TOBACCO PRODUCT COMPLIANCE WEBINAR:

UPDATES FOR IMPORTERS

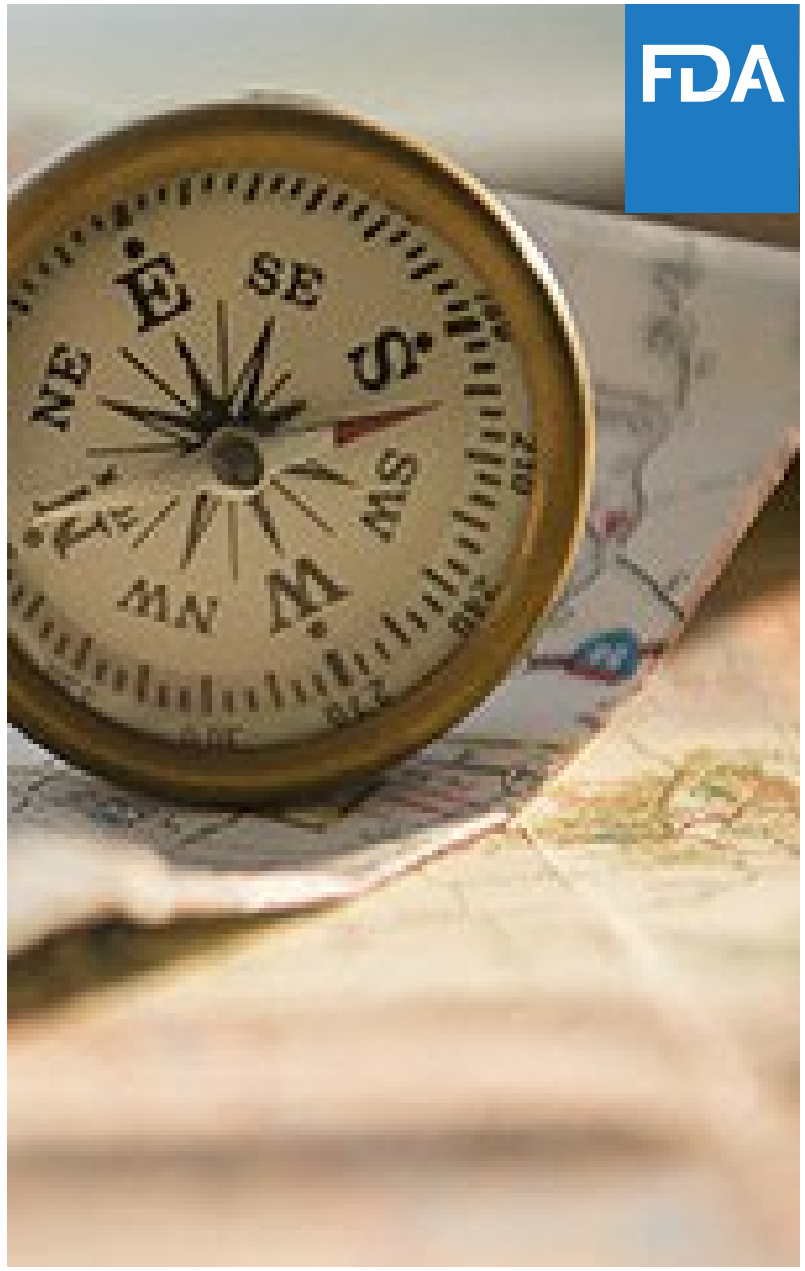
Office of Compliance and Enforcement, CTP, FDA

Imported Tobacco Products Must Comply with FD&C Act

- Tobacco products imported or offered for import must comply with all applicable requirements under the FD&C Act and its implementing regulations.
- FDA is responsible for determining whether an article offered for importation complies with or violates the legal requirements enforced by FDA.
- FDA and CBP closely collaborate to fulfill their responsibilities.

AGENDA

- FDA Jurisdiction Under FD&C Act
- FDA Requirements for Tobacco Products
- Importing Tobacco Products
- Recent Import Alerts



FDA Authorized to Regulate Tobacco Products

- FD&C Act authorizes FDA to regulate the manufacture, marketing, sale and distribution of tobacco products in the United States. This includes tobacco products offered for import.

- Amended Section 201(rr)(1) of the FD&C Act:

  "The term 'tobacco product' means any product made or derived from tobacco, **or containing nicotine from any source**, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."

FD&C Act Applies to U.S. Importers of Finished Tobacco Products

- Section 900(20) of the FD&C Act defines a "tobacco product manufacturer" as: "any person, including any repacker or relabeler, who –

  (A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

  (B) imports a finished tobacco product for sale or distribution in the United States."

Marketing Orders Required for New Tobacco Products

- Under Section 910 of the FD&C Act, a new tobacco product must have a marketing order in effect.

- "New Tobacco Product" is:
  (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
  (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Tobacco Products Marketing Orders

- Marketing a New Tobacco Product
- Premarket Tobacco Product Applications (PMTA)
  - Marketing Granted Orders (MGO)
  - Marketing Denial Orders (MDO)
- Substantial Equivalence (SE) Reports
  - Marketing Orders
- Provisional Not Substantially Equivalent Orders
- Provisional SE Products Removed From Review
- Exemption from Substantial Equivalence Requests (EX REQ)
  - Marketing Orders
- Pre-Existing Tobacco Products

Premarket Tobacco Product Marketing Granted Orders

Premarket Tobacco Product Marketing Granted Orders

To legally market a new tobacco product in the United States, a company must receive a written marketing order from FDA. Companies may receive marketing authorization through one of the three pathways; the following products have been issued marketing granted orders (MGO) under the PMTA pathway.

https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders

Unauthorized New Tobacco Products Subject to Enforcement

- FDA closely monitors industry compliance with tobacco laws and regulations under the FD&C Act, taking action when violations occur. All new tobacco products marketed in the United States without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action.

- Potential actions include:
  - Civil Money Penalties
  - Seizure
  - Injunction
  - Product offered for import may be detained or refused admission

https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products

Importing Tobacco Products

- Import Entry Screening: Automated systems help FDA review import entries while targeting FDA resources on the riskiest products. These systems electronically review entries and flag risky products or entries that are incomplete or contain inaccurate data. When a system flags an entry, FDA may ask for more information or request physical exam or sampling. https://www.fda.gov/industry/fda-import-process/entry-screening-systems-and-tools

- Import Alerts: Inform the FDA's field staff and the public that the agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of the FDA's laws and regulations. These violations could be related to the product, manufacturer, shipper and/or other information. Before importing into the United States, importers should know if their products are subject to DWPE. DWPE allows the agency to detain a product without physically examining it at the time of entry. https://www.fda.gov/industry/actions-enforcement/import-alerts

Detention and Refusal

- When products offered for import violate or appear to violate FDA laws and regulations, FDA may detain the product and issue a Notice of FDA Action with the designation of “Detained.” https://www.fda.gov/industry/fda-import-process/detention-hearing
- A refusal is FDA’s final decision that a detained shipment is in violation of FDA laws and regulations. A refused shipment must either be destroyed or exported under the supervision of Customs and Border Protection (CBP) and FDA within 90 days of the date of the Notice of FDA Action (Refusal Notice). https://www.fda.gov/industry/fda-import-process/import-refusals

NEW IMPORT ALERT 98-06

- Title: Detention Without Physical Examination of New Tobacco Products without Required Marketing Authorization.
- Product Description: New tobacco products that do not have the required FDA marketing authorization.
- Impact: Products that meet the criteria of the import alert may be detained without physical examination.

NEW IMPORT ALERT 98-08

- Title: Detention Without Physical Examination of Certain Regulated Tobacco Products Lacking Labeling Requirements Specified in Section 903(a)(2) of the FD&C Act
- Product Description: A tobacco product in package form does not bear a label that contains certain information, including
    1. the name and place of business of the tobacco product manufacturer, packer, or distributor;
    2. an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and
    3. the statement “sale only allowed in the United States.”
- Impact: Products that meet the criteria of the import alert may be detained without physical examination.

Compliance Education and Information on FDA's Tobacco Product Laws and Regulations

https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars

ADDITIONAL RESOURCES

- Additional resources for tobacco product importers can be found at our Center for Tobacco Products (CTP) website: http://www.fda.gov/TobaccoProducts/default.htm
- View FDA Tobacco Compliance Webinars: https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars
- View FDA's Manufacturing Webpage: https://www.fda.gov/tobacco-products/compliance-enforcement-training/manufacturing
- For General Inquiries, contact CTP via phone: 1-877-CTP-1373, or email: AskCTP@fda.hhs.gov
- We also have an email address dedicated to responding to questions from small businesses: Smallbiz.tobacco@fda.hhs.gov
- Sign up for "CTP News" and "CTP *Connect*" to receive CTP's email updates.

ADDITIONAL RESOURCES

- Contact FDA's Office of Regulatory Affairs (ORA):

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

- FDA's Imported Tobacco Homepage:

  https://www.fda.gov/industry/regulated-products/imported-tobacco