TOBACCO PRODUCT COMPLIANCE POLICY: UPDATES FOR IMPORTERS

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AGENDA

- ENDS Enforcement Guidance for Industry
- September 9, 2020 Application Deadline for Deemed New Tobacco Products
- New Sub-Class for use in Building Product Codes
- Impact on Imported Tobacco Products
- New Import Alerts

DEFINITIONS

Section 900(20) of the Federal Food, Drug, and Cosmetic Act (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."

DEFINITIONS

New tobacco product: (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. Section 910(a) of the FD&C Act.

DEFINITIONS

- Electronic nicotine delivery systems (ENDS): include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled.
- E-liquids: a type of ENDS product and generally refers to liquid nicotine and nicotine-containing e-liquids (i.e., liquid nicotine combined with colorings, flavorings, and/or other ingredients). Liquids that do not contain nicotine or other material made or derived from tobacco, but that are intended or reasonably expected to be used with or for the human consumption of a tobacco product, may be components or parts and, therefore, subject to FDA's tobacco control authorities.

OVERVIEW OF ENFORCEMENT PRIORITIES REGARDING CERTAIN ENDS PRODUCTS

- In April, FDA updated its guidance for industry entitled "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)."
- This is a revision to the January 2020 guidance which describes, among other things, how FDA intends to prioritize its enforcement resources with regard to ENDS products that do not have premarket authorization. FDA revised this guidance to change the date required to submit premarket authorization applications to the agency from May 12, 2020, to Sept. 9, 2020.

OVERVIEW OF ENFORCEMENT PRIORITIES REGARDING CERTAIN ENDS PRODUCTS

On February 6, 2020, FDA began prioritizing enforcement of premarket review requirements for certain ENDS products:

1) Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);

2) All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and

3) Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

OVERVIEW OF SEPTEMBER 9, 2020 APPLICATION DEADLINE FOR DEEMED NEW TOBACCO PRODUCTS

- On July 12, 2019, the U.S. District Court for the District of Maryland issued an order directing FDA to require that premarket authorization applications for all deemed new tobacco on the market as of August 8, 2016 be submitted to the Agency by May 12, 2020.
- On April 22, 2020, the court granted a 120-day extension, which now sets the premarket application deadline to September 9, 2020.
- FDA is providing a one-year period during which deemed tobacco products that were on the market as of August 8, 2016, with timely summitted applications might remain on the market pending FDA review.
- The order does not restrict FDA's authority to enforce the premarket review provisions against deemed products, or categories of deemed products, prior to September 9, 2020, or during the one-year review period.
- FDA intends to prioritize enforcement of any ENDS product that is offered for sale in the United States after September 9, 2020 and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

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 – a new subclass has been created for tobacco flavored products
- Process Indicator Code – one letter, indicates intended use
- Product – two numbers, further identifies product

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

PRODUCT CODE - EXAMPLES

Mango flavored E-cigarette:

- Industry – 98 (Tobacco)
- Class – L (ENDS)
- Subclass – C (Flavored – Other)
- PIC – A (For Consumer Use)
- Group – 01 (E-cigarette)

Full product code: 98LCA01

Tobacco flavored ENDS cartridge:

- Industry – 98 (Tobacco)
- Class – M (ENDS Component or Part)
- Subclass – D (Flavored – Tobacco)
- PIC – A (For Consumer Use)
- Group – 07 (ENDS cartridge)

Full product code: 98MDA07

NEW IMPORT ALERT 98-06

- Title: Detention Without Physical Examination of New Tobacco Products Without Required Marketing Authorization.
- Products affected: New tobacco products lacking the required FDA marketing authorization.
- Impact: Products that meet the criteria of the import alert will be detained and refused entry into the United States. Such products may be placed on a Red List.
  - Products imported for personal use are not exempt.
  - Products entering the U.S. through international mail facilities or through commercial carriers are not exempt.

NEW IMPORT ALERT 98-07

- Title: Detention Without Physical Examination of Electronic Nicotine Delivery Systems (ENDS) Lacking Premarket Authorization.
- Products affected: ENDS products lacking the required FDA marketing authorization.
- Impact: Divisions may detain without physical examination ENDS products that are identified on a Red List.
  - Products imported for personal use are not exempt.
  - Products entering the US through international mail facilities or through commercial carriers are not exempt.

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

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

ENDS Enforcement Priorities Final Guidance:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market