]
- According to a 2013-2014 survey, 81 percent of current youth e-cigarette users cited the availability of appealing flavors as the primary reason for use.[2]

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)
    - Statistics about E-cigarettes Use among U.S. Youth
    - FDA Regulation of Electronic Nicotine Delivery Systems

FDA Regulation of Electronic Nicotine Delivery Systems

In 2016, FDA finalized a rule extending CTP's regulatory authority to cover all tobacco products, including electronic nicotine delivery systems (ENDS) that meet the definition of a tobacco product. FDA regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories. Examples of components and parts of ENDS include:

- E-liquids
- A glass or plastic vial container of e-liquid
- Cartridges
- Atomizers
- Certain batteries
- Cartomizers and clearomizers
- Digital display or lights to adjust settings
- Tank systems
- Drip tips
- Flavorings for ENDS
- Programmable software

Products marketed for therapeutic purposes (for example, marketed as a product to help people quit smoking) are regulated by FDA Center for Drug Evaluation and Research (CDER). FDA published a rule clarifying when products made or derived from tobacco are regulated as tobacco products, drugs, and/ or devices.

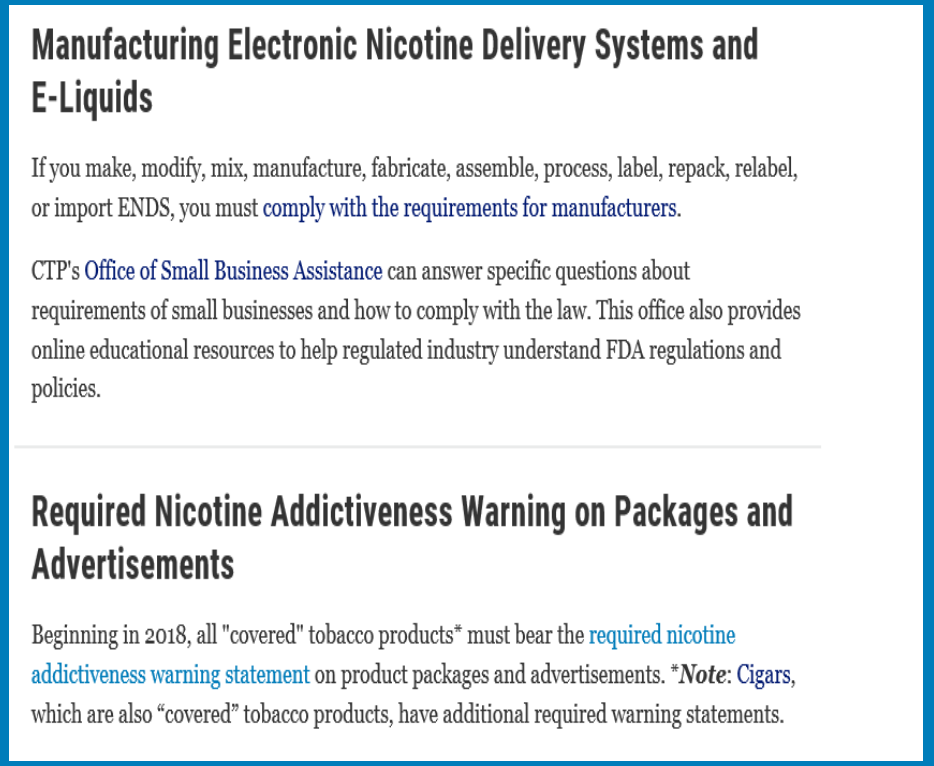
FDA Issues Draft Guidance: Modifications to Compliance Policy for Certain Deemed Tobacco Products

The guidance discusses changes to the compliance policies for premarket review requirements for certain deemed tobacco products, including flavored e-cigarettes and cigars, and describes how FDA intend to prioritize its enforcement of products that do not have premarket authorization.

- Read statement from FDA Commissioner Dr. Scott Gottlieb
- Submit a comment on the draft guidance

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)
    - Statistics about E-cigarettes Use among U.S. Youth
    - FDA Regulation of Electronic Nicotine Delivery Systems
    - Manufacturing Electronic Nicotine Delivery Systems and E-Liquids
    - Required Nicotine Addictiveness Warning on Packages and Advertisements



Manufacturing Electronic Nicotine Delivery Systems and E-Liquids

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import ENDS, you must comply with the requirements for manufacturers.

CTP's Office of Small Business Assistance can answer specific questions about requirements of small businesses and how to comply with the law. This office also provides online educational resources to help regulated industry understand FDA regulations and policies.

Required Nicotine Addictiveness Warning on Packages and Advertisements

Beginning in 2018, all "covered" tobacco products* must bear the required nicotine addictiveness warning statement on product packages and advertisements. ***Note***: Cigars, which are also "covered" tobacco products, have additional required warning statements.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)
    - Statistics about E-cigarettes Use among U.S. Youth
    - FDA Regulation of Electronic Nicotine Delivery Systems
    - Manufacturing Electronic Nicotine Delivery Systems and E-Liquids
    - Required Nicotine Addictiveness Warning on Packages and Advertisements
    - Retail Sales of Electronic Nicotine Delivery Systems and E-Liquids
    - Vape Shops that mix E-Liquids or modify products

Retail Sales of Electronic Nicotine Delivery Systems and, E-Liquids

If you sell ENDS, e-liquids, or their components or parts made or derived from tobacco, please read this summary of federal rules that retailers must follow.

You may also order flyers with rules for electronic nicotine delivery system sales or download a PDF to print yourself.

You can find a list of retailer responsibilities for ENDS in the final rule Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act. In addition, our website offers more information on regulations, guidance, and webinars for retailers.

Order FDA Rules for ENDS Sales Flyer

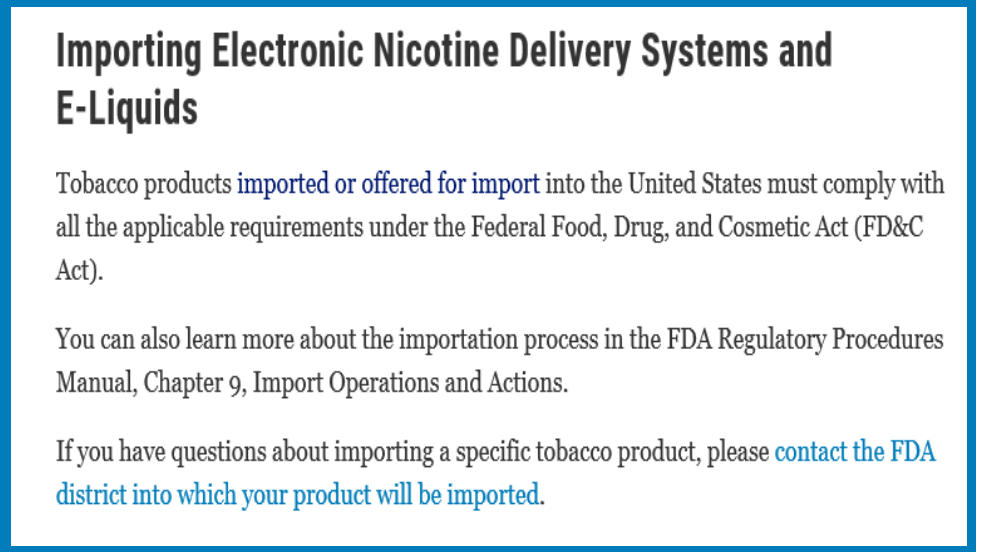
Order Print Copies

Vape Shops That Mix E-Liquids or Modify Products

If you operate a vape shop that mixes or prepares liquid nicotine or nicotine-containing e-liquids, or creates or modifies any type of ENDS, you may be considered a manufacturer. As a result, some vape shops may have legal responsibilities as both manufacturers and retailers of tobacco products. Please also see the Guidance: Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)
    - Statistics about E-cigarettes Use among U.S. Youth
    - FDA Regulation of Electronic Nicotine Delivery Systems
    - Manufacturing Electronic Nicotine Delivery Systems and E-Liquids
    - Required Nicotine Addictiveness Warning on Packages and Advertisements
    - Retail Sales of Electronic Nicotine Delivery Systems and E-Liquids
    - Vape Shops that mix E-Liquids or modify products
    - Importing Electronic Nicotine Delivery Systems and E-Liquids



Importing Electronic Nicotine Delivery Systems and E-Liquids

Tobacco products imported or offered for import into the United States must comply with all the applicable requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

You can also learn more about the importation process in the FDA Regulatory Procedures Manual, Chapter 9, Import Operations and Actions.

If you have questions about importing a specific tobacco product, please contact the FDA district into which your product will be imported.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Products, Ingredients, and Components
  - Vaporizers, E-Cigarettes and other Electronic Nicotine Delivery Systems (ENDS)
    - Statistics about E-cigarettes Use among U.S. Youth
    - FDA Regulation of Electronic Nicotine Delivery Systems
    - Manufacturing Electronic Nicotine Delivery Systems and E-Liquids
    - Required Nicotine Addictiveness Warning on Packages and Advertisements
    - Retail Sales of Electronic Nicotine Delivery Systems and E-Liquids
    - Vape Shops that mix E-Liquids or modify products
    - Importing Electronic Nicotine Delivery Systems and E-Liquids
    - Report A Problem with a Tobacco Product or Potential Tobacco Product Violations

Report a Problem with a Tobacco Product or Potential Tobacco Product Violations

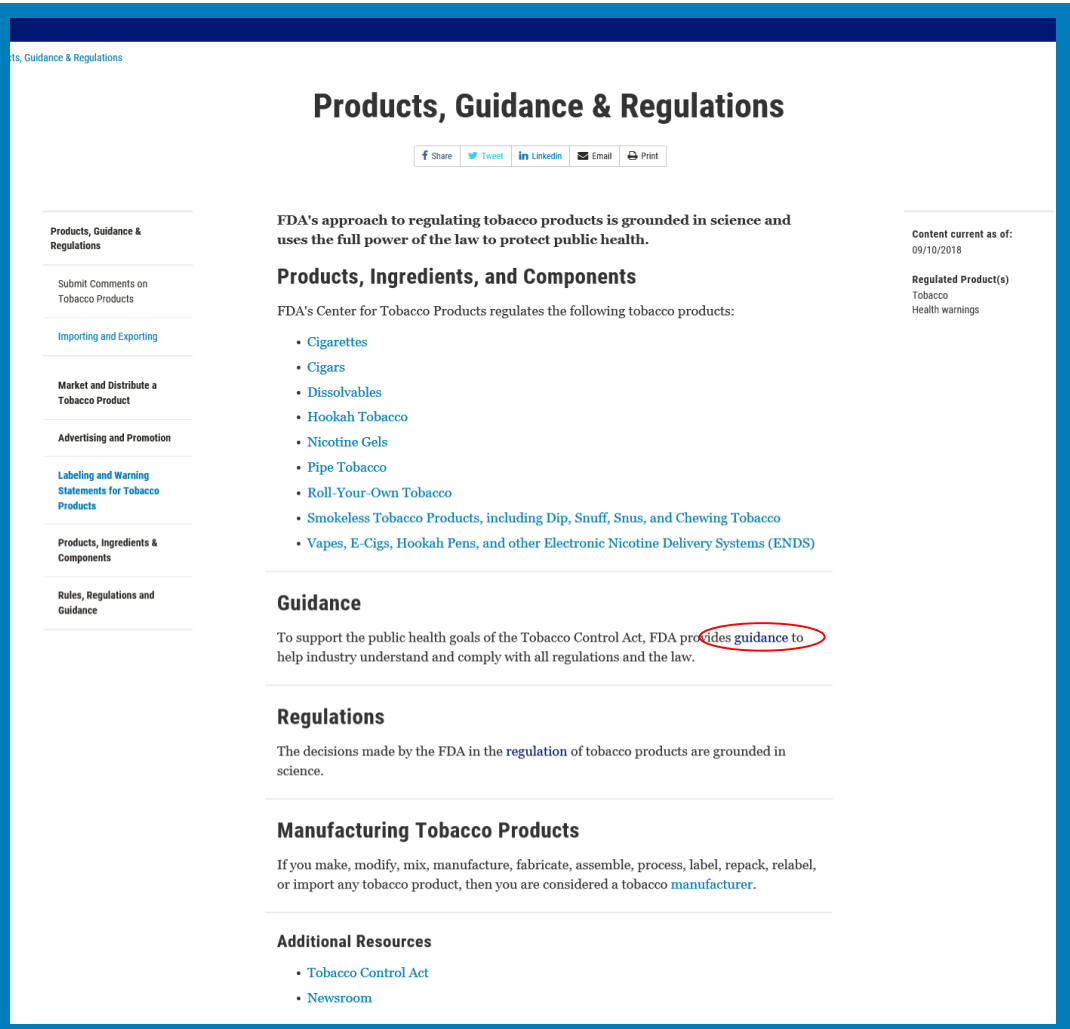
If you have experienced an unexpected health or safety issue with a specific tobacco product, you can report a problem with any tobacco product, including vapes, to the FDA. Knowledge about adverse experiences can help the FDA identify health or safety issues beyond those normally associated with product use.

If you believe these products are being sold to minors, or you see another potential violation of the FD&C Act or FDA's tobacco regulations, report the potential violation.

You can read the adverse experience reports for tobacco products to FDA in the FOIA Electronic Reading Room.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Guidance Documents



ts, Guidance & Regulations

Products, Guidance & Regulations

Share Tweet Linkedin Email Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

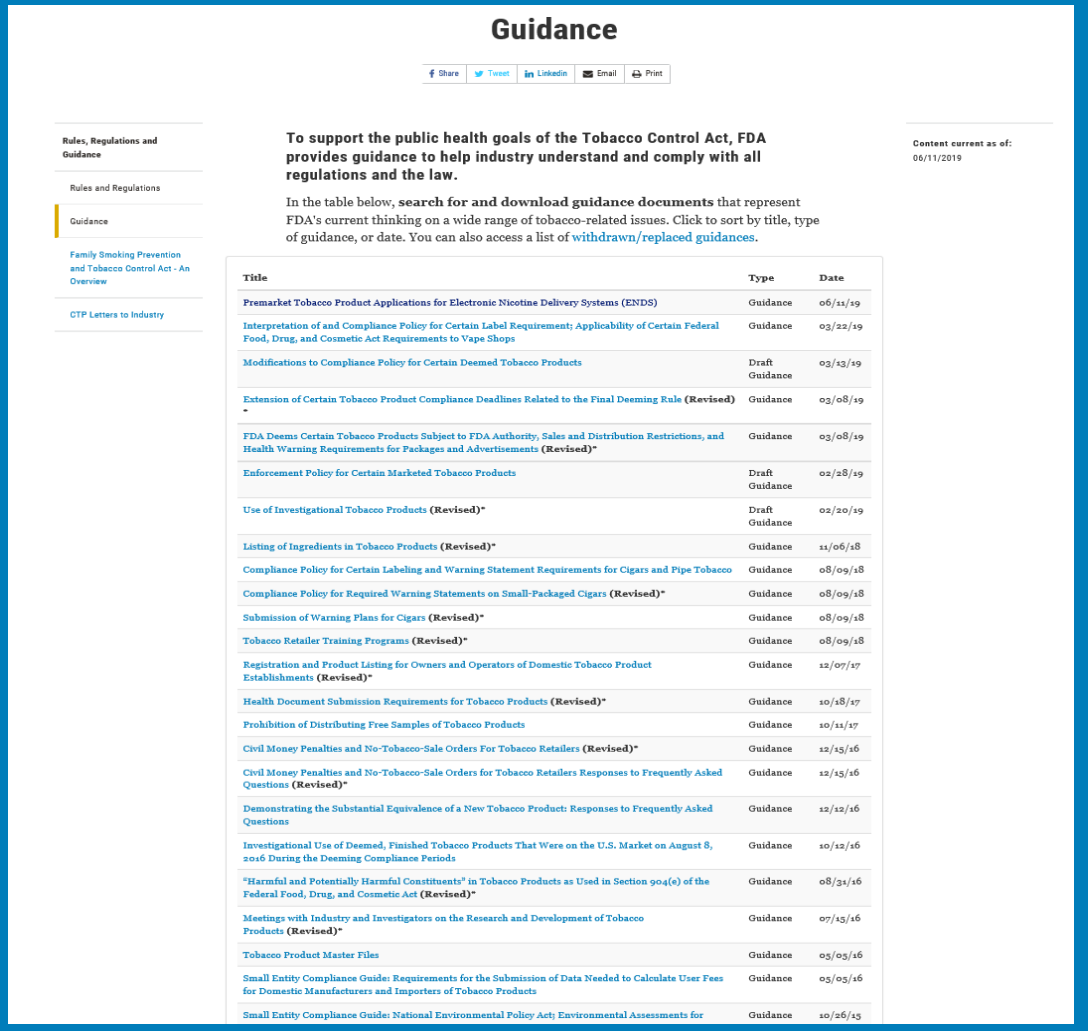
- Tobacco Control Act
- Newsroom

Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Guidance Documents
  - Draft
  - Final



Guidance

Share | Tweet | LinkedIn | Email | Print

Rules, Regulations and Guidance

- Rules and Regulations
- Guidance
- Family Smoking Prevention and Tobacco Control Act - An Overview
- CTP Letters to Industry

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

In the table below, **search for and download guidance documents** that represent FDA's current thinking on a wide range of tobacco-related issues. Click to sort by title, type of guidance, or date. You can also access a list of withdrawn/replaced guidances.

Content current as of: 06/11/2019

Title	Type	Date
Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)	Guidance	06/11/19
Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops	Guidance	03/22/19
Modifications to Compliance Policy for Certain Deemed Tobacco Products	Draft Guidance	03/13/19
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised) *	Guidance	03/08/19
FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)*	Guidance	03/08/19
Enforcement Policy for Certain Marketed Tobacco Products	Draft Guidance	02/28/19
Use of Investigational Tobacco Products (Revised)*	Draft Guidance	02/20/19
Listing of Ingredients in Tobacco Products (Revised)*	Guidance	11/06/18
Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco	Guidance	08/09/18
Compliance Policy for Required Warning Statements on Small-Packaged Cigars (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
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
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions	Guidance	12/12/16
Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016 During the Deeming Compliance Periods	Guidance	10/12/16
"Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act (Revised)*	Guidance	08/31/16
Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised)*	Guidance	07/15/16
Tobacco Product Master Files	Guidance	05/05/16
Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	Guidance	05/05/16
Small Entity Compliance Guide: National Environmental Policy Act; Environmental Assessments for	Guidance	10/26/15

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Guidance Documents
  - Draft
  - Final

Title	Type	Date
Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)	Guidance	06/11/19
Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops	Guidance	03/22/19
Modifications to Compliance Policy for Certain Deemed Tobacco Products	Draft Guidance	03/13/19
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule **(Revised)***	Guidance	03/08/19
FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements **(Revised)***	Guidance	03/08/19
Enforcement Policy for Certain Marketed Tobacco Products	Draft Guidance	02/28/19
Use of Investigational Tobacco Products **(Revised)***	Draft Guidance	02/20/19
Listing of Ingredients in Tobacco Products **(Revised)***	Guidance	11/06/18
Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco	Guidance	08/09/18
Compliance Policy for Required Warning Statements on Small-Packaged Cigars **(Revised)***	Guidance	08/09/18

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Guidance Documents
  - Draft
  - Final

Title	Type	Date
Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)	Guidance	06/11/19

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Guidance Documents
  - Draft
  - Final

This guidance is intended to assist persons submitting premarket tobacco product applications (PMTAs) for electronic nicotine delivery systems (ENDS) under section 910 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387j). This guidance communicates FDA's current thinking on these applications to improve the efficiency of application submission and review; however, the recommendations in this guidance are non-binding. When FDA reviews PMTAs for ENDS, it will base decisions on the obligations that arise from the FD&C Act and its implementing regulations. FDA anticipates that the experience gained through the publication of this guidance and review of PMTAs may contribute to future rulemaking and guidances.

The guidance explains, among other things:

- Products to which this guidance applies;
- When a PMTA is required under the statute and regulations;
- General procedures for review of an ENDS PMTA;
- What information the FD&C Act requires you to submit in a PMTA; and

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Guidance Documents
  - Draft
  - Final

Submit Comments

Submit comments on this guidance document electronically via docket ID: FDA-2013-S-0610 - Specific Electronic Submissions Intended For FDA's Dockets Management Staff (i.e., Citizen Petitions, Draft Proposed Guidance Documents, Variances, and other administrative record submissions)

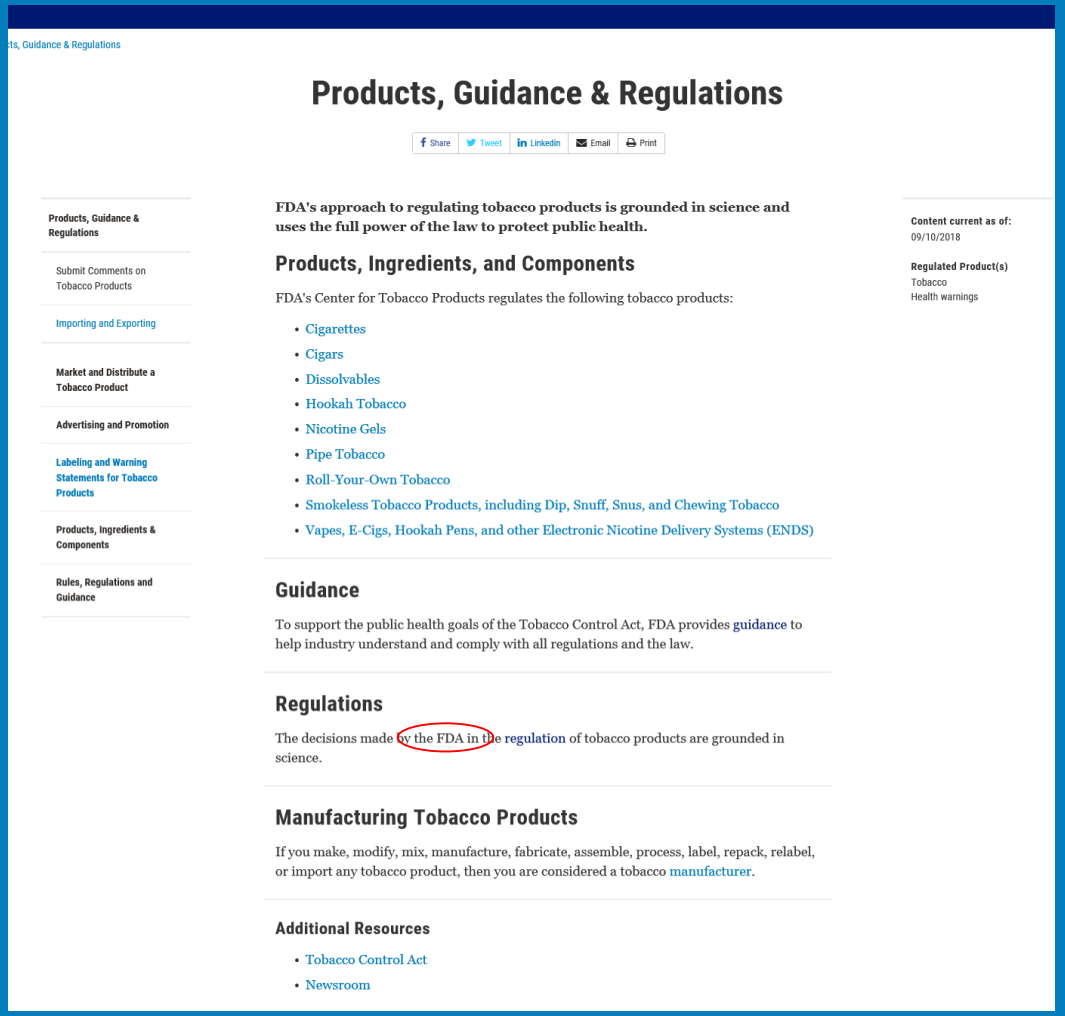
If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All comments should be identified with the title of the guidance.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Regulation Documents



cts, Guidance & Regulations

Products, Guidance & Regulations

Share Tweet Linkedin Email Print

Products, Guidance & Regulations

Submit Comments on Tobacco Products

Importing and Exporting

Market and Distribute a Tobacco Product

Advertising and Promotion

Labeling and Warning Statements for Tobacco Products

Products, Ingredients & Components

Rules, Regulations and Guidance

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.

Products, Ingredients, and Components

FDA's Center for Tobacco Products regulates the following tobacco products:

- Cigarettes
- Cigars
- Dissolvables
- Hookah Tobacco
- Nicotine Gels
- Pipe Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco Products, including Dip, Snuff, Snus, and Chewing Tobacco
- Vapes, E-Cigs, Hookah Pens, and other Electronic Nicotine Delivery Systems (ENDS)

Guidance

To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

Regulations

The decisions made by the FDA in the regulation of tobacco products are grounded in science.

Manufacturing Tobacco Products

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any tobacco product, then you are considered a tobacco manufacturer.

Additional Resources

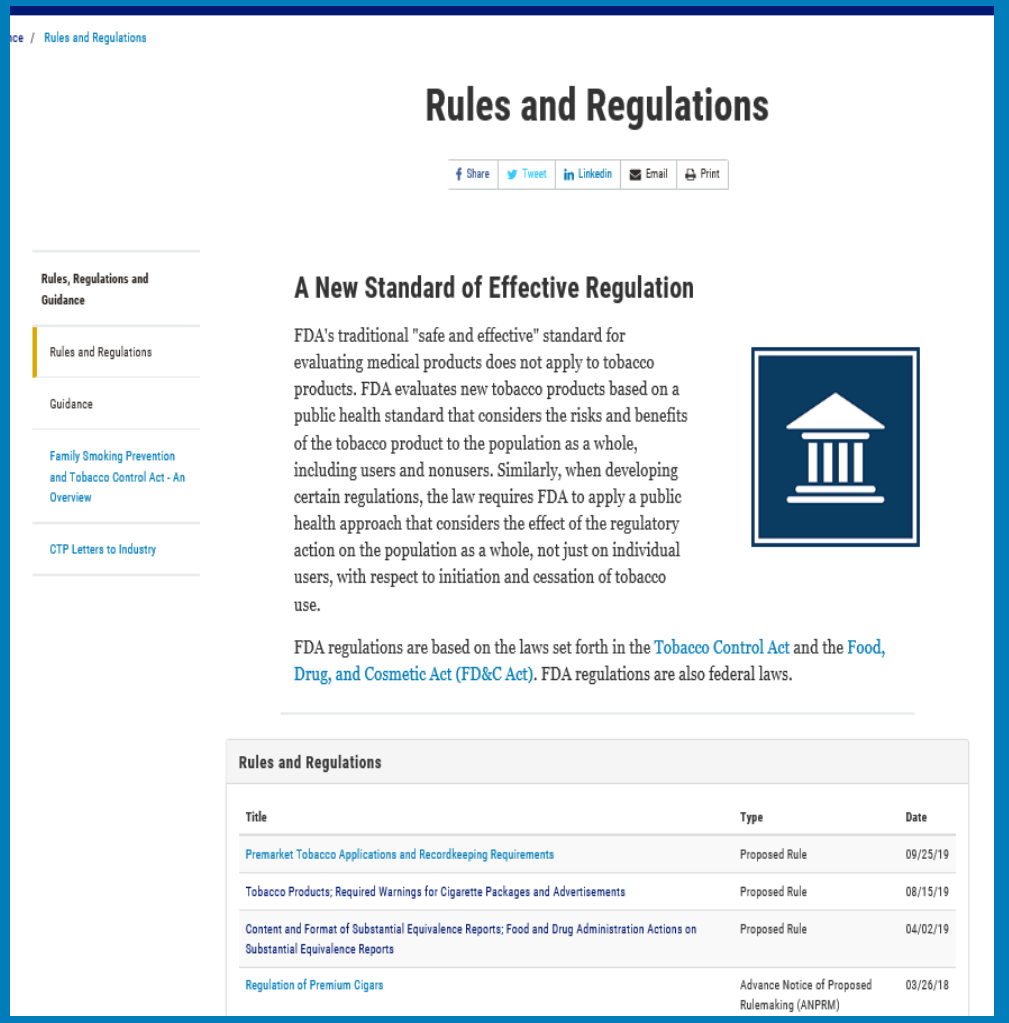
- Tobacco Control Act
- Newsroom

Content current as of:
09/10/2018

Regulated Product(s)
Tobacco
Health warnings

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Regulation Documents
  - Final
  - Proposed rule
  - Advance Notice of Proposed Rulemaking (ANPRM)



CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Regulation Documents
  - Final
  - Proposed rule
  - Advance Notice of Proposed Rulemaking (ANPRM)

Rules and Regulations

Title	Type	Date
Premarket Tobacco Applications and Recordkeeping Requirements	Proposed Rule	09/25/19
Tobacco Products; Required Warnings for Cigarette Packages and Advertisements	Proposed Rule	08/15/19
Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports	Proposed Rule	04/02/19
Regulation of Premium Cigars	Advance Notice of Proposed Rulemaking (ANPRM)	03/26/18

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Regulation Documents
  - Final
  - Proposed rule
  - Advance Notice of Proposed Rulemaking (ANPRM)

Sections | Browse | Search | Reader Aids | My FR | Search Documents

0 Sign in Sign up

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Proposed Rule

Premarket Tobacco Product Applications and Recordkeeping Requirements

A Proposed Rule by the Food and Drug Administration on 09/25/2019

This document has a comment period that ends in 54 days. (11/25/2019)

SUBMIT A FORMAL COMMENT

Read the 19 public comments

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Proposed rule.

SUMMARY:

The Food and Drug Administration (FDA) is issuing a proposed rule that would set forth requirements for premarket tobacco product applications (PMTAs) and would require manufacturers to maintain records establishing that their tobacco products are legally marketed. The proposed rule would help to ensure that PMTAs contain sufficient information for FDA to determine whether a marketing order should be issued for a new tobacco product, including detailed information regarding the physical aspects of a tobacco product, as well as full reports of information to demonstrate the scope of, and details regarding, investigations that may show the potential health risks of the product. The proposed rule would codify the general procedures FDA would follow when evaluating PMTAs, including application acceptance, application filing, and inspections, and would also create postmarket reporting requirements for applicants that receive marketing orders. The proposed rule would allow for the submission of PMTAs in alternative formats in certain instances to reduce the burden of submitting a PMTA for modifications to a product that previously received a PMTA marketing order or resubmitting a PMTA to address deficiencies specified in a no marketing order. The proposed rule would also require tobacco product manufacturers to keep records regarding the legal marketing of certain tobacco products without a PMTA, such as documents showing that a tobacco product is not required to undergo premarket review or has received premarket authorization.

DATES:

Submit either electronic or written comments on the proposed rule by November 25, 2019.

ADDRESSES:

DOCUMENT DETAILS

Printed version: PDF

Publication Date: 09/25/2019

Agencies: Food and Drug Administration

Dates: Submit either electronic or written comments on the proposed rule by November 25, 2019.

Comments Close: 11/25/2019

Document Type: Proposed Rule

Document Citation: 84 FR 50566

Page: 50566-50658 (93 pages)

CFR: 21 CFR 1100, 21 CFR 1107, 21 CFR 1114

Agency/Docket Number: Docket No. FDA-2019-N-2854

RIN: 0910-AH44

Document Number: 2019-20315

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

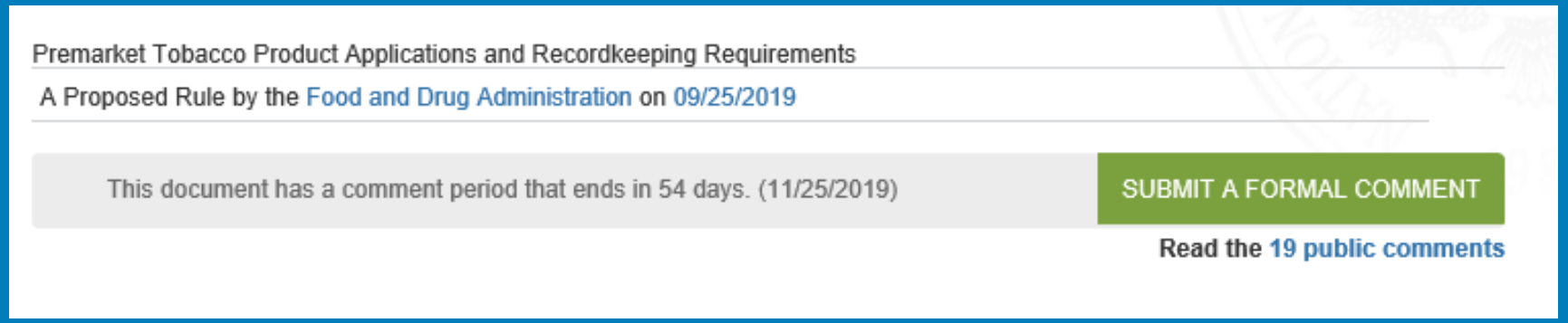
- Regulation Documents
  - Final
  - Proposed rule
  - Advance Notice of Proposed Rulemaking (ANPRM)

SUMMARY:

The Food and Drug Administration (FDA) is issuing a proposed rule that would set forth requirements for premarket tobacco product applications (PMTAs) and would require manufacturers to maintain records establishing that their tobacco products are legally marketed. The proposed rule would help to ensure that PMTAs contain sufficient information for FDA to determine whether a marketing order should be issued for a new tobacco product, including detailed information regarding the physical aspects of a tobacco product, as well as full reports of information to demonstrate the scope of, and details regarding, investigations that may show the potential health risks of the product. The proposed rule would codify the general procedures FDA would follow when evaluating PMTAs, including application acceptance, application filing, and inspections, and would also create postmarket reporting requirements for applicants that receive marketing orders. The proposed rule would allow for the submission of PMTAs in alternative formats in certain instances to reduce the burden of submitting a PMTA for modifications to a product that previously received a PMTA marketing order or resubmitting a PMTA to address deficiencies specified in a no marketing order. The proposed rule would also require tobacco product manufacturers to keep records regarding the legal marketing of certain tobacco products without a PMTA, such as documents showing that a tobacco product is not required to undergo premarket review or has received premarket authorization.

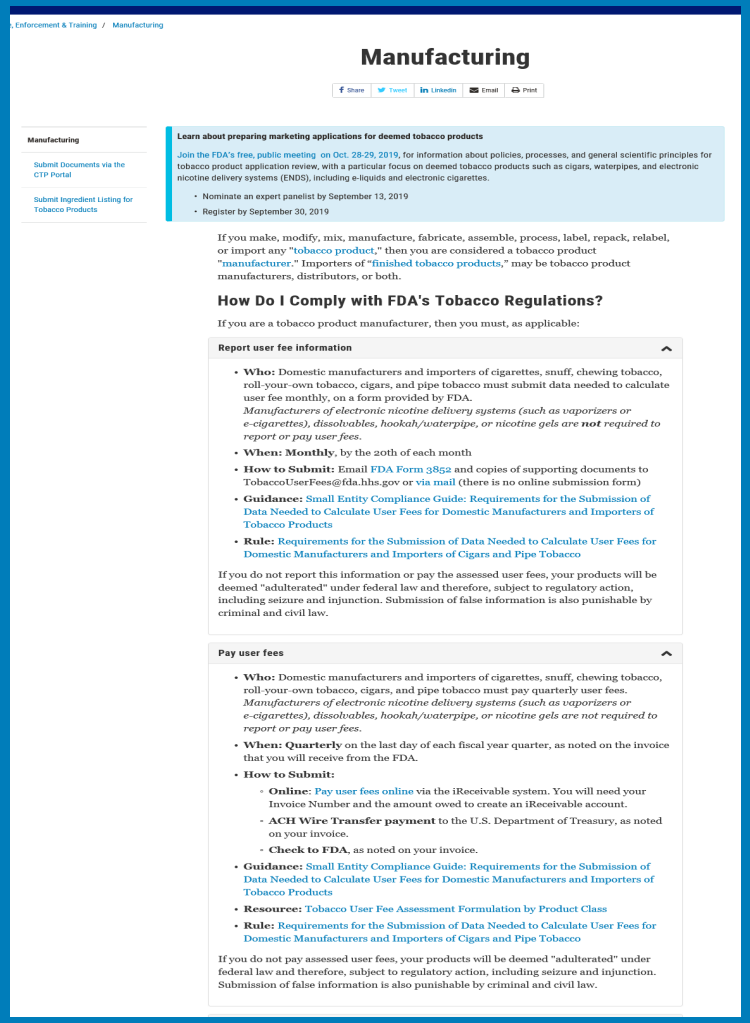
CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Regulation Documents
  - Final
  - Proposed rule
  - Advance Notice of Proposed Rulemaking (ANPRM)



CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Manufacturing Tobacco Products
  - Compliance with tobacco regulations
  - User fees



, Enforcement & Training / Manufacturing

Manufacturing

Share Tweet LinkedIn Email Print

Manufacturing

Submit Documents via the CTP Portal

Submit Ingredient Listing for Tobacco Products

Learn about preparing marketing applications for deemed tobacco products

Join the FDA's free, public meeting on Oct. 28-29, 2019, for information about policies, processes, and general scientific principles for tobacco product application review, with a particular focus on deemed tobacco products such as cigars, waterpipes, and electronic nicotine delivery systems (ENDS), including e-liquids and electronic cigarettes.

- Nominate an expert panelist by September 13, 2019
- Register by September 30, 2019

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any "tobacco product," then you are considered a tobacco product "manufacturer." Importers of "finished tobacco products," may be tobacco product manufacturers, distributors, or both.

How Do I Comply with FDA's Tobacco Regulations?

If you are a tobacco product manufacturer, then you must, as applicable:

Report user fee information

- **Who:** Domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco must submit data needed to calculate user fee monthly, on a form provided by FDA. *Manufacturers of electronic nicotine delivery systems (such as vaporizers or e-cigarettes), dissolvables, hookah/waterpipe, or nicotine gels are **not** required to report or pay user fees.*
- **When: Monthly**, by the 20th of each month
- **How to Submit:** Email FDA Form 3852 and copies of supporting documents to TobaccoUserFees@fda.hhs.gov or via mail (there is no online submission form)
- **Guidance:** Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products
- **Rule:** Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco

If you do not report this information or pay the assessed user fees, your products will be deemed "adulterated" under federal law and therefore, subject to regulatory action, including seizure and injunction. Submission of false information is also punishable by criminal and civil law.

Pay user fees

- **Who:** Domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco must pay quarterly user fees. *Manufacturers of electronic nicotine delivery systems (such as vaporizers or e-cigarettes), dissolvables, hookah/waterpipe, or nicotine gels are not required to report or pay user fees.*
- **When: Quarterly** on the last day of each fiscal year quarter, as noted on the invoice that you will receive from the FDA.
- **How to Submit:**
  - **Online:** Pay user fees online via the iReceivable system. You will need your Invoice Number and the amount owed to create an iReceivable account.
  - **ACH Wire Transfer payment** to the U.S. Department of Treasury, as noted on your invoice.
  - **Check to FDA**, as noted on your invoice.
- **Guidance:** Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products
- **Resource:** Tobacco User Fee Assessment Formulation by Product Class
- **Rule:** Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco

If you do not pay assessed user fees, your products will be deemed "adulterated" under federal law and therefore, subject to regulatory action, including seizure and injunction. Submission of false information is also punishable by criminal and civil law.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

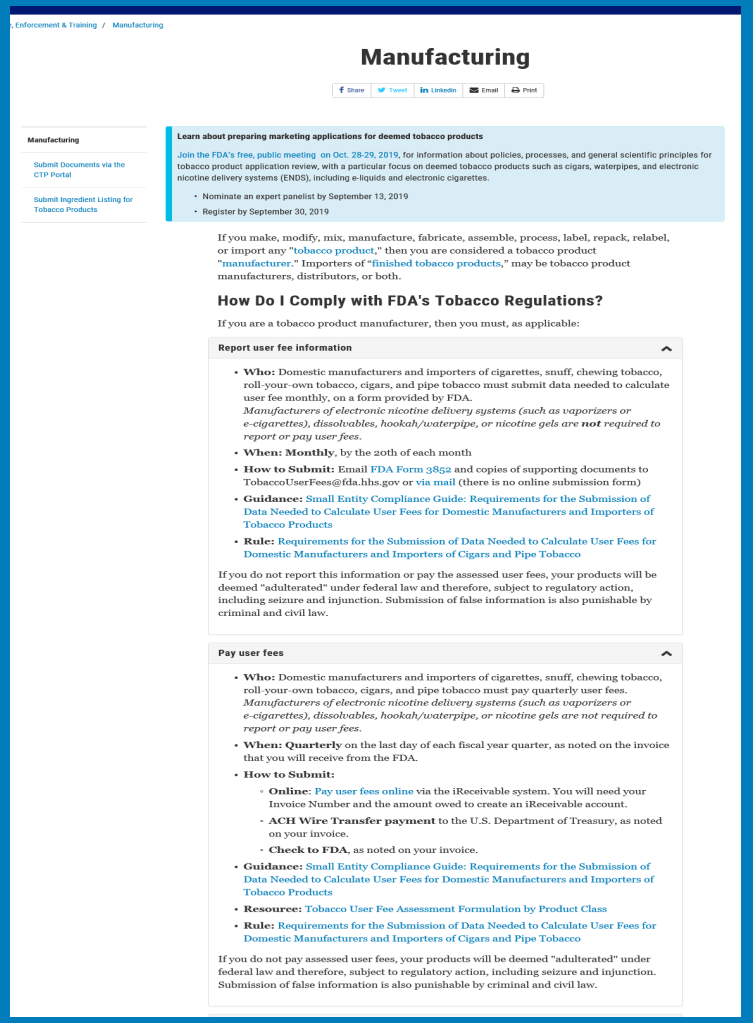
- Manufacturing Tobacco Products
  - Compliance with tobacco regulations
  - User fees
  - Registration

Register your establishment and submit list of products, including labeling and advertisements

- **Who:** Every person who owns or operates any domestic establishment engaged in manufacturing tobacco products.
- **When:**
  - **Immediately upon first engaging in tobacco product manufacturing:** Any "new" tobacco product, including deemed "finished tobacco products" manufactured on or after August 8, 2016.
  - **Annually by June 30:** Submit certain changes to the product listing. Examples of changes that require a submission include:
    - Introduction of any tobacco products for commercial distribution that were not included in a previous listing
    - Discontinuation of manufacturing, preparation, compounding, or processing any tobacco products for commercial distribution
    - Resumed manufacturing, preparation, compounding or processing any tobacco products previously listed as discontinued
      Note: Only those making certain changes are required to submit or update their product listing information by June 30. Information previously submitted to FDA should not be resubmitted.

CONTENT: PRODUCTS, GUIDANCE & REGULATIONS

- Manufacturing Tobacco Products
  - Compliance with tobacco regulations
  - User fees
  - Registration
  - Submission of
    - health documents
    - ingredient listings
    - warning plans
    - HPHCs
    - an application
    - an MRTPA
  - Resources for electronic submissions



, Enforcement & Training / Manufacturing

Manufacturing

Share | Tweet | LinkedIn | Email | Print

Manufacturing

Submit Documents via the CTP Portal

Submit Ingredient Listing for Tobacco Products

Learn about preparing marketing applications for deemed tobacco products

Join the FDA's free, public meeting on Oct. 28-29, 2019, for information about policies, processes, and general scientific principles for tobacco product application review, with a particular focus on deemed tobacco products such as cigars, waterpipes, and electronic nicotine delivery systems (ENDS), including e-liquids and electronic cigarettes.

- Nominate an expert panelist by September 13, 2019
- Register by September 30, 2019

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any "tobacco product," then you are considered a tobacco product "manufacturer." Importers of "finished tobacco products," may be tobacco product manufacturers, distributors, or both.

How Do I Comply with FDA's Tobacco Regulations?

If you are a tobacco product manufacturer, then you must, as applicable:

Report user fee information

- **Who:** Domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco must submit data needed to calculate user fee monthly, on a form provided by FDA. *Manufacturers of electronic nicotine delivery systems (such as vaporizers or e-cigarettes), dissolvables, hookah/waterpipe, or nicotine gels are **not** required to report or pay user fees.*
- **When: Monthly**, by the 20th of each month
- **How to Submit:** Email FDA Form 3852 and copies of supporting documents to TobaccoUserFees@fda.hhs.gov or via mail (there is no online submission form)
- **Guidance:** Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products
- **Rule:** Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco

If you do not report this information or pay the assessed user fees, your products will be deemed "adulterated" under federal law and therefore, subject to regulatory action, including seizure and injunction. Submission of false information is also punishable by criminal and civil law.

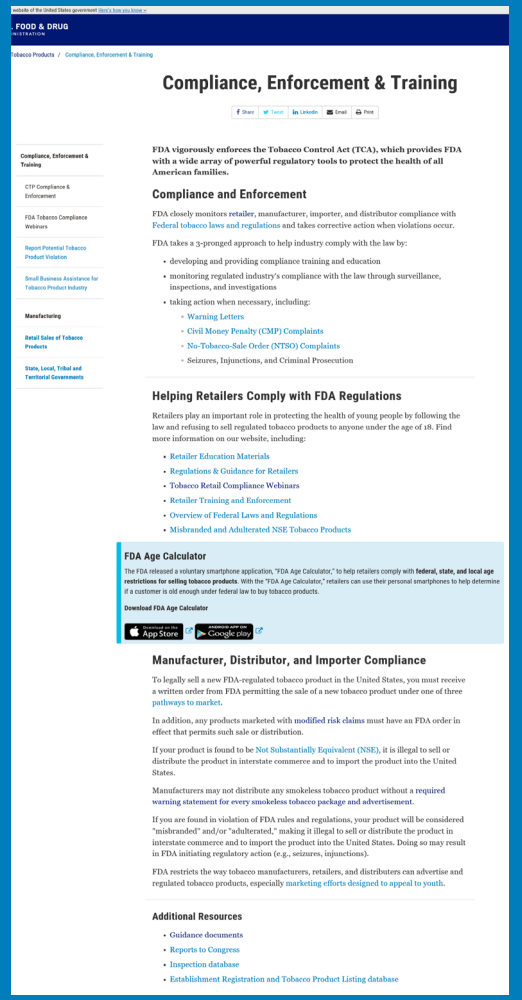
Pay user fees

- **Who:** Domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco must pay quarterly user fees. *Manufacturers of electronic nicotine delivery systems (such as vaporizers or e-cigarettes), dissolvables, hookah/waterpipe, or nicotine gels are not required to report or pay user fees.*
- **When: Quarterly** on the last day of each fiscal year quarter, as noted on the invoice that you will receive from the FDA.
- **How to Submit:**
  - **Online:** Pay user fees online via the iReceivable system. You will need your Invoice Number and the amount owed to create an iReceivable account.
  - **ACH Wire Transfer payment** to the U.S. Department of Treasury, as noted on your invoice.
  - **Check to FDA**, as noted on your invoice.
- **Guidance:** Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products
- **Resource:** Tobacco User Fee Assessment Formulation by Product Class
- **Rule:** Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco

If you do not pay assessed user fees, your products will be deemed "adulterated" under federal law and therefore, subject to regulatory action, including seizure and injunction. Submission of false information is also punishable by criminal and civil law.

CONTENT: COMPLIANCE AND ENFORCEMENT TRAINING

- Compliance, Enforcement & Training



website of the United States government Here's how you know

FOOD & DRUG ADMINISTRATION

Tobacco Products / Compliance, Enforcement & Training

Compliance, Enforcement & Training

Share Tweet LinkedIn Email Print

Compliance, Enforcement & Training

CTP Compliance & Enforcement

FDA Tobacco Compliance Webinars

Report Potential Tobacco Product Violation

Small Business Assistance for Tobacco Product Industry

Manufacturing

Retail Sales of Tobacco Products

State, Local, Tribal and Territorial Governments

FDA vigorously enforces the Tobacco Control Act (TCA), which provides FDA with a wide array of powerful regulatory tools to protect the health of all American families.

Compliance and Enforcement

FDA closely monitors **retailer**, manufacturer, importer, and distributor compliance with Federal tobacco laws and regulations and takes corrective action when violations occur.

FDA takes a 3-pronged approach to help industry comply with the law by:

- developing and providing compliance training and education
- monitoring regulated industry's compliance with the law through surveillance, inspections, and investigations
- taking action when necessary, including:
  - Warning Letters
  - Civil Money Penalty (CMP) Complaints
  - No-Tobacco-Sale Order (NTSO) Complaints
  - Seizures, Injunctions, and Criminal Prosecution

Helping Retailers Comply with FDA Regulations

Retailers play an important role in protecting the health of young people by following the law and refusing to sell regulated tobacco products to anyone under the age of 18. Find more information on our website, including:

- Retailer Education Materials
- Regulations & Guidance for Retailers
- **Tobacco Retail Compliance Webinars**
- Retailer Training and Enforcement
- Overview of Federal Laws and Regulations
- Misbranded and Adulterated NSE Tobacco Products

FDA Age Calculator

The FDA released a voluntary smartphone application, "FDA Age Calculator," to help retailers comply with **federal, state, and local age restrictions for selling tobacco products**. With the "FDA Age Calculator," retailers can use their personal smartphones to help determine if a customer is old enough under federal law to buy tobacco products.

Download FDA Age Calculator

Download on the App Store | ANDROID APP ON Google play

Manufacturer, Distributor, and Importer Compliance

To legally sell a new FDA-regulated tobacco product in the United States, you must receive a written order from FDA permitting the sale of a new tobacco product under one of three pathways to market.

In addition, any products marketed with **modified risk claims** must have an FDA order in effect that permits such sale or distribution.

If your product is found to be Not Substantially Equivalent (NSE), it is illegal to sell or distribute the product in interstate commerce and to import the product into the United States.

Manufacturers may not distribute any smokeless tobacco product without a **required warning statement for every smokeless tobacco package and advertisement**.

If you are found in violation of FDA rules and regulations, your product will be considered "misbranded" and/or "adulterated," making it illegal to sell or distribute the product in interstate commerce and to import the product into the United States. Doing so may result in FDA initiating regulatory action (e.g., seizures, injunctions).

FDA restricts the way tobacco manufacturers, retailers, and distributers can advertise and regulated tobacco products, especially marketing efforts designed to appeal to youth.

Additional Resources

- **Guidance documents**
- Reports to Congress
- Inspection database
- Establishment Registration and Tobacco Product Listing database

CONTENT: COMPLIANCE AND ENFORCEMENT TRAINING

- Compliance, Enforcement & Training
  - Compliance and Enforcement
    - Warning letters
    - Civil Money Penalties (CMPs)
    - No-Tobacco-Sale Orders (NSTOs)

Tobacco Retailer Warning Letters - Overview

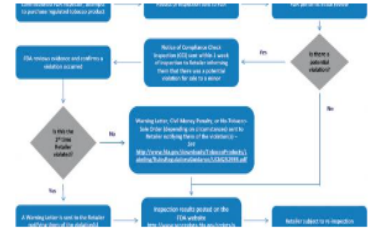
Share | Tweet | Linkedin | Email | Print

We generally send warning letters to retailers the first time a tobacco compliance check inspection reveals a violation of the federal tobacco laws and regulations that FDA enforces.

During Undercover Buy Inspections, the retailer is unaware an inspection is taking place. The minor and inspector will not identify themselves.

Failure to promptly and adequately correct all violations and ensure compliance with all applicable laws and regulations may lead to enforcement actions, including Civil Money Penalties or No-Tobacco-Sale Orders.

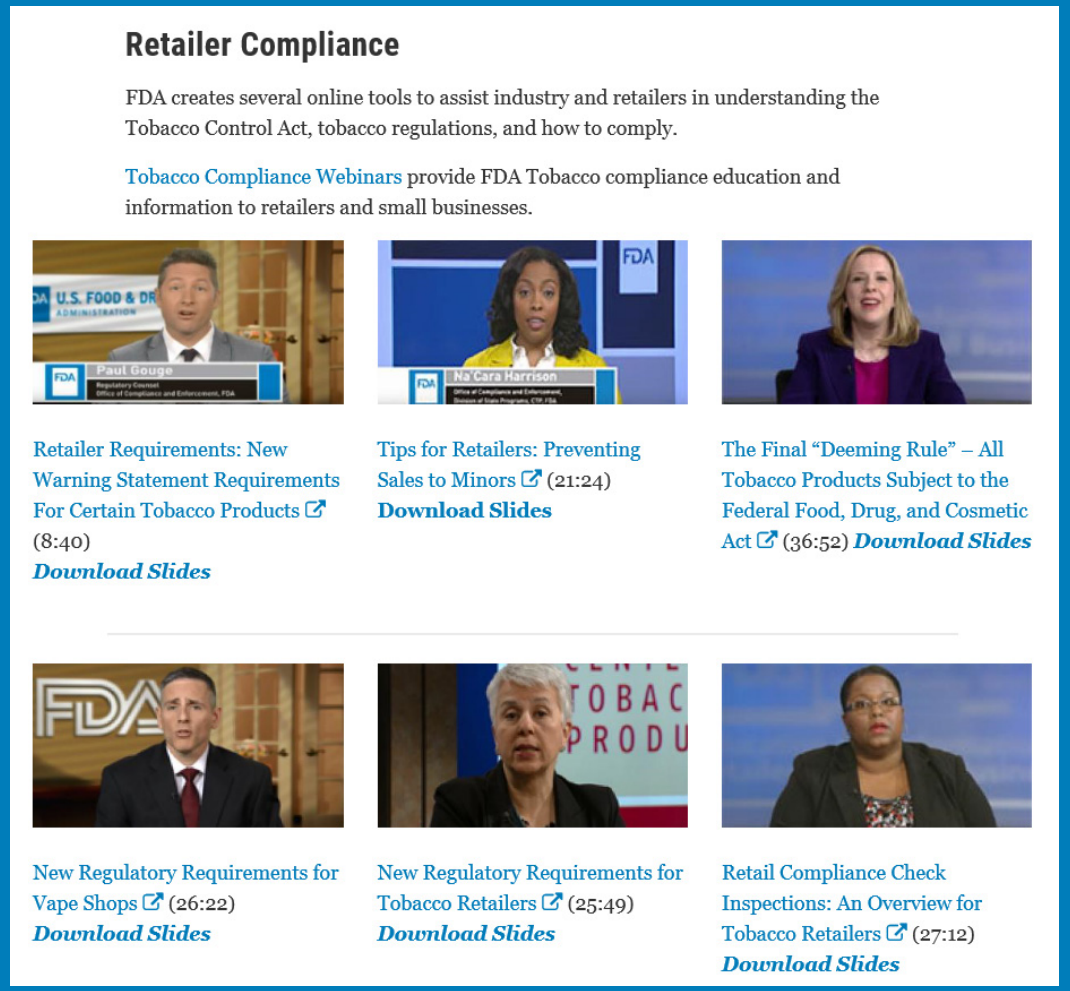
We issue warning letters to traditional "brick and mortar" retail stores nationwide and online retailers. All warning letters issued as the result of compliance check inspections of tobacco retailers prior to October 1, 2016, have been archived via the FDA Web Archive.



Click for full version of Undercover Buy Inspections

CONTENT: COMPLIANCE AND ENFORCEMENT TRAINING

- Compliance, Enforcement & Training
  - Compliance and Enforcement
    - Warning letters
    - Civil Money Penalties (CMPs)
    - No-Tobacco-Sale Orders (NSTOs)
  - Compliance information for Manufacturers & Retailers
    - Retailer education information
    - Webinars
    - Retailer training and enforcement
    - Misbranded and adulterated NSE tobacco products
  - Manufacturer, Distributor, and Importer Compliance



Retailer Compliance

FDA creates several online tools to assist industry and retailers in understanding the Tobacco Control Act, tobacco regulations, and how to comply.

Tobacco Compliance Webinars provide FDA Tobacco compliance education and information to retailers and small businesses.

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

Tips for Retailers: Preventing Sales to Minors (21:24) **Download Slides**

The Final "Deeming Rule" – All Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act (36:52) ***Download Slides***

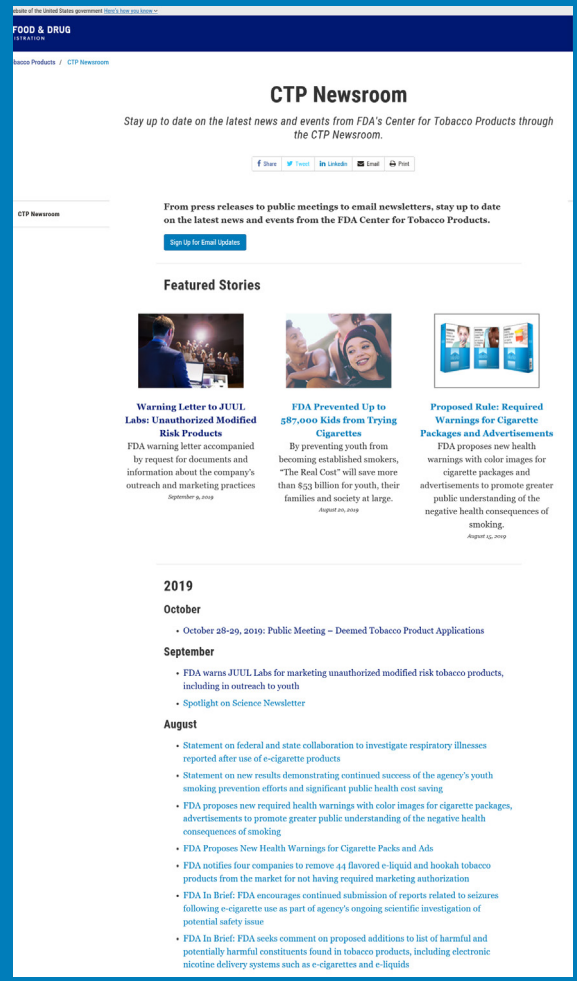
New Regulatory Requirements for Vape Shops (26:22) ***Download Slides***

New Regulatory Requirements for Tobacco Retailers (25:49) ***Download Slides***

Retail Compliance Check Inspections: An Overview for Tobacco Retailers (27:12) ***Download Slides***

CONTENT: NEWSROOM

- Newsroom
  - Press releases
  - Commissioner Statements
  - CTP in Briefs
  - Web Features



FOOD & DRUG

Tobacco Products / CTP Newsroom

CTP Newsroom

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

Share Tweet LinkedIn Email Print

CTP Newsroom

From press releases to public meetings to email newsletters, stay up to date on the latest news and events from the FDA Center for Tobacco Products.

Sign Up for Email Updates

Featured Stories

Warning Letter to JUUL Labs: Unauthorized Modified Risk Products
FDA warning letter accompanied by request for documents and information about the company's outreach and marketing practices
September 9, 2019

FDA Prevented Up to 587,000 Kids from Trying Cigarettes
By preventing youth from becoming established smokers, "The Real Cost" will save more than $53 billion for youth, their families and society at large.
August 20, 2019

Proposed Rule: Required Warnings for Cigarette Packages and Advertisements
FDA proposes new health warnings with color images for cigarette packages and advertisements to promote greater public understanding of the negative health consequences of smoking.
August 15, 2019

2019

October

- October 28-29, 2019: Public Meeting – Deemed Tobacco Product Applications

September

- FDA warns JUUL Labs for marketing unauthorized modified risk tobacco products, including in outreach to youth
- Spotlight on Science Newsletter

August

- Statement on federal and state collaboration to investigate respiratory illnesses reported after use of e-cigarette products
- Statement on new results demonstrating continued success of the agency's youth smoking prevention efforts and significant public health cost saving
- FDA proposes new required health warnings with color images for cigarette packages, advertisements to promote greater public understanding of the negative health consequences of smoking
- FDA Proposes New Health Warnings for Cigarette Packs and Ads
- FDA notifies four companies to remove 44 flavored e-liquid and hookah tobacco products from the market for not having required marketing authorization
- FDA In Brief: FDA encourages continued submission of reports related to seizures following e-cigarette use as part of agency's ongoing scientific investigation of potential safety issue
- FDA In Brief: FDA seeks comment on proposed additions to list of harmful and potentially harmful constituents found in tobacco products, including electronic nicotine delivery systems such as e-cigarettes and e-liquids

CONTENT: NEWSROOM

- Newsroom
  - Press releases
  - Commissioner Statements
  - CTP in Briefs
  - Web Features

Featured Stories

Proposed Rule: PMTA and Recordkeeping Requirements

FDA's proposed rule, when final, would set forth requirements related to the content, format, and FDA's review and communications procedures for premarket tobacco product applications.

September 20, 2019

Warning Letter to JUUL Labs: Unauthorized Modified Risk Products

FDA warning letter accompanied by request for documents and information about the company's outreach and marketing practices

September 9, 2019

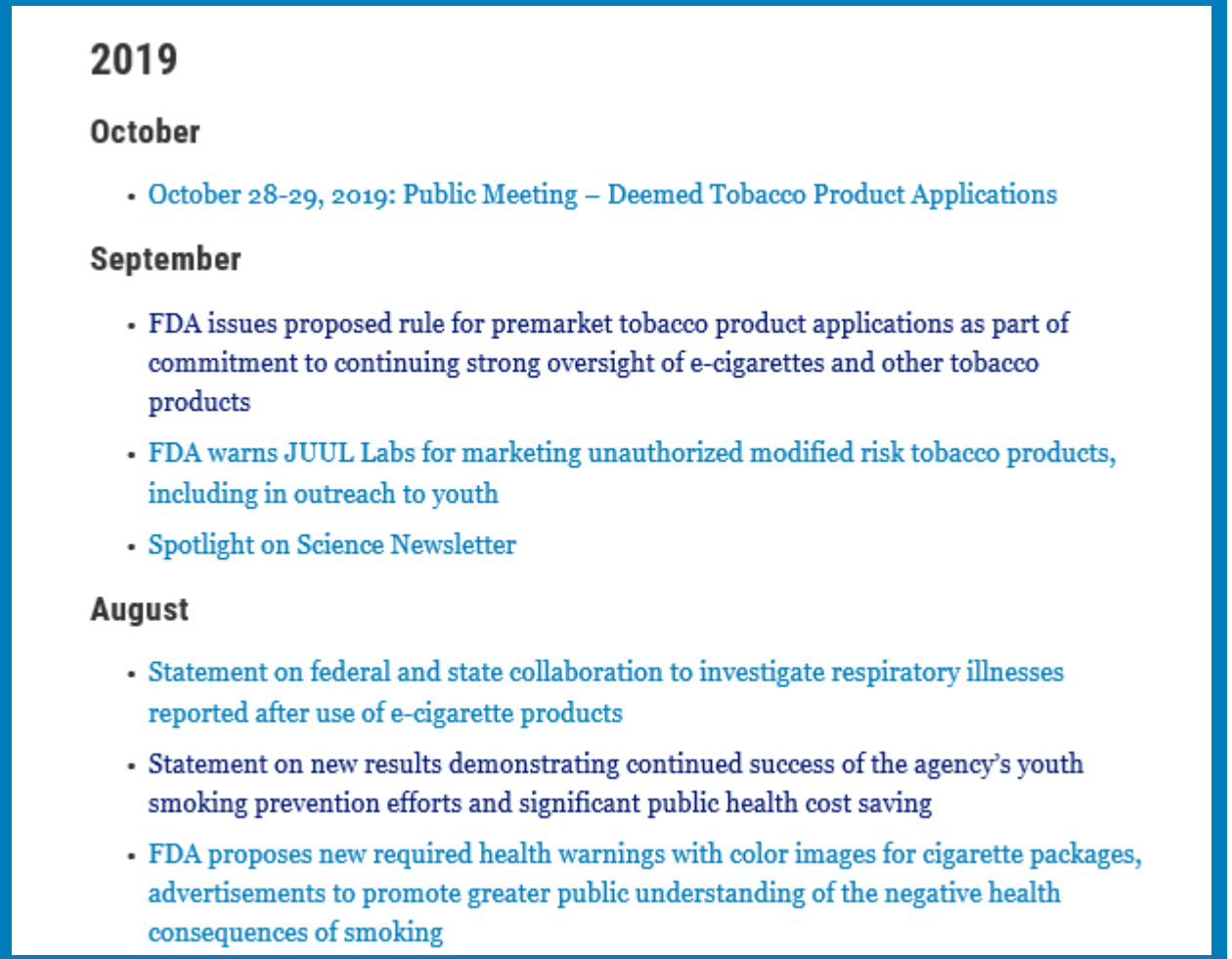
FDA Prevented Up to 587,000 Kids from Trying Cigarettes

By preventing youth from becoming established smokers, "The Real Cost" will save more than $53 billion for youth, their families and society at large.

August 20, 2019

CONTENT: NEWSROOM

- Newsroom
  - Press releases
  - Commissioner Statements
  - CTP in Briefs
  - Web Features



2019

October

- October 28-29, 2019: Public Meeting – Deemed Tobacco Product Applications

September

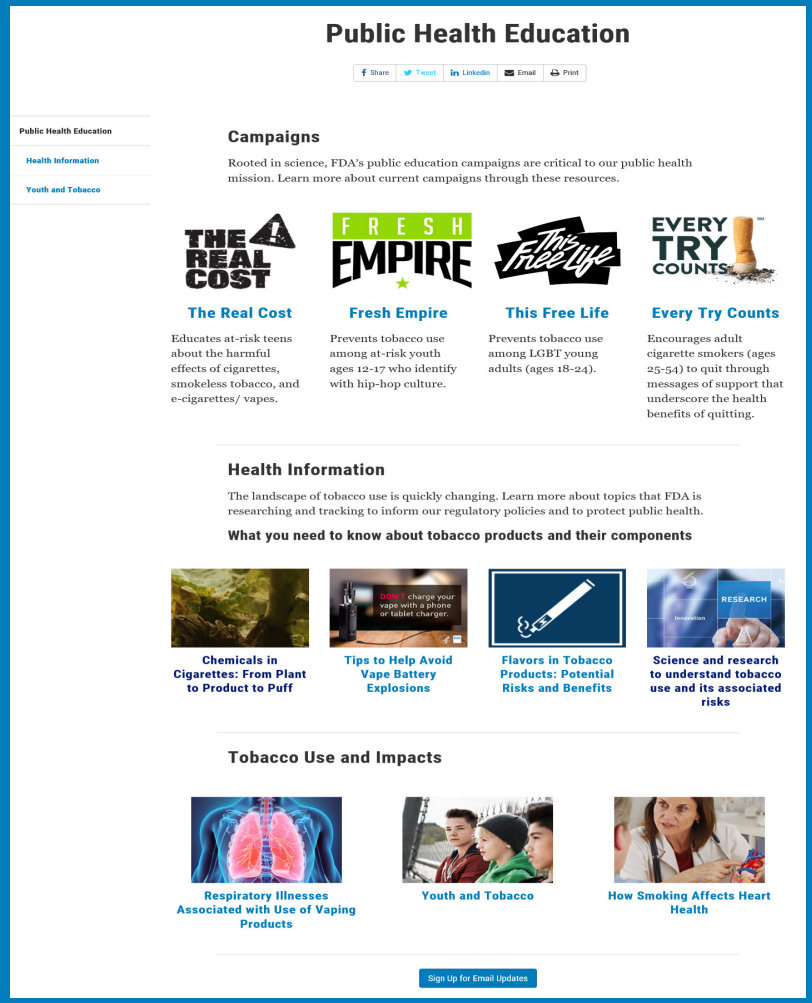
- FDA issues proposed rule for premarket tobacco product applications as part of commitment to continuing strong oversight of e-cigarettes and other tobacco products
- FDA warns JUUL Labs for marketing unauthorized modified risk tobacco products, including in outreach to youth
- Spotlight on Science Newsletter

August

- Statement on federal and state collaboration to investigate respiratory illnesses reported after use of e-cigarette products
- Statement on new results demonstrating continued success of the agency's youth smoking prevention efforts and significant public health cost saving
- FDA proposes new required health warnings with color images for cigarette packages, advertisements to promote greater public understanding of the negative health consequences of smoking

CONTENT: PUBLIC HEALTH EDUCATION

- Public Health Education

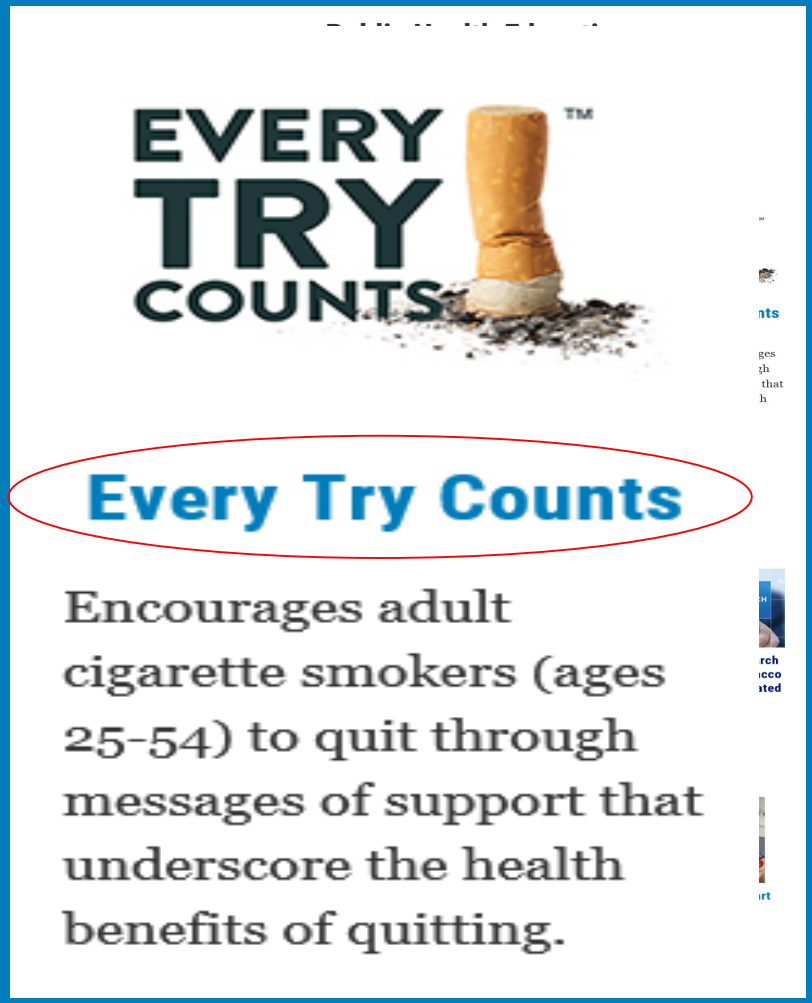


CONTENT: PUBLIC HEALTH EDUCATION

- Public Health Education
  – Campaigns (e.g. The Real Cost)

CONTENT: PUBLIC HEALTH EDUCATION

- Public Health Education
  - Campaigns (e.g. The Real Cost)

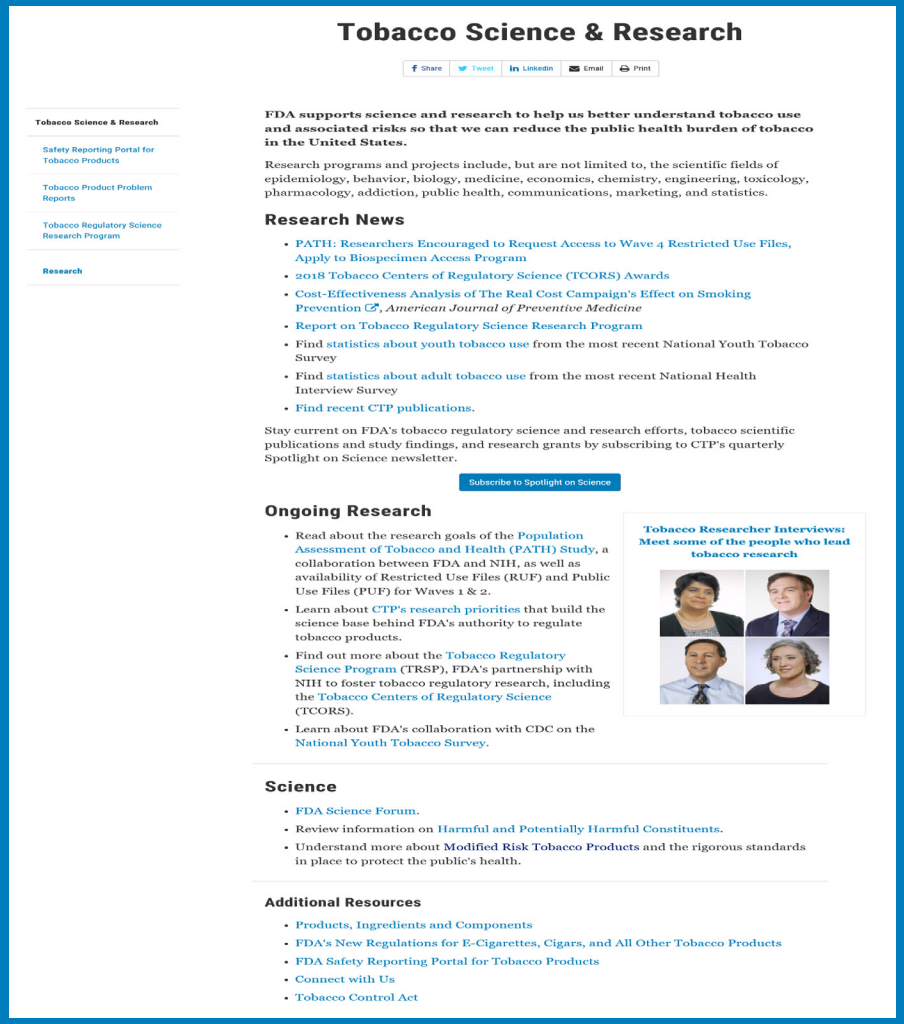


CONTENT: PUBLIC HEALTH EDUCATION

- Public Health Education
  - Campaigns (e.g. The Real Cost)
  - Consumer health articles
  - Youth information

CONTENT: SCIENCE & RESEARCH

- Science & Research



Tobacco Science & Research

Share | Tweet | LinkedIn | Email | Print

Tobacco Science & Research
Safety Reporting Portal for Tobacco Products
Tobacco Product Problem Reports
Tobacco Regulatory Science Research Program
Research

FDA supports science and research to help us better understand tobacco use and associated risks so that we can reduce the public health burden of tobacco in the United States.

Research programs and projects include, but are not limited to, the scientific fields of epidemiology, behavior, biology, medicine, economics, chemistry, engineering, toxicology, pharmacology, addiction, public health, communications, marketing, and statistics.

Research News

- PATH: Researchers Encouraged to Request Access to Wave 4 Restricted Use Files, Apply to Biospecimen Access Program
- 2018 Tobacco Centers of Regulatory Science (TCORS) Awards
- Cost-Effectiveness Analysis of The Real Cost Campaign's Effect on Smoking Prevention, *American Journal of Preventive Medicine*
- Report on Tobacco Regulatory Science Research Program
- Find statistics about youth tobacco use from the most recent National Youth Tobacco Survey
- Find statistics about adult tobacco use from the most recent National Health Interview Survey
- Find recent CTP publications.

Stay current on FDA's tobacco regulatory science and research efforts, tobacco scientific publications and study findings, and research grants by subscribing to CTP's quarterly Spotlight on Science newsletter.

Subscribe to Spotlight on Science

Ongoing Research

- Read about the research goals of the Population Assessment of Tobacco and Health (PATH) Study, a collaboration between FDA and NIH, as well as availability of Restricted Use Files (RUF) and Public Use Files (PUF) for Waves 1 & 2.
- Learn about CTP's research priorities that build the science base behind FDA's authority to regulate tobacco products.
- Find out more about the Tobacco Regulatory Science Program (TRSP), FDA's partnership with NIH to foster tobacco regulatory research, including the Tobacco Centers of Regulatory Science (TCORS).
- Learn about FDA's collaboration with CDC on the National Youth Tobacco Survey.

Tobacco Researcher Interviews: Meet some of the people who lead tobacco research

Science

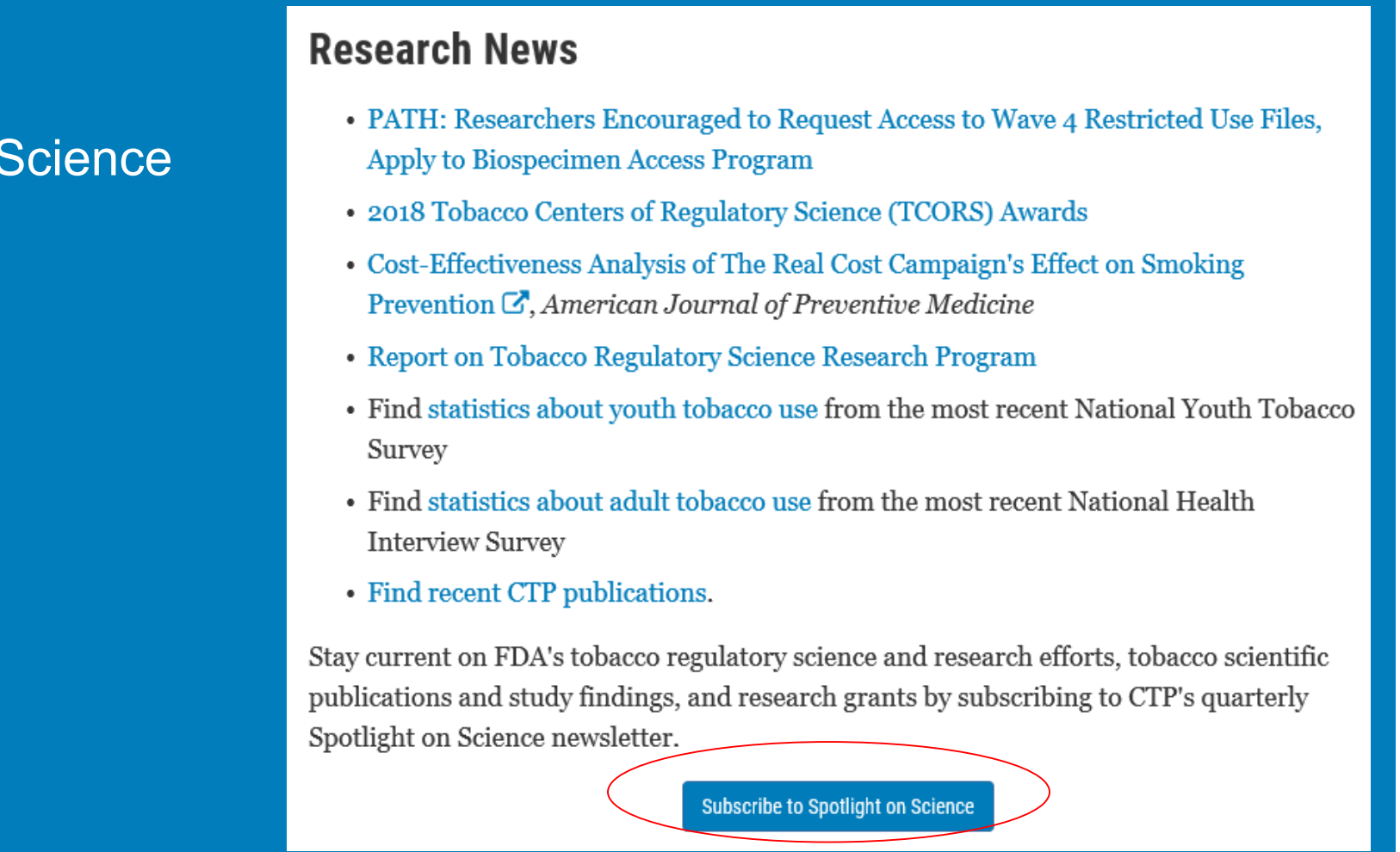
- FDA Science Forum.
- Review information on Harmful and Potentially Harmful Constituents.
- Understand more about Modified Risk Tobacco Products and the rigorous standards in place to protect the public's health.

Additional Resources

- Products, Ingredients and Components
- FDA's New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products
- FDA Safety Reporting Portal for Tobacco Products
- Connect with Us
- Tobacco Control Act

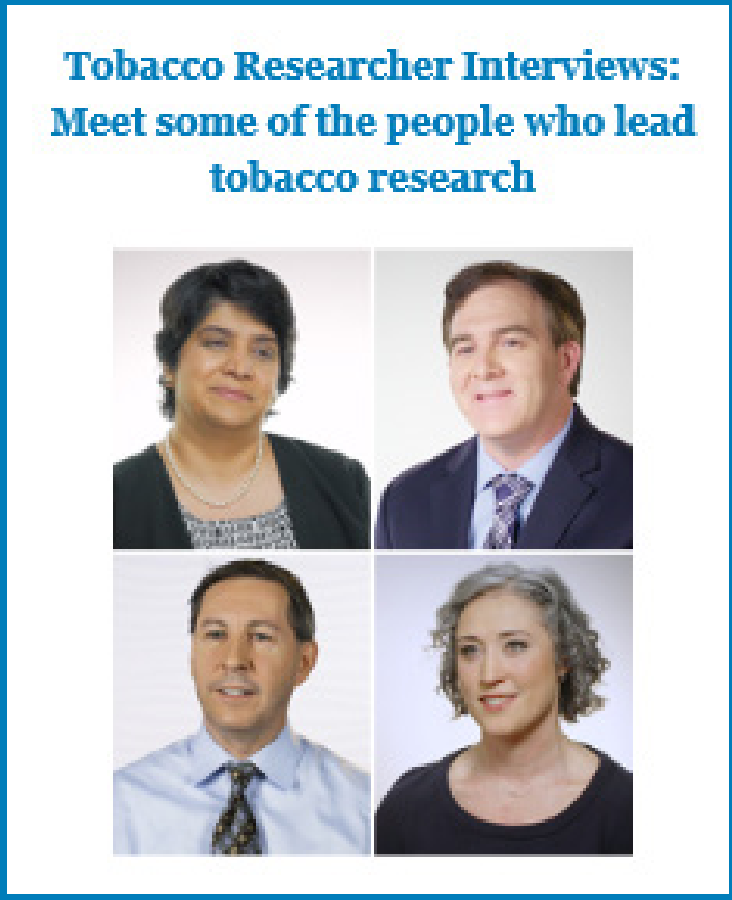
CONTENT: SCIENCE & RESEARCH

- Science & Research
  - Research News
  - Subscribe to Spotlight on Science



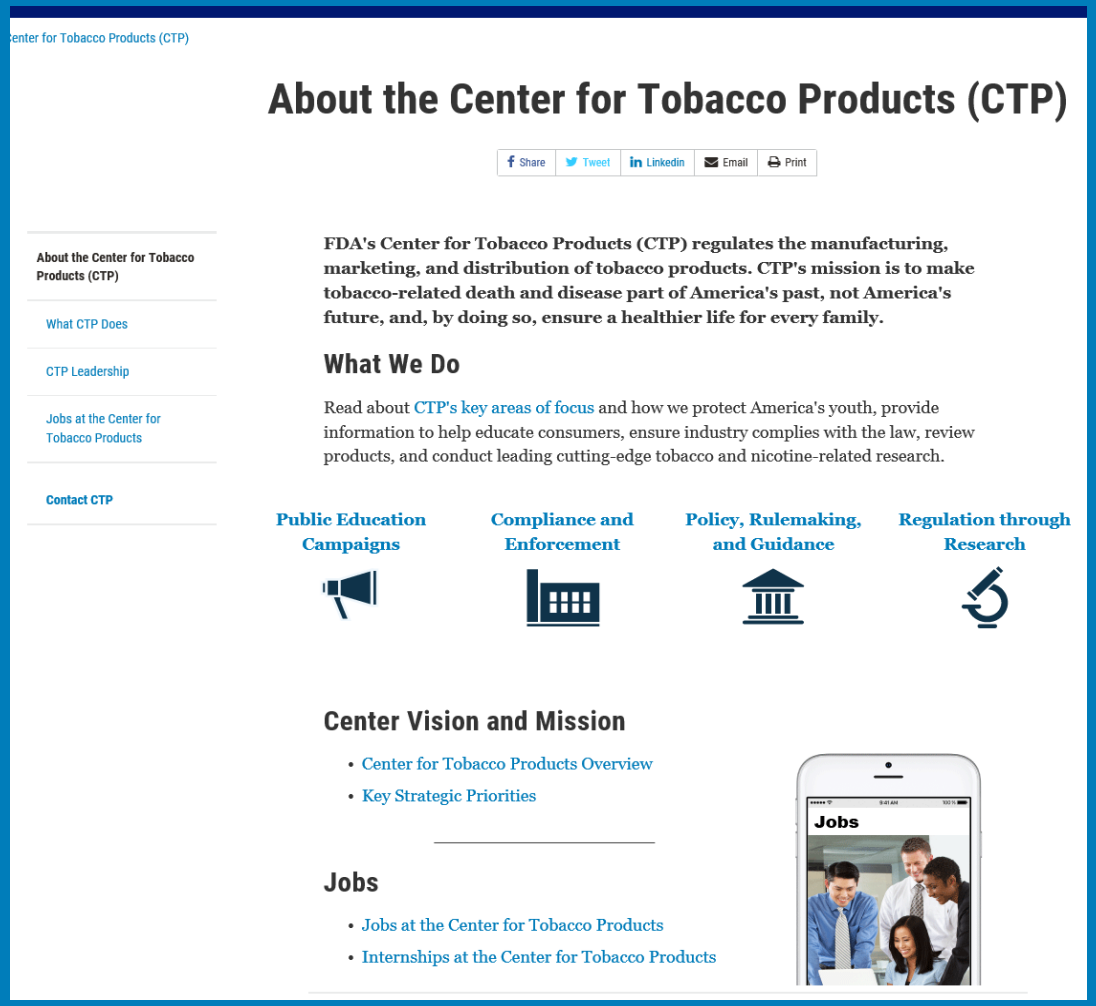
CONTENT: SCIENCE & RESEARCH

- Science & Research
  - Research News
  - Subscribe to Spotlight on Science
  - Tobacco Research Interviews
  - Ongoing Research
  - FDA Science forum



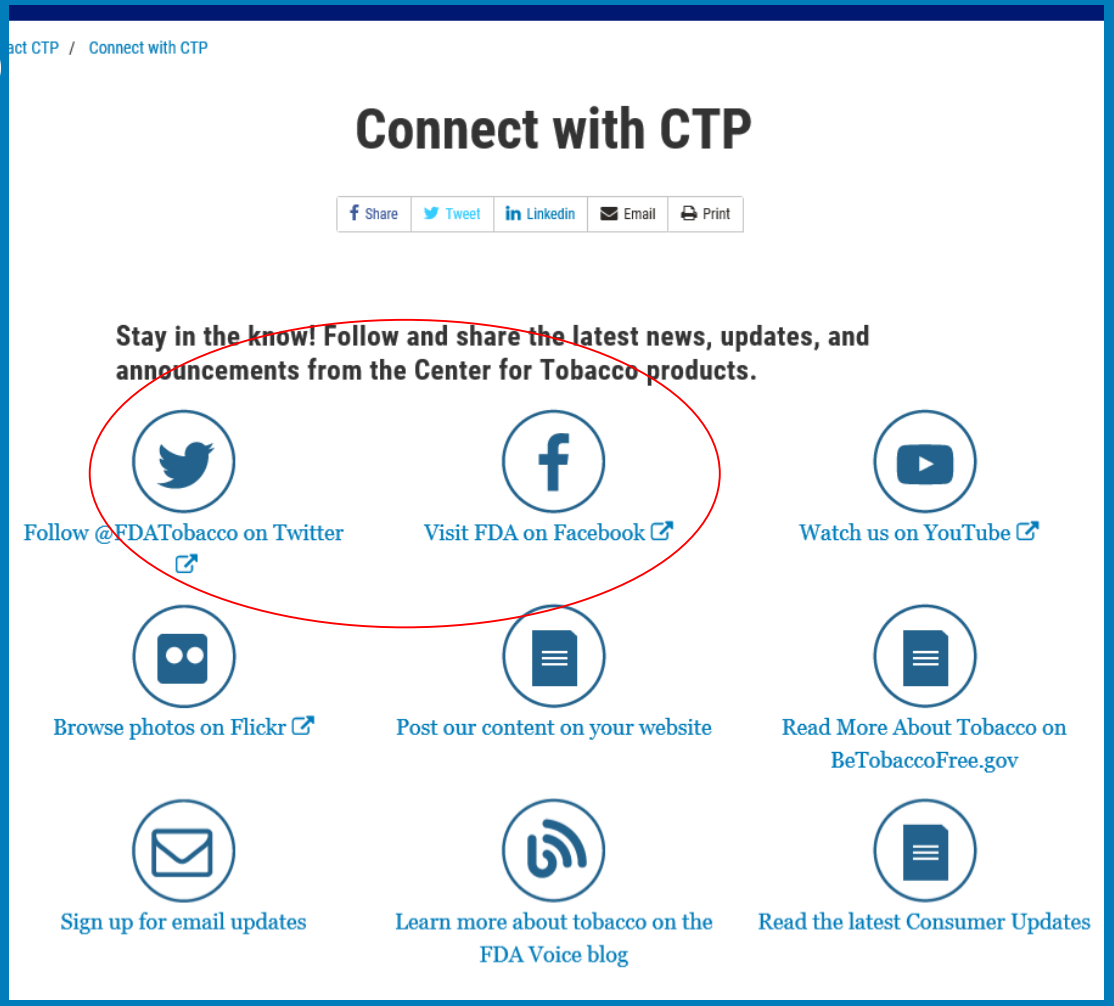
CONTENT: ABOUT THE CENTER FOR TOBACCO PRODUCTS

- About the Center for Tobacco Products (CTP)
  - What We Do
  - Center Vision and Mission
  - Jobs
  - Leadership



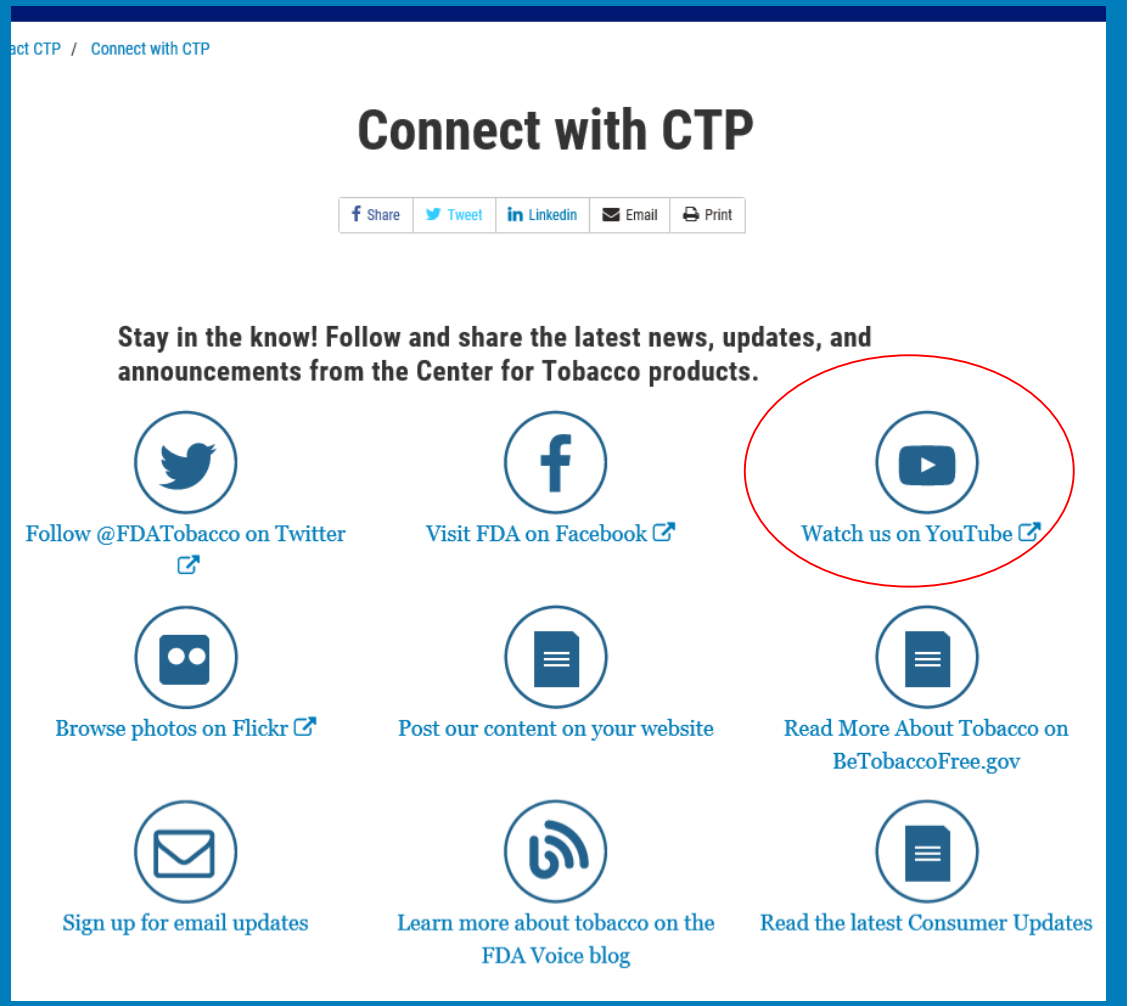
CONTENT: ABOUT THE CENTER FOR TOBACCO PRODUCTS

- About the Center for Tobacco Products (CTP)
  - What We Do
  - Center Vision and Mission
  - Jobs
  - Leadership
  - How to work with Us
  - Accomplishments and Budget information



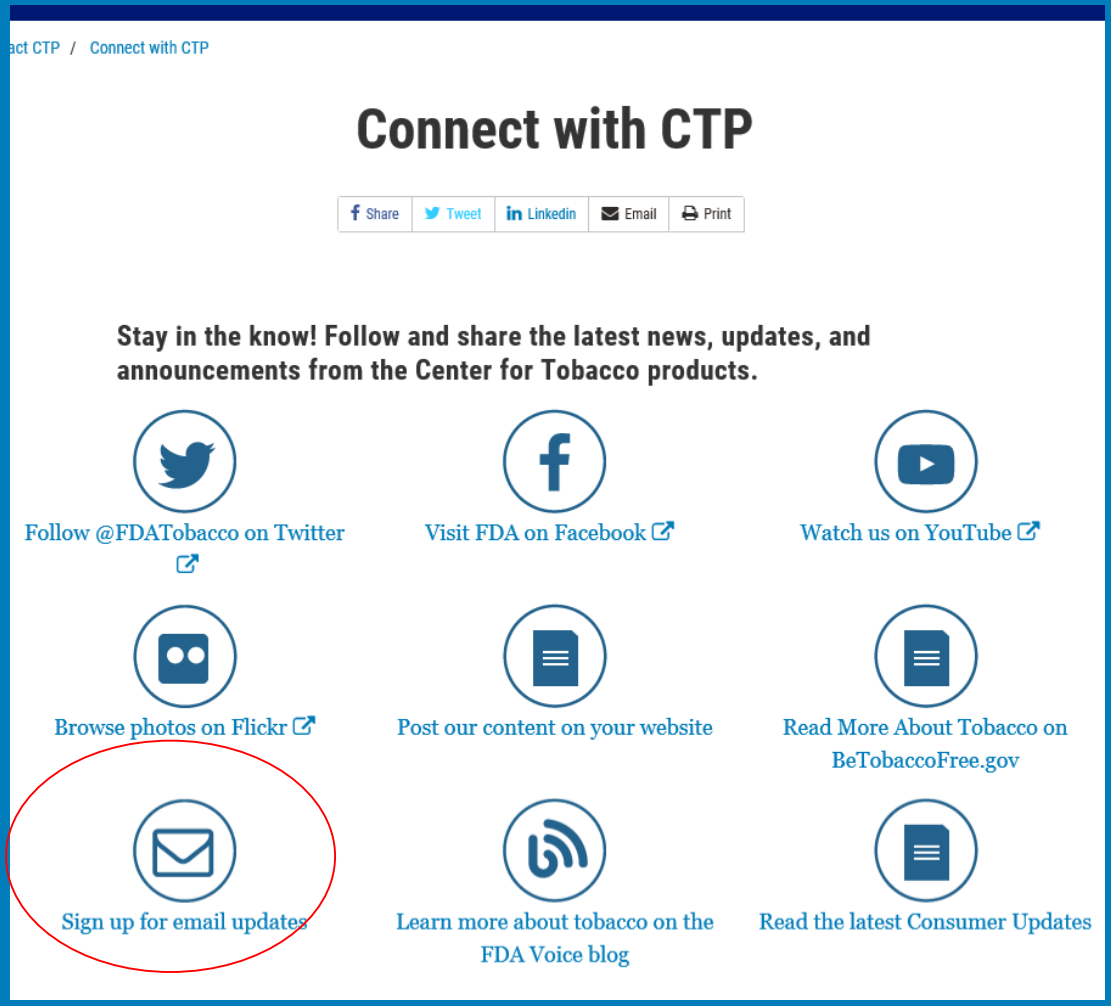
CONTENT: ABOUT THE CENTER FOR TOBACCO PRODUCTS

- About the Center for Tobacco Products (CTP)
  - What We Do
  - Center Vision and Mission
  - Jobs
  - Leadership
  - How to work with Us
  - Accomplishments and Budget information



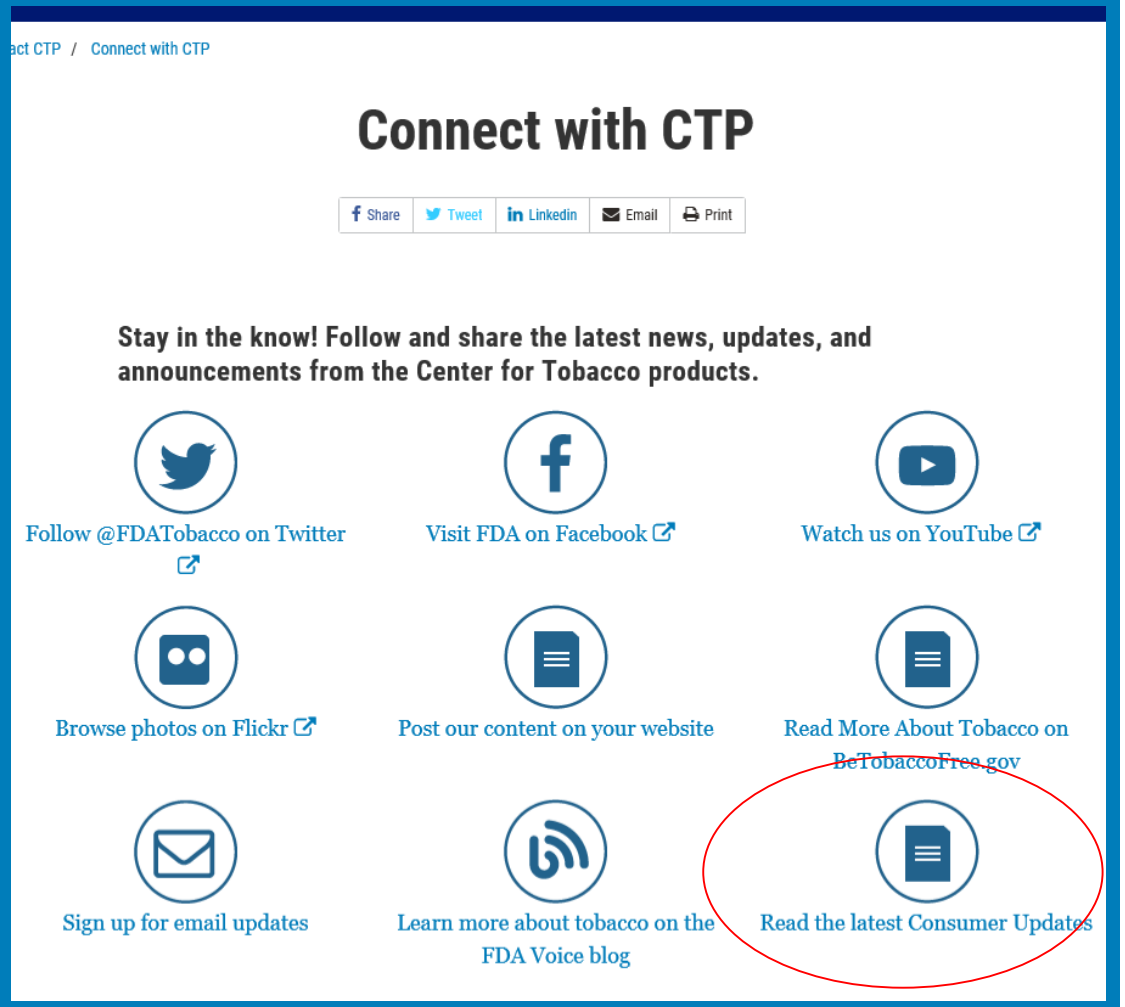
CONTENT: ABOUT THE CENTER FOR TOBACCO PRODUCTS

- About the Center for Tobacco Products (CTP)
  - What We Do
  - Center Vision and Mission
  - Jobs
  - Leadership
  - How to work with Us
  - Accomplishments and Budget information

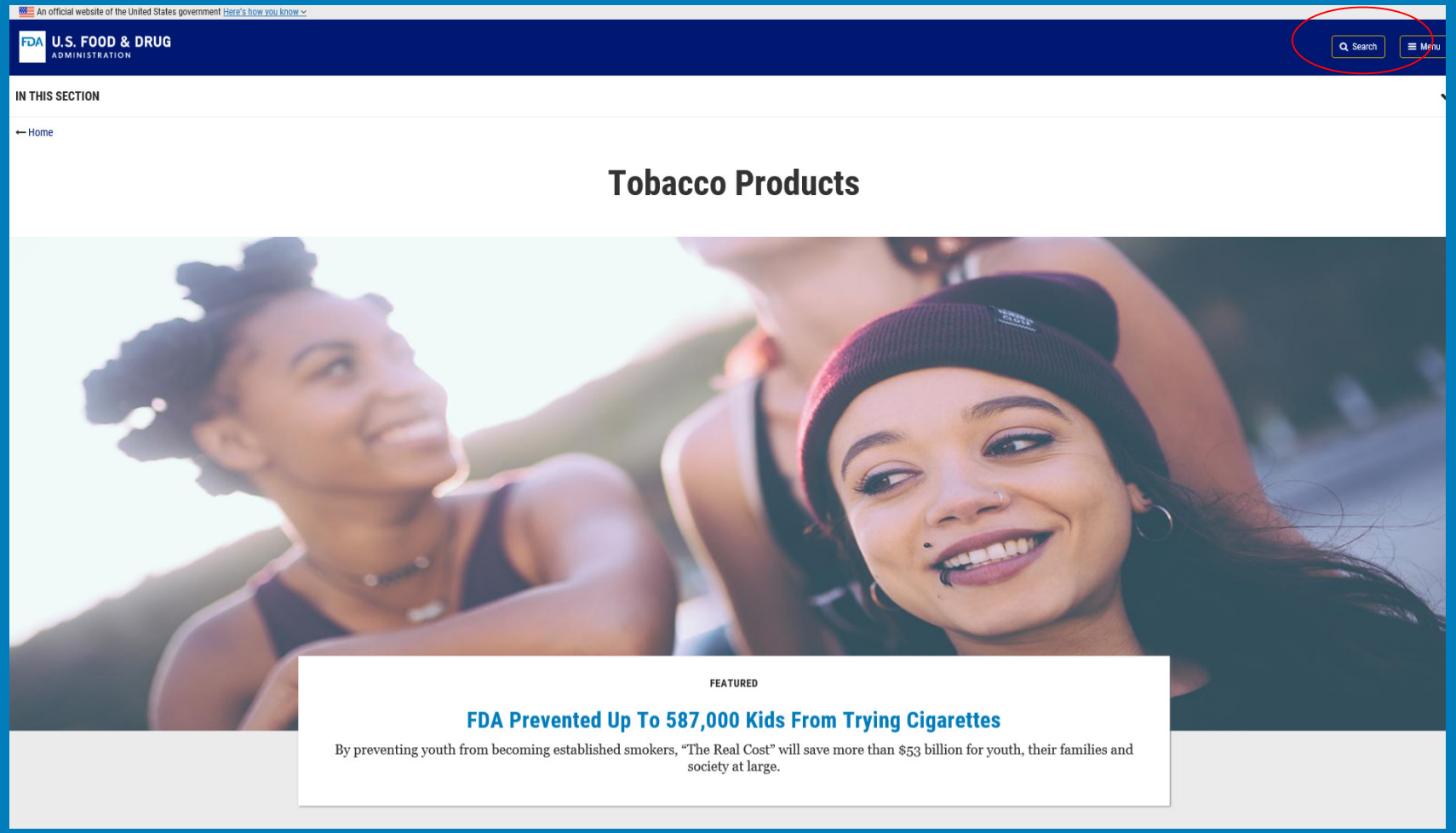


CONTENT: ABOUT THE CENTER FOR TOBACCO PRODUCTS

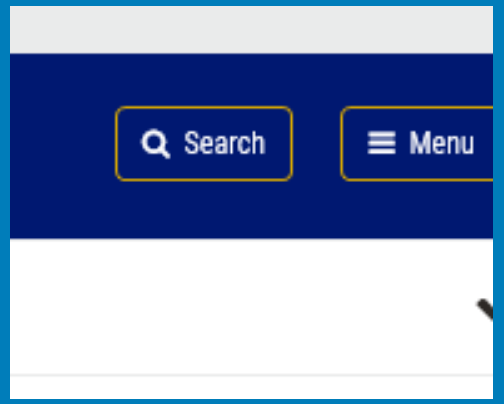
- About the Center for Tobacco Products (CTP)
  - What We Do
  - Center Vision and Mission
  - Jobs
  - Leadership
  - How to work with Us
  - Accomplishments and Budget information



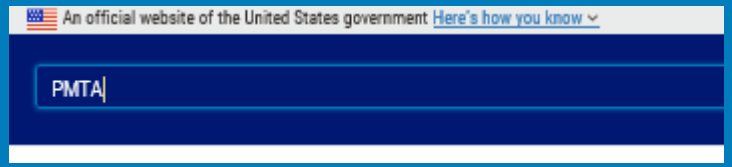
CONTENT: SEARCHING



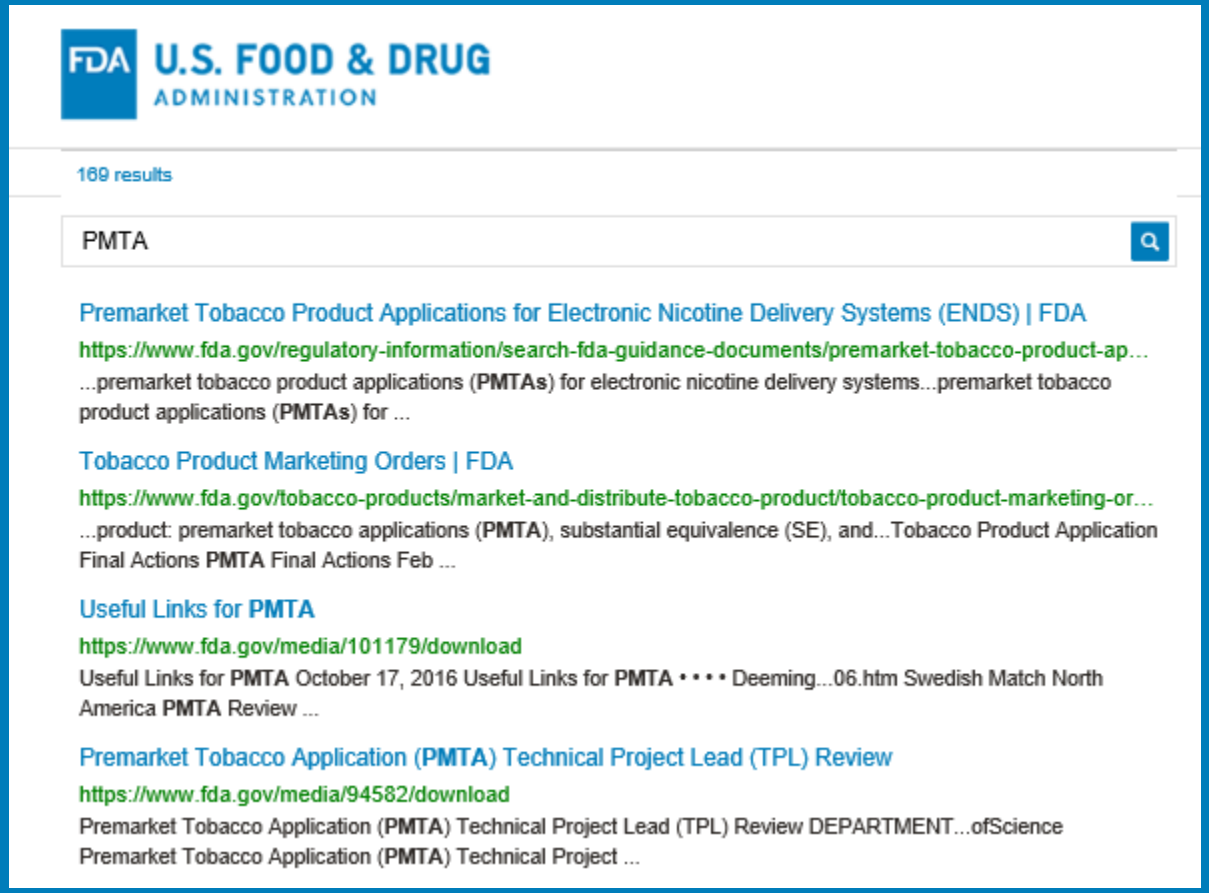
CONTENT: SEARCHING



CONTENT: SEARCHING



CONTENT: SEARCHING

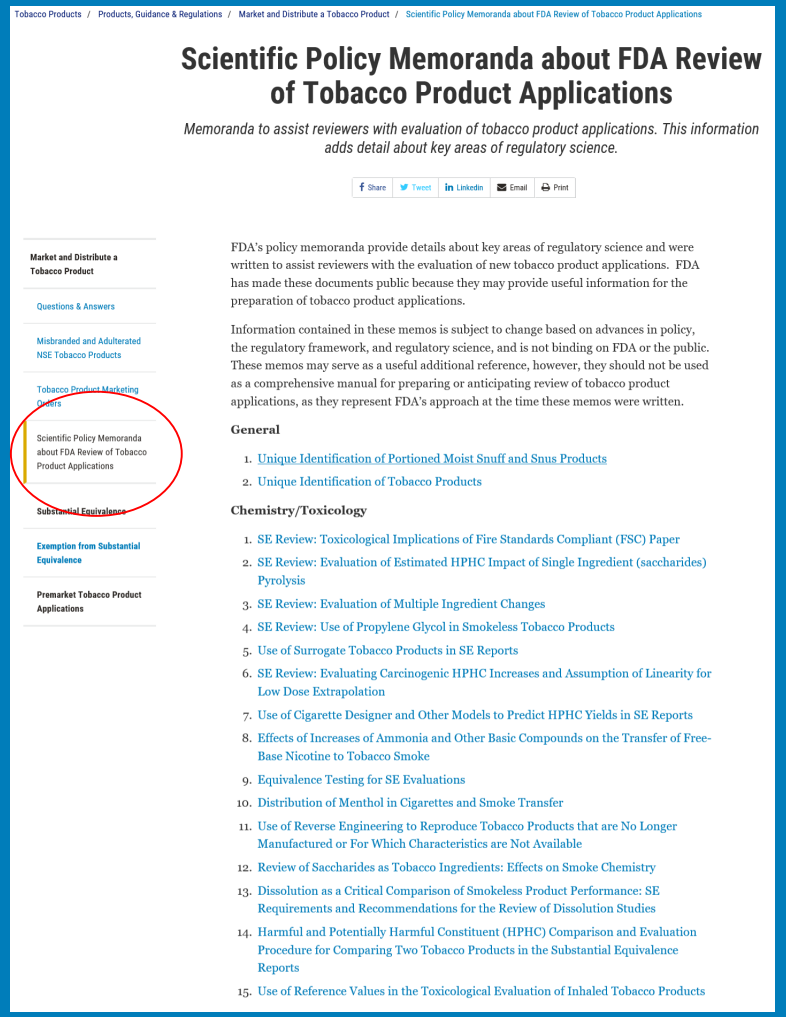


NEW & UPDATED SITE CONTENT

SITE CONTENT: NEW SITE PAGES

- Tobacco Products Section
  - New site page
    - Scientific Policy Memorandums

      The memorandums serve as a resource to manufacturers in the preparation of tobacco product applications by providing information on specific topics, including harmful and potentially harmful constituent evaluations, the use of surrogate tobacco products in place of the new and predicate tobacco products, and how product quantity changes are evaluated. The information in these memos should help lead to a more efficient and predictable marketing authorization process for both manufacturers and the FDA.



SITE CONTENT: NEW SITE PAGES

- Tobacco Products Section
  - New site page
    - Scientific Policy Memorandums

      The memorandums serve as a resource to manufacturers in the preparation of tobacco product applications by providing information on specific topics, including harmful and potentially harmful constituent evaluations, the use of surrogate tobacco products in place of the new and predicate tobacco products, and how product quantity changes are evaluated. The information in these memos should help lead to a more efficient and predictable marketing authorization process for both manufacturers and the FDA.

SITE CONTENT: NEW SITE PAGES

- Tobacco Products Section
  - New site page
    - Scientific Policy Memorandums

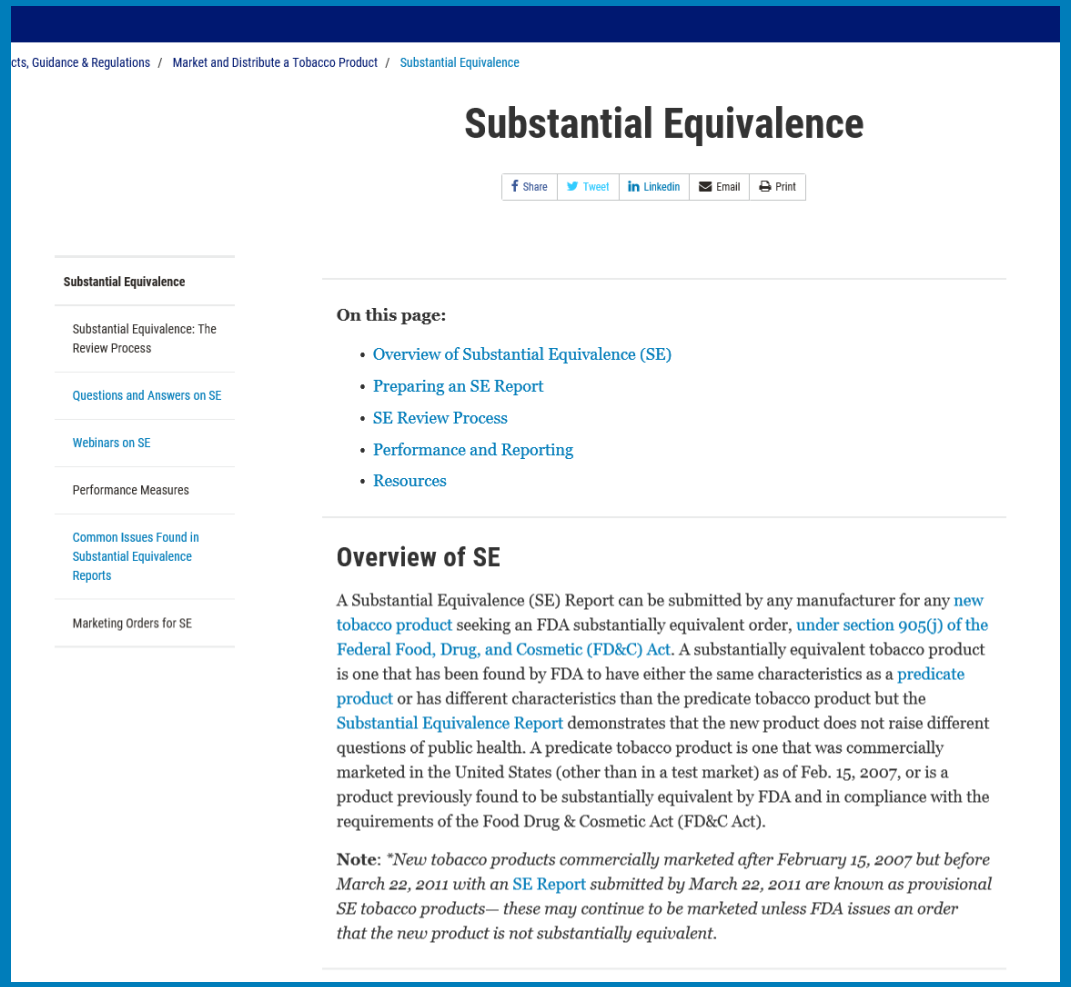
      The memorandums serve as a resource to manufacturers in the preparation of tobacco product applications by providing information on specific topics, including harmful and potentially harmful constituent evaluations, the use of surrogate tobacco products in place of the new and predicate tobacco products, and how product quantity changes are evaluated. The information in these memos should help lead to a more efficient and predictable marketing authorization process for both manufacturers and the FDA.

Social Science

1. Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for Statutorily Regulated Tobacco Products

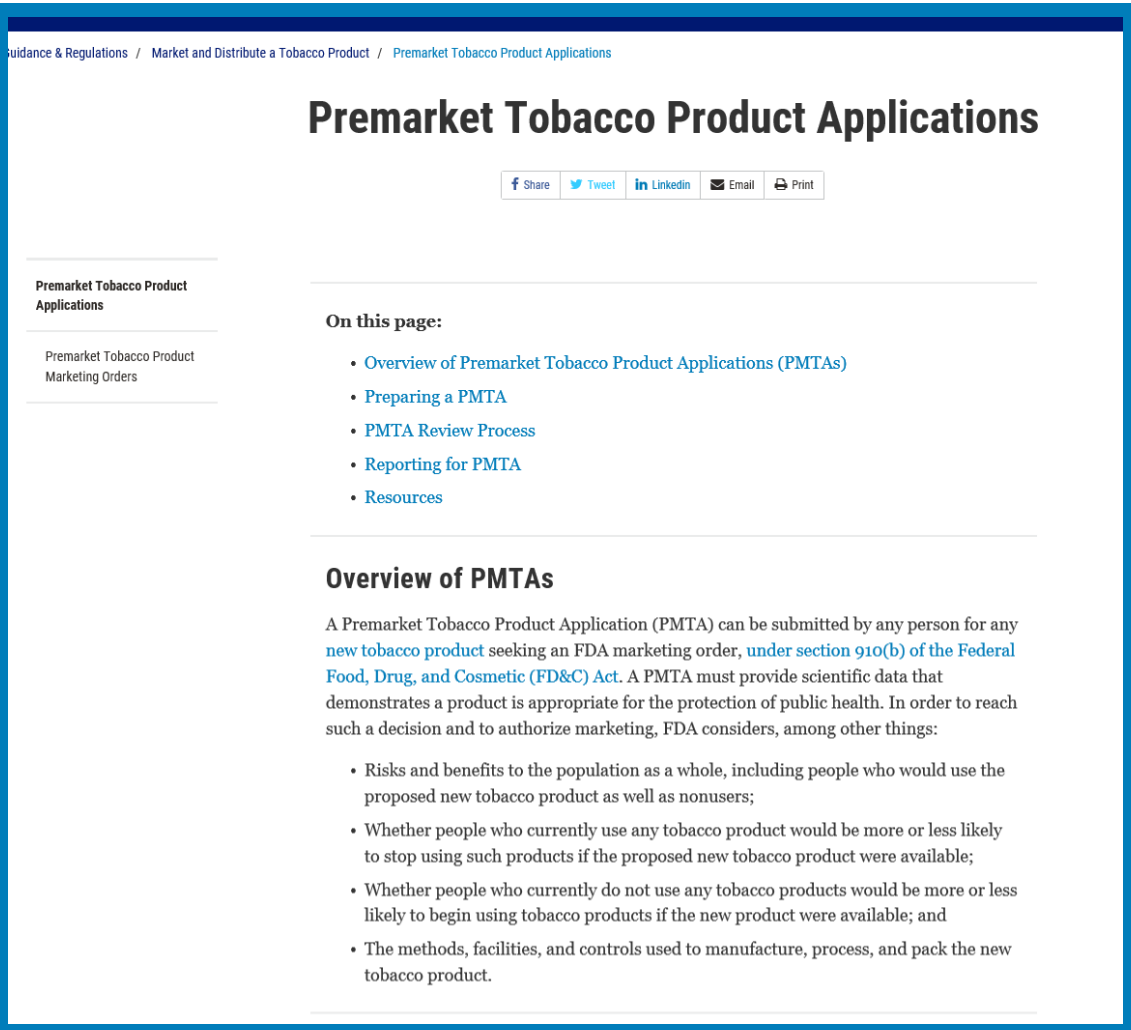
SITE CONTENT: UPDATED SITE PAGES

- Updated site pages
  - Submission and pathway pages updated
    - SE, EX, PMTA, MRTPA, & TPMF
    - Streamlined for consistency
    - Provides information on preparing applications and submissions
    - How to submit information
    - The Review Process
    - Performance and Reporting information
    - Resources



SITE CONTENT: UPDATED SITE PAGES

PMTA Pathway page
– Overview of PMTA



uidance & Regulations / Market and Distribute a Tobacco Product / Premarket Tobacco Product Applications

Premarket Tobacco Product Applications

Share Tweet Linkedin Email Print

Premarket Tobacco Product Applications

Premarket Tobacco Product Marketing Orders

On this page:

- Overview of Premarket Tobacco Product Applications (PMTAs)
- Preparing a PMTA
- PMTA Review Process
- Reporting for PMTA
- Resources

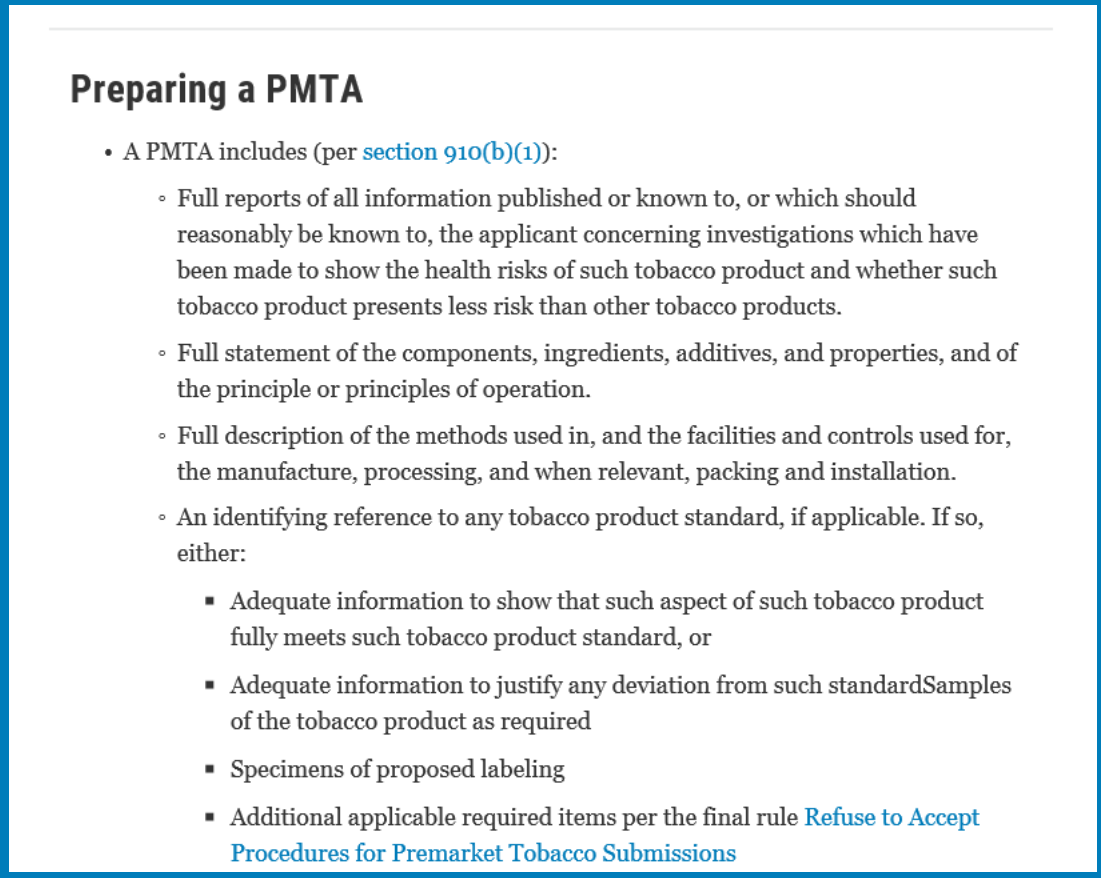
Overview of PMTAs

A Premarket Tobacco Product Application (PMTA) can be submitted by any person for any new tobacco product seeking an FDA marketing order, under section 910(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act. A PMTA must provide scientific data that demonstrates a product is appropriate for the protection of public health. In order to reach such a decision and to authorize marketing, FDA considers, among other things:

- Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product as well as nonusers;
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available;
- Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available; and
- The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product.

SITE CONTENT: UPDATED SITE PAGES

PMTA Pathway page
- Overview of PMTA
- Preparing a PMTA

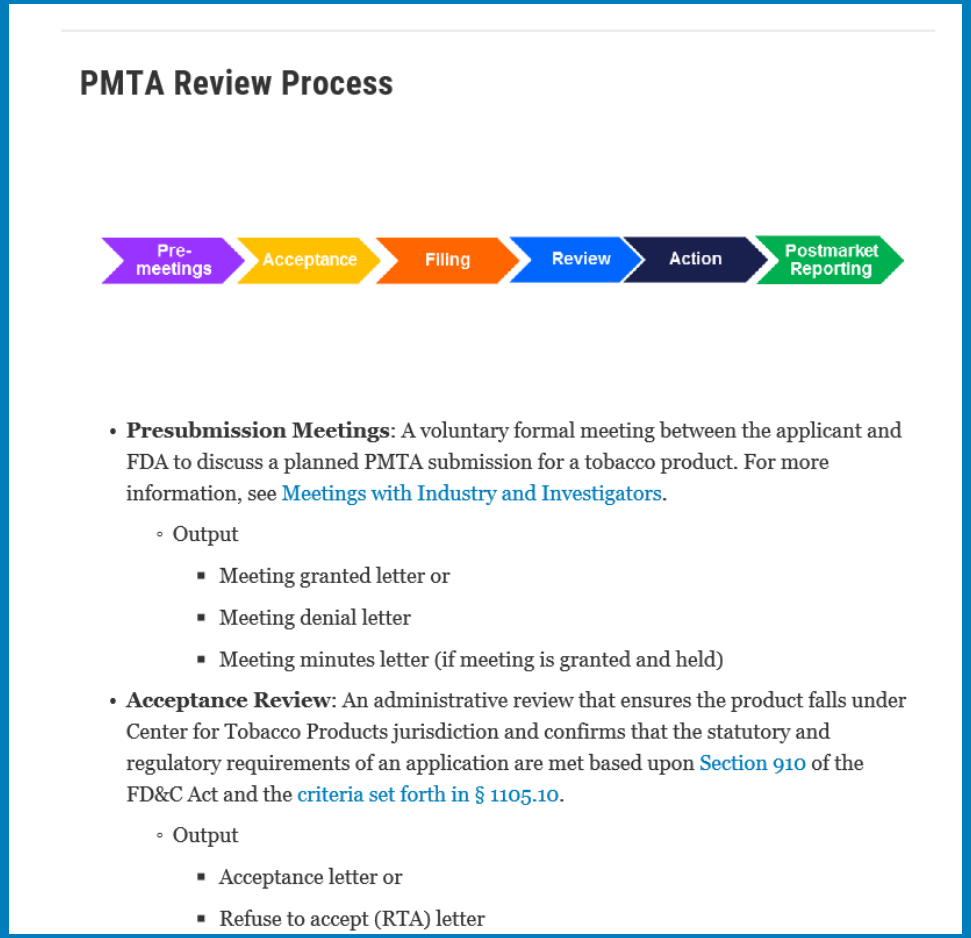


Preparing a PMTA

- A PMTA includes (per section 910(b)(1)):
  - Full reports of all information published or known to, or which should reasonably be known to, the applicant concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products.
  - Full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation.
  - Full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation.
  - An identifying reference to any tobacco product standard, if applicable. If so, either:
    - Adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard, or
    - Adequate information to justify any deviation from such standardSamples of the tobacco product as required
    - Specimens of proposed labeling
    - Additional applicable required items per the final rule Refuse to Accept Procedures for Premarket Tobacco Submissions

SITE CONTENT: UPDATED SITE PAGES

PMTA Pathway page
- Overview of PMTA
- Preparing a PMTA
- Review Process



PMTA Review Process

- **Presubmission Meetings**: A voluntary formal meeting between the applicant and FDA to discuss a planned PMTA submission for a tobacco product. For more information, see Meetings with Industry and Investigators.
  - Output
    - Meeting granted letter or
    - Meeting denial letter
    - Meeting minutes letter (if meeting is granted and held)
- **Acceptance Review**: An administrative review that ensures the product falls under Center for Tobacco Products jurisdiction and confirms that the statutory and regulatory requirements of an application are met based upon Section 910 of the FD&C Act and the criteria set forth in § 1105.10.
  - Output
    - Acceptance letter or
    - Refuse to accept (RTA) letter

SITE CONTENT: UPDATED SITE PAGES

PMTA Pathway page
- Overview of PMTA
- Preparing a PMTA
- Review Process
- Reporting
- Resources

Reporting for PMTA

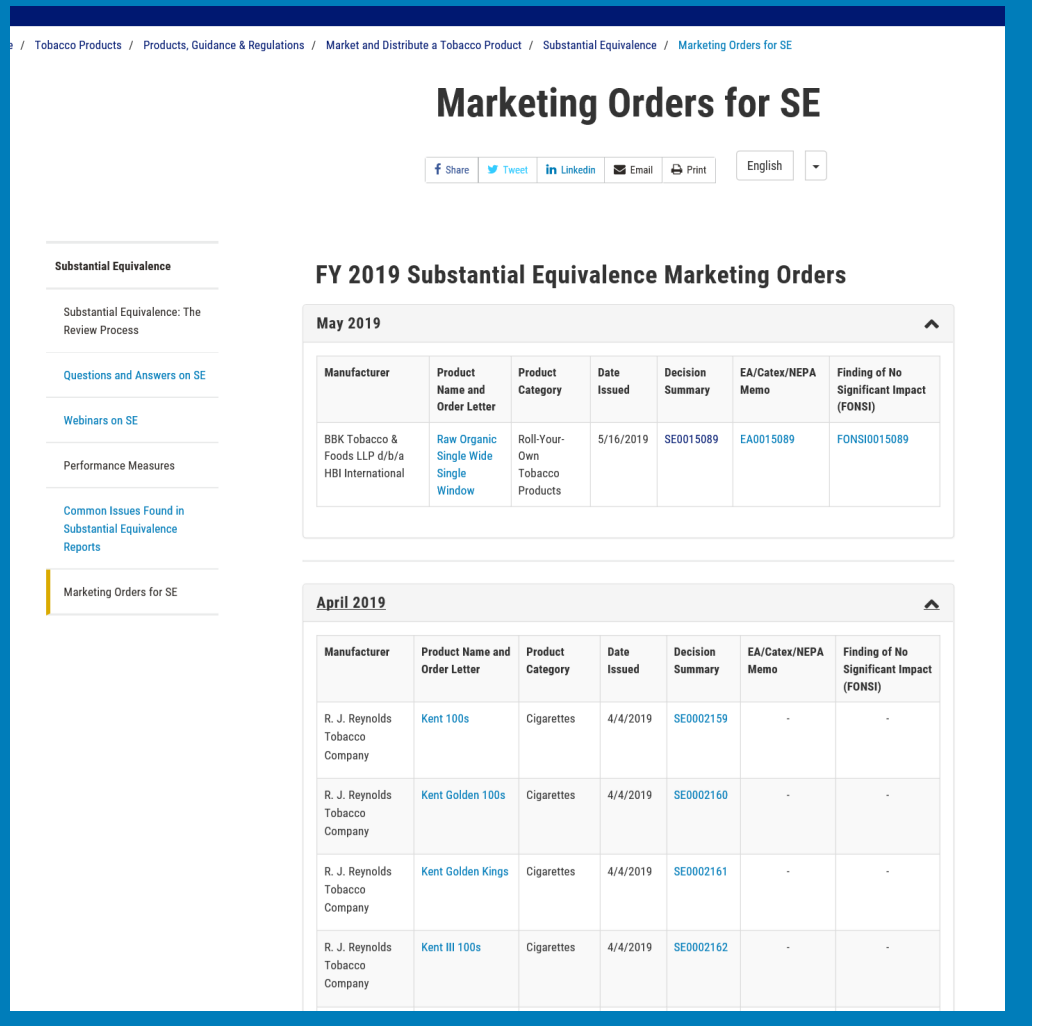
- Marketing Orders for PMTA

PMTA Resources

- Proposed Rule: Premarket Tobacco Product Applications and Recordkeeping Requirements
- Guidance
  - Draft Guidance: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) (2016)
  - Draft Guidance: Applications for Premarket Review of New Tobacco Products (2011)
- Tobacco Compliance Webinars for Manufacturers
- Reference Tools
  - PMTA Review Process: Presentation from the 2018 Tobacco Product Application Review Public Meeting
  - Information and Resources on Application Review Programs: Presentation from the 2018 Tobacco Product Application Review Public Meeting
  - CTP Electronic Submissions Standards and Activities: Presentation from the 2018 Tobacco Product Application Review Public Meeting
  - Refuse to File Determinations
  - Public Health Rationale for Recommended Restrictions on New Tobacco Product Labeling, Advertising, Marketing, and Promotion

CONTENT: MARKETING ORDERS

SE Marketing Orders



Tobacco Products / Products, Guidance & Regulations / Market and Distribute a Tobacco Product / Substantial Equivalence / Marketing Orders for SE

Marketing Orders for SE

Share | Tweet | Linkedin | Email | Print | English

- Substantial Equivalence
- Substantial Equivalence: The Review Process
- Questions and Answers on SE
- Webinars on SE
- Performance Measures
- Common Issues Found in Substantial Equivalence Reports
- Marketing Orders for SE

FY 2019 Substantial Equivalence Marketing Orders

May 2019

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
BBK Tobacco & Foods LLP d/b/a HBI International	Raw Organic Single Wide Single Window	Roll-Your-Own Tobacco Products	5/16/2019	SE0015089	EA0015089	FONSI0015089

April 2019

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
R. J. Reynolds Tobacco Company	Kent 100s	Cigarettes	4/4/2019	SE0002159	-	-
R. J. Reynolds Tobacco Company	Kent Golden 100s	Cigarettes	4/4/2019	SE0002160	-	-
R. J. Reynolds Tobacco Company	Kent Golden Kings	Cigarettes	4/4/2019	SE0002161	-	-
R. J. Reynolds Tobacco Company	Kent III 100s	Cigarettes	4/4/2019	SE0002162	-	-

CONTENT: MARKETING ORDERS

SE Marketing Orders

– Product name and order letter

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
BBK Tobacco & Foods LLP d/b/a HBI International	Raw Organic Single Wide Single Window	Roll-Your-Own Tobacco Products	5/16/2019	SE0015089	EA0015089	FONSI0015089

CONTENT: MARKETING ORDERS

SE Marketing Orders

- Product name and order letter
- Decision Summaries

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
BBK Tobacco & Foods LLP d/b/a HBI International	Raw Organic Single Wide Single Window	Roll-Your-Own Tobacco Products	5/16/2019	SE0015089	EA0015089	FONSI0015089

CONTENT: MARKETING ORDERS

SE Marketing Orders
- Product name and order letter
- Decision Summaries
- Environmental Assessment (EA)

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
BBK Tobacco & Foods LLP d/b/a HBI International	Raw Organic Single Wide Single Window	Roll-Your-Own Tobacco Products	5/16/2019	SE0015089	EA0015089	FONSI0015089

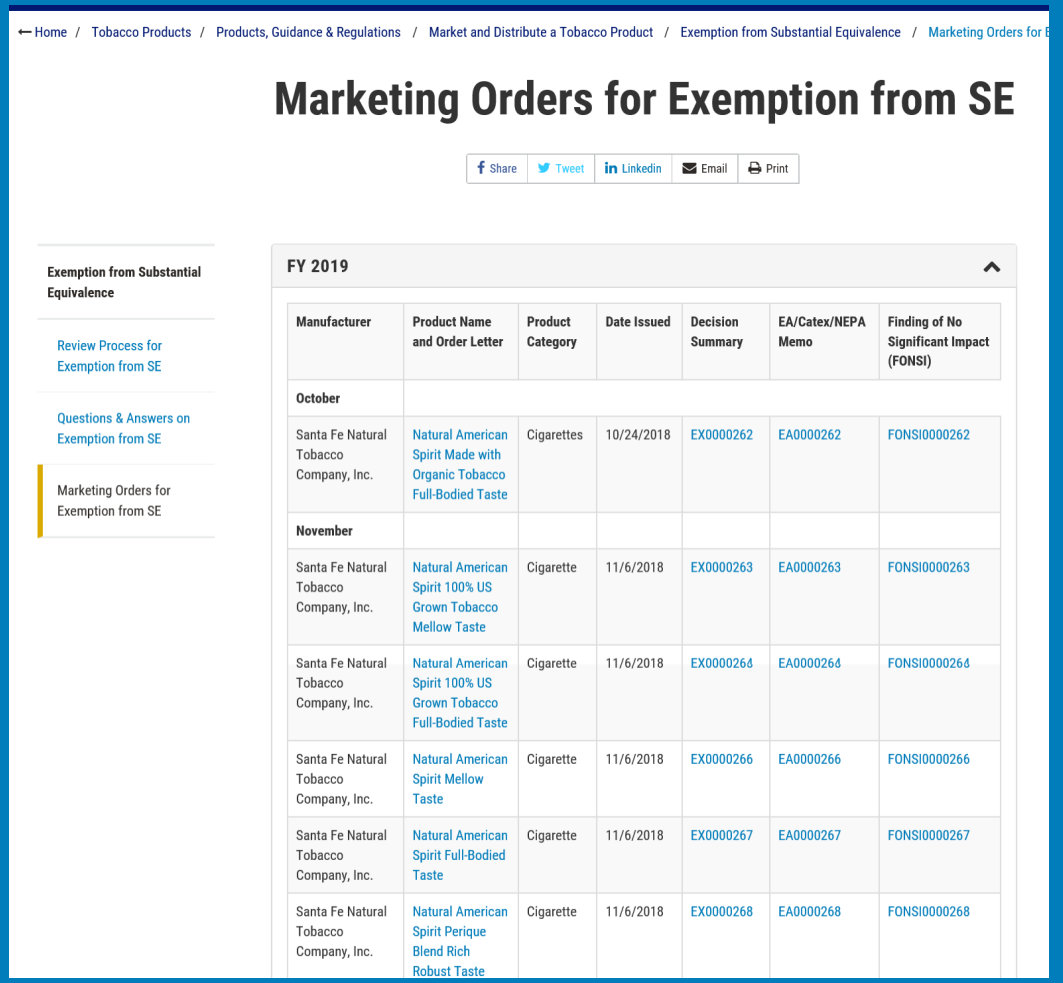
CONTENT: MARKETING ORDERS

SE Marketing Orders
- Product name and order letter
- Decision Summaries
- Environmental Assessment (EA)
- Finding of No Significant Impact (FONSI)

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
BBK Tobacco & Foods LLP d/b/a HBI International	Raw Organic Single Wide Single Window	Roll-Your-Own Tobacco Products	5/16/2019	SE0015089	EA0015089	FONSI0015089

CONTENT: MARKETING ORDERS

Exemption from SE Marketing Orders



← Home / Tobacco Products / Products, Guidance & Regulations / Market and Distribute a Tobacco Product / Exemption from Substantial Equivalence / Marketing Orders for E

Marketing Orders for Exemption from SE

Share | Tweet | Linkedin | Email | Print

Exemption from Substantial Equivalence

- Review Process for Exemption from SE
- Questions & Answers on Exemption from SE
- Marketing Orders for Exemption from SE

FY 2019

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
October						
Santa Fe Natural Tobacco Company, Inc.	Natural American Spirit Made with Organic Tobacco Full-Bodied Taste	Cigarettes	10/24/2018	EX0000262	EA0000262	FONSI0000262
November						
Santa Fe Natural Tobacco Company, Inc.	Natural American Spirit 100% US Grown Tobacco Mellow Taste	Cigarette	11/6/2018	EX0000263	EA0000263	FONSI0000263
Santa Fe Natural Tobacco Company, Inc.	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste	Cigarette	11/6/2018	EX0000264	EA0000264	FONSI0000264
Santa Fe Natural Tobacco Company, Inc.	Natural American Spirit Mellow Taste	Cigarette	11/6/2018	EX0000266	EA0000266	FONSI0000266
Santa Fe Natural Tobacco Company, Inc.	Natural American Spirit Full-Bodied Taste	Cigarette	11/6/2018	EX0000267	EA0000267	FONSI0000267
Santa Fe Natural Tobacco Company, Inc.	Natural American Spirit Perique Blend Rich Robust Taste	Cigarette	11/6/2018	EX0000268	EA0000268	FONSI0000268

CONTENT: MARKETING ORDERS

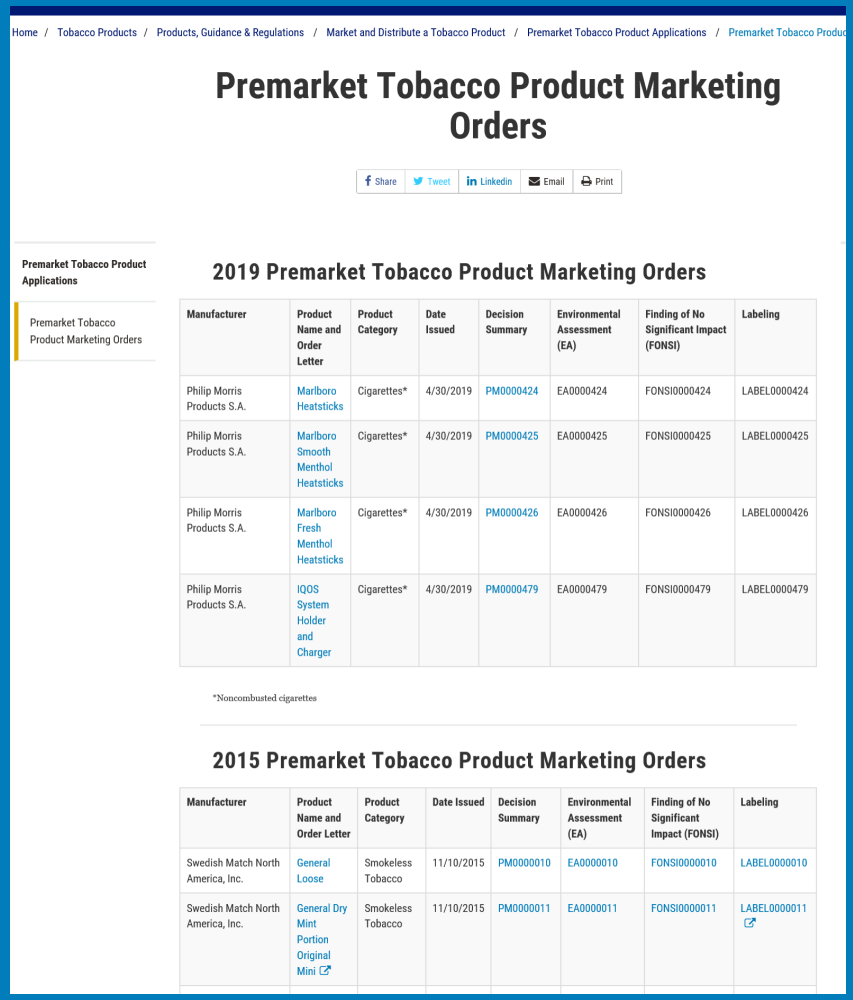
Exemption from SE Marketing Orders

- Product name and order letter
- Decision Summaries
- Environmental Assessment (EA)
- Finding of No Significant Impact (FONSI)

Product Name and Order Letter	Product Category	Date Issued	Decision Summary	EA/Catex/NEPA Memo	Finding of No Significant Impact (FONSI)
Natural American Spirit Made with Organic Tobacco Full-Bodied Taste	Cigarettes	10/24/2018	EX0000262	EA0000262	FONSI0000262

CONTENT: MARKETING ORDERS

PMTA Marketing Orders



Home / Tobacco Products / Products, Guidance & Regulations / Market and Distribute a Tobacco Product / Premarket Tobacco Product Applications / Premarket Tobacco Produc

Premarket Tobacco Product Marketing Orders

Share Tweet Linkedin Email Print

Premarket Tobacco Product Applications

Premarket Tobacco Product Marketing Orders

2019 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)	Labeling
Philip Morris Products S.A.	Marlboro Heatsticks	Cigarettes*	4/30/2019	PM0000424	EA0000424	FONSI0000424	LABEL0000424
Philip Morris Products S.A.	Marlboro Smooth Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000425	EA0000425	FONSI0000425	LABEL0000425
Philip Morris Products S.A.	Marlboro Fresh Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000426	EA0000426	FONSI0000426	LABEL0000426
Philip Morris Products S.A.	IQOS System Holder and Charger	Cigarettes*	4/30/2019	PM0000479	EA0000479	FONSI0000479	LABEL0000479

*Noncombusted cigarettes

2015 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)	Labeling
Swedish Match North America, Inc.	General Loose	Smokeless Tobacco	11/10/2015	PM0000010	EA0000010	FONSI0000010	LABEL0000010
Swedish Match North America, Inc.	General Dry Mint Portion Original Mini	Smokeless Tobacco	11/10/2015	PM0000011	EA0000011	FONSI0000011	LABEL0000011

CONTENT: MARKETING ORDERS

PMTA Marketing Orders

– Product name and order letter

2019 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)	Labeling
Philip Morris Products S.A.	Marlboro Heatsticks	Cigarettes*	4/30/2019	PM0000424	EA0000424	FONSI0000424	LABEL0000424
Philip Morris Products S.A.	Marlboro Smooth Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000425	EA0000425	FONSI0000425	LABEL0000425
Philip Morris Products S.A.	Marlboro Fresh Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000426	EA0000426	FONSI0000426	LABEL0000426
Philip Morris Products S.A.	IQOS System Holder and Charger	Cigarettes*	4/30/2019	PM0000479	EA0000479	FONSI0000479	LABEL0000479

CONTENT: MARKETING ORDERS

PMTA Marketing Orders

- Product name and order letter
- Decision Summaries

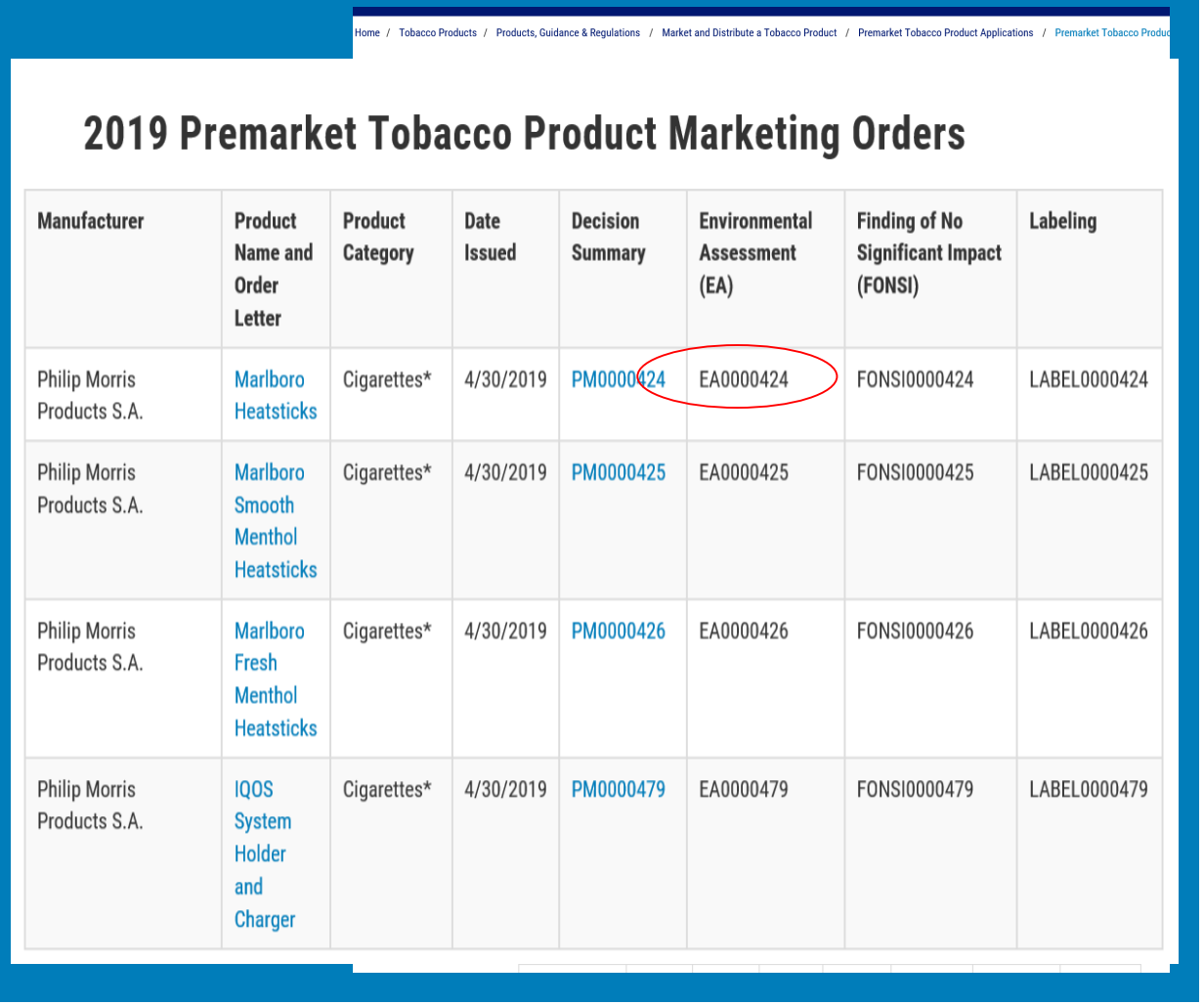
2019 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)	Labeling
Philip Morris Products S.A.	Marlboro Heatsticks	Cigarettes*	4/30/2019	PM0000424	EA0000424	FONSI0000424	LABEL0000424
Philip Morris Products S.A.	Marlboro Smooth Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000425	EA0000425	FONSI0000425	LABEL0000425
Philip Morris Products S.A.	Marlboro Fresh Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000426	EA0000426	FONSI0000426	LABEL0000426
Philip Morris Products S.A.	IQOS System Holder and Charger	Cigarettes*	4/30/2019	PM0000479	EA0000479	FONSI0000479	LABEL0000479

CONTENT: MARKETING ORDERS

PMTA Marketing Orders

- Product name and order letter
- Decision Summaries
- Environmental Assessment (EA)



Home / Tobacco Products / Products, Guidance & Regulations / Market and Distribute a Tobacco Product / Premarket Tobacco Product Applications / Premarket Tobacco Produc

2019 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)	Labeling
Philip Morris Products S.A.	Marlboro Heatsticks	Cigarettes*	4/30/2019	PM0000424	EA0000424	FONSI0000424	LABEL0000424
Philip Morris Products S.A.	Marlboro Smooth Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000425	EA0000425	FONSI0000425	LABEL0000425
Philip Morris Products S.A.	Marlboro Fresh Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000426	EA0000426	FONSI0000426	LABEL0000426
Philip Morris Products S.A.	IQOS System Holder and Charger	Cigarettes*	4/30/2019	PM0000479	EA0000479	FONSI0000479	LABEL0000479

CONTENT: MARKETING ORDERS

PMTA Marketing Orders
- Product name and order letter
- Decision Summaries
- Environmental Assessment (EA)
- Finding of No Significant Impact (FONSI)

2019 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)	Labeling
Philip Morris Products S.A.	Marlboro Heatsticks	Cigarettes*	4/30/2019	PM0000424	EA0000424	FONSI0000424	LABEL0000424
Philip Morris Products S.A.	Marlboro Smooth Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000425	EA0000425	FONSI0000425	LABEL0000425
Philip Morris Products S.A.	Marlboro Fresh Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000426	EA0000426	FONSI0000426	LABEL0000426
Philip Morris Products S.A.	IQOS System Holder and Charger	Cigarettes*	4/30/2019	PM0000479	EA0000479	FONSI0000479	LABEL0000479

CONTENT: MARKETING ORDERS

PMTA Marketing Orders
- Product name and order letter
- Decision Summaries
- Environmental Assessment (EA)
- Finding of No Significant Impact (FONSI)
- Labels

2019 Premarket Tobacco Product Marketing Orders

Manufacturer	Product Name and Order Letter	Product Category	Date Issued	Decision Summary	Environmental Assessment (EA)	Finding of No Significant Impact (FONSI)	Labeling
Philip Morris Products S.A.	Marlboro Heatsticks	Cigarettes*	4/30/2019	PM0000424	EA0000424	FONSI0000424	LABEL0000424
Philip Morris Products S.A.	Marlboro Smooth Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000425	EA0000425	FONSI0000425	LABEL0000425
Philip Morris Products S.A.	Marlboro Fresh Menthol Heatsticks	Cigarettes*	4/30/2019	PM0000426	EA0000426	FONSI0000426	LABEL0000426
Philip Morris Products S.A.	IQOS System Holder and Charger	Cigarettes*	4/30/2019	PM0000479	EA0000479	FONSI0000479	LABEL0000479

HOW TO CONTACT CENTER FOR TOBACCO PRODUCTS

CONTACT: GENERAL INFORMATION

Contact CTP

1-877-287-1373 (9am EST-4pm EST)
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 20993-0002

Learn More

CONTACT: GENERAL INFORMATION

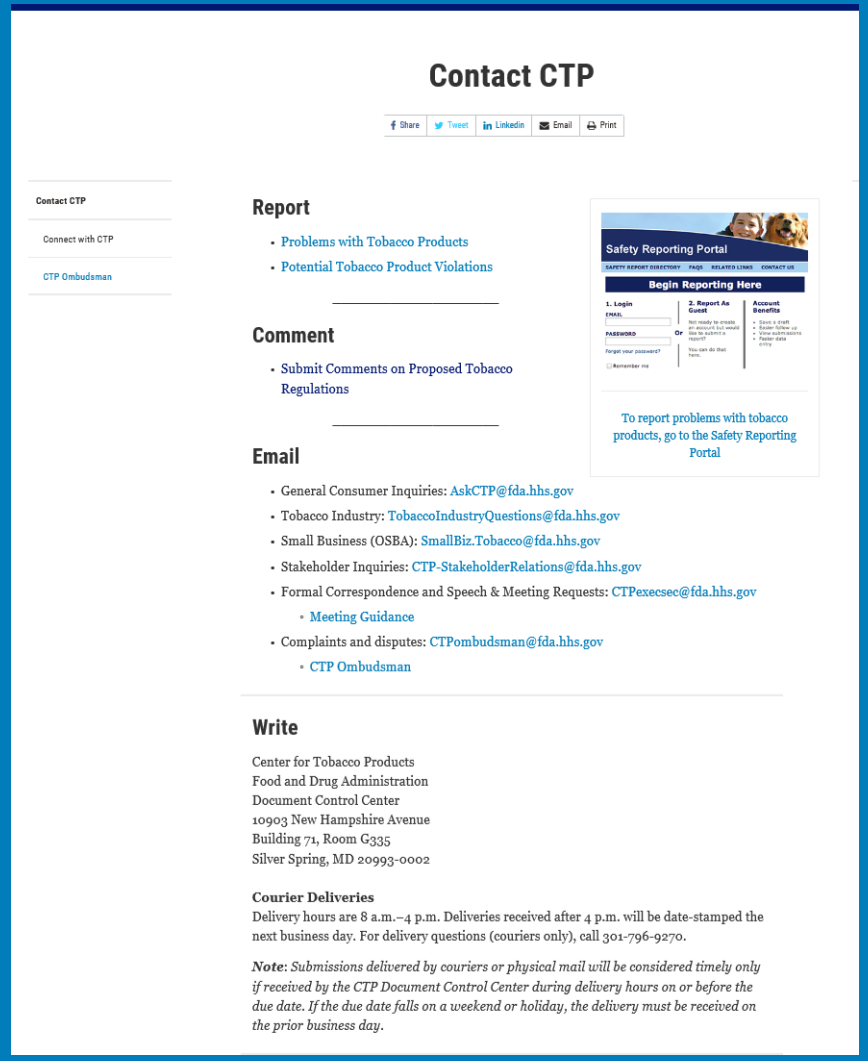
Contact CTP

1-877-287-1373 (9am EST-4pm EST)
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 20993-0002

CONTACT: DOCUMENT CONTROL CENTER

The Document Control Center (DCC)



Contact CTP

Share Tweet LinkedIn Email Print

Contact CTP
Connect with CTP
CTP Ombudsman

Report

- Problems with Tobacco Products
- Potential Tobacco Product Violations

Comment

- Submit Comments on Proposed Tobacco Regulations

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.

***Note**: Submissions delivered by couriers or physical mail will be considered timely only if received by the CTP Document Control Center during delivery hours on or before the due date. If the due date falls on a weekend or holiday, the delivery must be received on the prior business day.*

CONTACT: DOCUMENT CONTROL CENTER

The Document Control Center (DCC)

Write

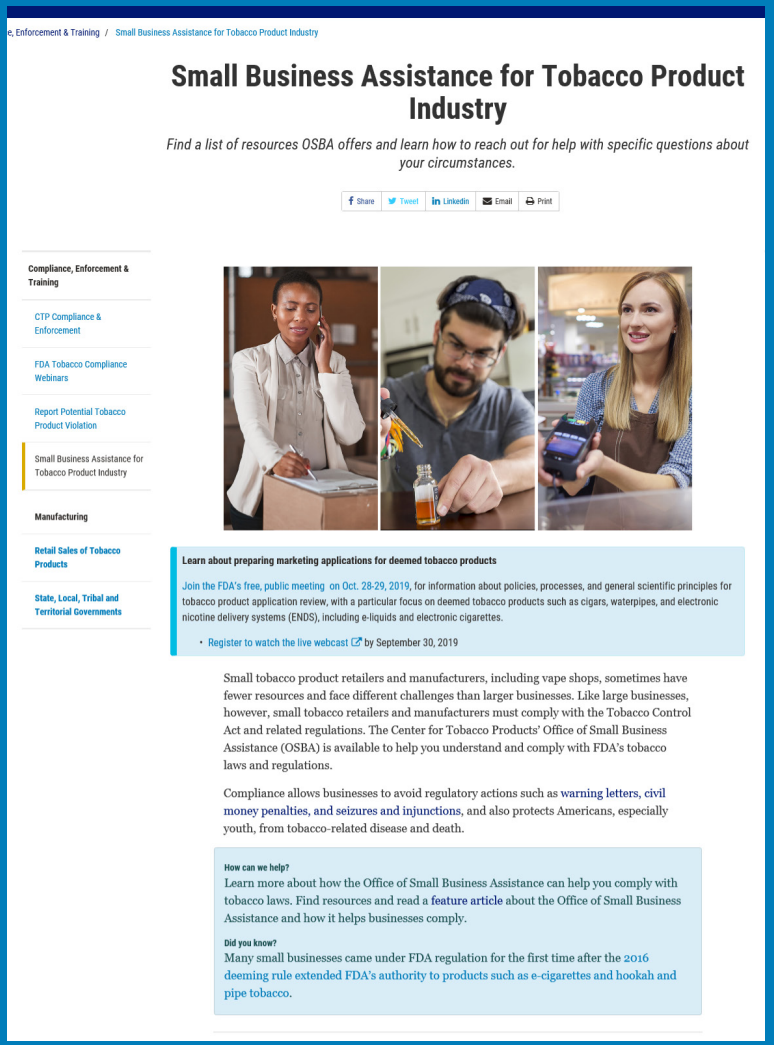
Center for Tobacco Products
Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

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.

***Note**: Submissions delivered by couriers or physical mail will be considered timely only if received by the CTP Document Control Center during delivery hours on or before the due date. If the due date falls on a weekend or holiday, the delivery must be received on the prior business day.*

CONTACT: SMALL BUSINESS OFFICE

Small Business assistance
- list of resources
- assistance with compliance



e, Enforcement & Training / Small Business Assistance for Tobacco Product Industry

Small Business Assistance for Tobacco Product Industry

Find a list of resources OSBA offers and learn how to reach out for help with specific questions about your circumstances.

Share Tweet Linkedin Email Print

Compliance, Enforcement & Training
- CTP Compliance & Enforcement
- FDA Tobacco Compliance Webinars
- Report Potential Tobacco Product Violation
- Small Business Assistance for Tobacco Product Industry

Manufacturing

Retail Sales of Tobacco Products

State, Local, Tribal and Territorial Governments

Learn about preparing marketing applications for deemed tobacco products

Join the FDA's free, public meeting on Oct. 28-29, 2019, for information about policies, processes, and general scientific principles for tobacco product application review, with a particular focus on deemed tobacco products such as cigars, waterpipes, and electronic nicotine delivery systems (ENDS), including e-liquids and electronic cigarettes.

- Register to watch the live webcast by September 30, 2019

Small tobacco product retailers and manufacturers, including vape shops, sometimes have fewer resources and face different challenges than larger businesses. Like large businesses, however, small tobacco retailers and manufacturers must comply with the Tobacco Control Act and related regulations. The Center for Tobacco Products' Office of Small Business Assistance (OSBA) is available to help you understand and comply with FDA's tobacco laws and regulations.

Compliance allows businesses to avoid regulatory actions such as warning letters, civil money penalties, and seizures and injunctions, and also protects Americans, especially youth, from tobacco-related disease and death.

How can we help?

Learn more about how the Office of Small Business Assistance can help you comply with tobacco laws. Find resources and read a feature article about the Office of Small Business Assistance and how it helps businesses comply.

Did you know?

Many small businesses came under FDA regulation for the first time after the 2016 deeming rule extended FDA's authority to products such as e-cigarettes and hookah and pipe tobacco.

CONTACT: SMALL BUSINESS OFFICE

Small Business assistance
- list of resources
- assistance with compliance

More Questions?

Contact Us

Please reach out by email, phone, or mail for technical assistance, help finding the right resources, and the opportunity to communicate your small-business viewpoint to FDA.

Email:
SmallBiz.Tobacco@fda.hhs.gov

Phone:
1-877-287-1373 (Monday–Friday, 9:00 a.m.–4:00 p.m. Eastern Time)

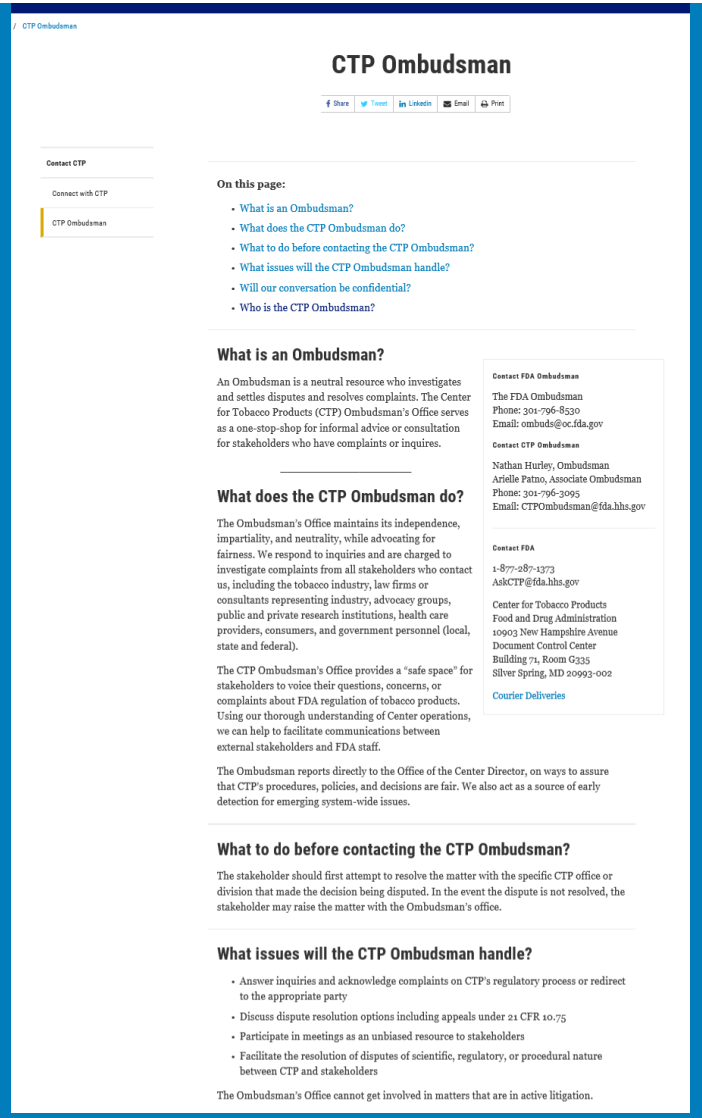
Mail:
FDA/CTP Office of Compliance and Enforcement
Document Control Center
Building 71, Room G335
10903 New Hampshire Ave.
Silver Spring, MD 20993

CONTACT: OMBUDSMAN

Ombudsman (Mr. Nathan Hurley)

and

Associate Ombudsman (Ms. Arielle Patno)



/ CTP Ombudsman

CTP Ombudsman

Share | Tweet | LinkedIn | Email | Print

Contact CTP

Connect with CTP

CTP Ombudsman

On this page:

- What is an Ombudsman?
- What does the CTP Ombudsman do?
- What to do before contacting the CTP Ombudsman?
- What issues will the CTP Ombudsman handle?
- Will our conversation be confidential?
- Who is the CTP Ombudsman?

What is an Ombudsman?

An Ombudsman is a neutral resource who investigates and settles disputes and resolves complaints. The Center for Tobacco Products (CTP) Ombudsman's Office serves as a one-stop-shop for informal advice or consultation for stakeholders who have complaints or inquires.

Contact FDA Ombudsman

The FDA Ombudsman
Phone: 301-796-8530
Email: ombuds@oc.fda.gov

Contact CTP Ombudsman

Nathan Hurley, Ombudsman
Arielle Patno, Associate Ombudsman
Phone: 301-796-3095
Email: CTPOmbudsman@fda.hhs.gov

Contact FDA

1-877-287-1373
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

What does the CTP Ombudsman do?

The Ombudsman's Office maintains its independence, impartiality, and neutrality, while advocating for fairness. We respond to inquiries and are charged to investigate complaints from all stakeholders who contact us, including the tobacco industry, law firms or consultants representing industry, advocacy groups, public and private research institutions, health care providers, consumers, and government personnel (local, state and federal).

The CTP Ombudsman's Office provides a "safe space" for stakeholders to voice their questions, concerns, or complaints about FDA regulation of tobacco products. Using our thorough understanding of Center operations, we can help to facilitate communications between external stakeholders and FDA staff.

The Ombudsman reports directly to the Office of the Center Director, on ways to assure that CTP's procedures, policies, and decisions are fair. We also act as a source of early detection for emerging system-wide issues.

What to do before contacting the CTP Ombudsman?

The stakeholder should first attempt to resolve the matter with the specific CTP office or division that made the decision being disputed. In the event the dispute is not resolved, the stakeholder may raise the matter with the Ombudsman's office.

What issues will the CTP Ombudsman handle?

- Answer inquiries and acknowledge complaints on CTP's regulatory process or redirect to the appropriate party
- Discuss dispute resolution options including appeals under 21 CFR 10.75
- Participate in meetings as an unbiased resource to stakeholders
- Facilitate the resolution of disputes of scientific, regulatory, or procedural nature between CTP and stakeholders

The Ombudsman's Office cannot get involved in matters that are in active litigation.

CONTACT: OMBUDSMAN

Ombudsman (Mr. Nathan Hurley)

and

Associate Ombudsman (Ms. Arielle Patno)

Contact FDA Ombudsman

The FDA Ombudsman
Phone: 301-796-8530
Email: ombuds@oc.fda.gov

Contact CTP Ombudsman

Nathan Hurley, Ombudsman
Arielle Patno, Associate Ombudsman
Phone: 301-796-3095
Email: CTPOmbudsman@fda.hhs.gov

TAKE HOME POINTS

Featured information on the CTP website

New site pages

Updates site pages

Contact CTP