

# TOBACCO PRODUCT COMPLIANCE POLICY: UPDATES FOR MANUFACTURERS

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# AGENDA

- ENDS Enforcement Guidance for Industry
- September 9, 2020 Application Deadline for Deemed New Tobacco Products
- Manufacturer Responsibilities



Manufacturer: 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.”

Vape shop: establishments that engage in a variety of activities related to Electronic Nicotine Delivery Systems, including:

- Selling a variety of products to consumers including ENDS devices, ENDS replacement pieces, ENDS hardware, ENDS pre-mixed flavored e-liquids, and other ENDS-related products.
- Mixing and/or preparing combinations of e-liquids for direct sale to consumers for use in ENDS or creating or modifying aerosolizing apparatuses for direct sale to consumers for use in ENDS.

# DEFINITIONS

Depending on the activities a vape shop engages in, it may be subject to all of the statutory and regulatory requirements applicable to a tobacco product retailer, a tobacco product manufacturer, or both.

A vape shop is considered a manufacturer if it, for example, mixes or prepares e-liquids, creates or modifies aerosolizing apparatuses, repackages ENDS products, or relabels ENDS products.

# 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 applications for all deemed new tobacco products 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.
- The order provided for a one-year period during which products with timely filed 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 offered for sale in the U.S. 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).

# MANUFACTURER RESPONSIBILITIES

- If you are a tobacco product manufacturer, including a manufacturer of ENDS products, you must obtain premarket authorization prior to marketing your product. FDA will determine whether the products meet applicable public health standards and may be authorized for marketing.
- If you make certain changes to your tobacco product list, you must update your product listings in FDA Unified Registration and Listing System (FURLS) by December 31, 2020. See section 905(i)(3) of the FD&C Act.

# MANUFACTURER RESPONSIBILITIES

Tobacco product manufacturers, including those vape shops that engage in manufacturing activities, must also:

- Submit a premarket authorization application for any deemed new tobacco products on the market as of August 8, 2016 by September 9, 2020.

# RESOURCES

CTP Website available at:

<http://www.fda.gov/TobaccoProducts/default.htm>

For General Inquiries contact via email or phone:

[AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov)

1-877-CTP-1373

Inquiries from small businesses:

[Smallbiz.tobacco@fda.hhs.gov](mailto:Smallbiz.tobacco@fda.hhs.gov)

Sign up for “CTP News” and “CTP *Connect*” to receive CTP’s email updates.

# RESOURCES

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/registration-and-product-listing-owners-and-operators-domestic-tobacco-product-establishments>

Registration and Listing mailbox:

[CTPRegistrationandListing@fda.hhs.gov](mailto:CTPRegistrationandListing@fda.hhs.gov)

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>