# IMPORTING TOBACCO PRODUCTS: UPDATES FOR IMPORTERS

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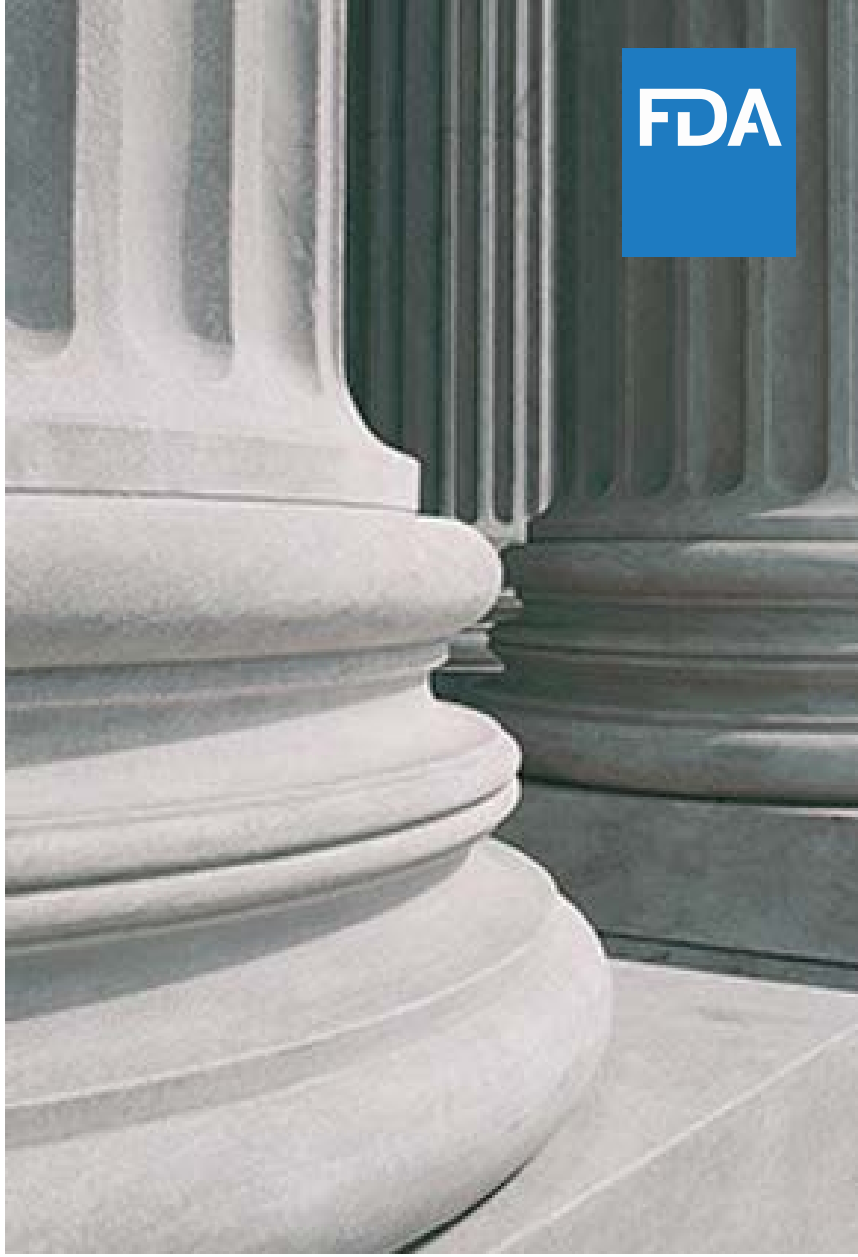

# AGENDA

- Updated Compliance Dates
- Automated Commercial Environment (ACE)
- Establishment Registration
- Personal Use Importations
- Prior Notice
- Product Codes
- Tariff Classification
- User Fees

# UPDATE ON COMPLIANCE DATES AND DEADLINES

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| **Listing of ingredients in tobacco products submitted for each tobacco product by brand and quantity in each brand and subbrand.**<br><br>**(§§ 904(a)(1) and 904(c) of the FD&C Act)[1]** | • **Finished Cigarette Products**<br>• **Finished Cigarette Tobacco Products**<br>• **Finished Smokeless Tobacco Products**<br>• **Finished Roll-Your-Own Tobacco Products** | **Ingredient lists are due at least 90 days before the product is delivered for introduction into interstate commerce.** |
| | • Deemed Finished Tobacco Products | Deemed tobacco products first marketed on or before August 8, 2016: ingredient listings are due by May 8, 2018 or November 8, 2018 for small-scale tobacco product manufacturers.[2]<br><br>Deemed products that were first marketed after August 8, 2016: ingredient listings are due at least 90 days prior to delivery for introduction into interstate commerce. |

[1] FDA intends to limit enforcement of the ingredient listing requirements to finished tobacco products.
[2] For purposes of this compliance policy, FDA considers "small-scale tobacco product manufacturers" to be a manufacturer of any regulated tobacco product with 150 employees or fewer and annual total revenue of $5,000,000 or less.

# UPDATE ON COMPLIANCE DATES AND DEADLINES

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| **Reporting quantities of harmful and potentially harmful constituents (HPHCs) for tobacco products by brand and subbrand. [1]**<br><br>**(§ 904(a)(3) of the FD&C Act)** | • **Finished Cigarette Products**<br>• **Finished Cigarette Tobacco Products**<br>• **Finished Smokeless Tobacco Products**<br>• **Finished Roll-Your-Own Tobacco Products** | **Submit HPHCs at least 90 days prior to marketing the product.** |
| | • Deemed Finished Tobacco Products | November 8, 2019 or at least 90 days prior to marketing for products entering the market after November 8, 2019. |
| **Packages and advertisements must bear the required nicotine addictiveness warning. [2]**<br><br>**(21 C.F.R. § 1143.3)** | • **Cigarette Tobacco**<br>• **Roll-Your-Own Tobacco**<br>• **Deemed, Covered Tobacco Products (other than cigars and those that do not contain nicotine)** | **Advertisements must bear the addictiveness warning beginning August 10, 2018.**<br><br>**Manufacturers cannot manufacture products with non-compliant packages beginning August 10, 2018, and cannot distribute such products beginning September 11, 2018.** |

[1] FDA intends to limit enforcement of the HPHC requirements to finished tobacco products.
[2] Covered tobacco products that do not contain nicotine may bear an alternative warning statement.

# UPDATE ON COMPLIANCE DATES AND DEADLINES

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| **Premarket review required for all new tobacco products: PMTA, SE, and SE exemption[1]**<br><br>**(§§ 910 and 905(j) of the FD&C Act)** | • **New Finished Cigarette Products**<br>• **New Finished Cigarette Tobacco Products**<br>• **New Finished Smokeless Tobacco Products**<br>• **New Finished Roll-Your-Own Tobacco Products** | **Any new tobacco product must have premarket authorization.**<br><br>**However, if a new tobacco product was commercially marketed after February 15, 2007, but before March 22, 2011, and a substantial equivalence report was submitted before March 23, 2011, then the new tobacco product may continue to be marketed unless FDA issues an order finding the product not substantially equivalent (however, if that new tobacco product has otherwise received premarket authorization, it may continue to be marketed)** |
| | • New Deemed Finished Tobacco Products | New deemed tobacco products on the market as of August 8, 2016: compliance period to submit a substantial equivalence exemption request, substantial equivalence report, or premarket tobacco product application is:<br>• August 8, 2021 for combustible tobacco products<br>• August 8, 2022 for noncombustible tobacco products<br><br>This compliance period will continue until the agency renders a decision on an application (i.e., issuance of: a Marketing Order; a No Marketing Order; a Refuse to File; or Refuse to Accept) or the application is withdrawn.<br><br>New deemed tobacco products not on the market as of August 8, 2016: Marketing authorization required prior to marketing the tobacco product. |

[1] FDA intends to limit enforcement of the premarket requirements to finished tobacco products.

# UPDATE ON COMPLIANCE DATES AND DEADLINES

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| **For tobacco products in package form, the label must bear the following:**<br>• **The name and place of business of the tobacco product manufacturer, packer, or distributor**<br>• **The quantity of the contents in terms of weight, measure, or numerical count**<br>• **The percentage of domestic and foreign-grown tobacco in the product [1]**<br>• **The statement "Sale only allowed in the United States".**<br>• **(§§903(a)(2) and 920(a) of the FD&C Act)** | • **Smokeless Tobacco Products in package form[2]** | **The products will be deemed misbranded unless they bear a label containing the required information.** |
| | • Deemed Tobacco Products in package form | Starting August 10, 2018, deemed finished tobacco products will be misbranded unless they bear a label containing the required information. |

[1] In the draft guidance, Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops, which is publicly available, FDA indicated that: it interprets section 903(a)(2)(C) of the FD&C Act as only applying to tobacco products that are made or derived from tobacco; and, at this time, it does not intend to enforce section 903(a)(2)(C) of the FD&C Act for those products. When the guidance is finalized it will represent FDA's current thinking on the issues contained within.

[2] Those who manufacture, package, sell, offer to sell, distribute or import for sale or distribution cigarettes within the United States will not be expected to comply with section 903(a)(2) of the FD&C Act with respect to cigarette packaging and labels until further notice from FDA. *See* FDA Letter to Industry: Cigarette Packaging and Advertising Compliance Update – Impact of Ongoing Litigation.

# AUTOMATED COMMERCIAL ENVIRONMENT OVERVIEW

- ACE is a system for reporting importations
- System maintained by Customs and Border Protection (CBP)
- If product is FDA regulated, CBP forwards data to FDA
- To contact CBP see: https://www.cbp.gov/contact
- If a product you are importing has been detained by FDA, please contact FDA's Office of Regulatory Affairs field personnel at the location in which your product is detained: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/document/ucm123522.pdf
- FDA's ACE final rule can be found at: https://www.federalregister.gov/documents/2016/11/29/2016-28582/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment

# AUTOMATED COMMERCIAL ENVIRONMENT

Required data elements for tobacco products:

- Country of Production
- FDA Product Code
- Intended Use Code
- Email and phone number for importer of record
- Brand Name of Product
  - Brand name not required if product is investigational or for further manufacturing

# AUTOMATED COMMERCIAL ENVIRONMENT

Optional data elements:

- FEI Number = FDA Establishment Identification Number

- An Affirmation of Compliance (AOC) is a data element used to indicate compliance with an FDA requirement.
  - At this time all AOCs for tobacco products are optional.
  - Imported products are still required to meet the legal standards for importation.

- Please see the FDA supplemental guidance for the Automated Commercial Environment/International Trade Data System (ACE/ITDS)

# ESTABLISHMENT REGISTRATION

- Anyone who manufactures, prepares, compounds, or processes a regulated tobacco product in the United States must register with FDA and list their products with FDA
  - Registration must be updated annually [December 31st]
  - Product listings must be updated biannually [June 30th and December 31st]
- Currently, only applies to DOMESTIC establishments
- All other requirements of FD&C act including premarket authorization apply equally to foreign and domestic products

- Please see "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" for information on how to register and list

# PERSONAL USE IMPORTATIONS

- The FD&C Act does not exempt tobacco products imported for personal use from applicable requirements for tobacco product imports

- Please see chapter 9 of the Regulatory Procedures Manual for FDA's policy on personal use quantities of FDA-regulated imported products in baggage and mail: http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm

# PRIOR NOTICE

- Prior notice is required for the importation of human and animal food
- Prior notice is not required or applicable to the importation of regulated tobacco products

# PRODUCT CODE

The FDA Product Code is seven characters long and is broken into the following fields:

- Industry – 98 for tobacco products
- Class – one letter, indicates type of product
- Subclass – one letter, indicates product flavor
- Process Indicator Code – one letter, indicates intended use
- Product – two numbers, further identifies product

To access the product code builder:
https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm?action=main.pcb

# PRODUCT CODE - EXAMPLES

Cherry flavored moist snuff

- Industry – Tobacco – 98
- Class – Smokeless – C
- Flavor – Other – C
- Intended Use –
  for consumer use – A
- Specific Product –
  Moist Snuff – 05

- Full product code: 98CCA05

Bulk cigar tobacco which will be manufactured into cigars in the US

- Industry – Tobacco – 98
- Class – Cigar – G
- Flavor – Unflavored – A
- Intended Use –
  For Further Manufacturing – B
- Specific Product –
  Cigar Tobacco, Bulk – 01

- Full product code: 98GAB01

# TARIFF CLASSIFICATION

The term tariff classification

- Identifies imported and exported goods for
  - purposes of duty and tax collection
  - enforcement of national laws
  - international treaties
  - analysis for economic and business planning
  - international trade negotiations

Your tariff classification does not determine whether your product is a tobacco product.

For more information on tariff schedules: https://hts.usitc.gov/current

# USER FEES

Domestic Manufacturers of the Following Tobacco Products are subject to user fees:

- Cigarettes
- Snuff
- Chewing tobacco
- Roll your own tobacco
- Cigars
- Pipe tobacco

More information about user fees may be found in the link below:

https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm417012.htm

# USER FEES

FDA will notify you of the amount of the quarterly assessment no later than 30 calendar days before the end of each fiscal year quarter with the following information:

- Amount of the assessment;
- Due date;
- Class assessment information;
- Domestic manufacturer or importer assessment information;
- Any adjustments made by FDA;
- How to pay the fees;
- Interest information; and
- Dispute contact information

# RESOURCES

Additional resources for tobacco product importers can be found at our Center for Tobacco Products website.

For General Inquiries contact via email or phone:

AskCTP@fda.hhs.gov

1-877-CTP-1373

Office of Regulatory Affairs (ORA)-

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ContactORA/default.htm

We also have an email address dedicated to responding to questions from small businesses. Smallbiz.tobacco@fda.hhs.gov

At our website, you can sign up for “CTP News” and “CTP *Connect”* to receive email updates from the Center for Tobacco Products.