

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

[en Español \(http://esp.fda.gov/TobaccoProducts/default.htm\)](http://esp.fda.gov/TobaccoProducts/default.htm)

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



Vaporizers, vape pens, hookah pens, electronic cigarettes (E-Cigarettes), and e-pipes are some of the many types of Electronic Nicotine Delivery Systems (ENDS).

These products use liquid containing nicotine, as well as varying compositions of **flavorings** ([/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm](http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm)), propylene glycol, glycerin, and other ingredients. The liquid is heated into an aerosol that the user inhales.

What do ENDS look like?

Many ENDS are manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble pens or other everyday items. Larger devices such as tank systems or mods bear little or no resemblance to cigarettes.

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Statistics about ENDS Use

- More than 3 million middle and high school students were current users of e-cigarettes in 2015, up from an estimated 2.46 million in 2014.^{1,2}
- Sixteen percent of high school and 5.3 percent of middle school students were current users of e-cigarettes in 2015, making e-cigarettes the most commonly used tobacco product among youth for the second consecutive year.¹
- During 2011-2015, e-cigarette use rose from 1.5 percent to 16.0 percent among high school students and from 0.6 percent to 5.3 percent among middle school students.¹
- In 2013-2014, 81% of current youth e-cigarette users cited the availability of appealing flavors as the primary reason for use.³
- In 2014, 12.6% of U.S. adults had ever tried an e-cigarette, and about 3.7% of adults used e-cigarettes daily or some days.⁴

FDA Regulation of ENDS

In 2016, FDA finalized a rule extending our regulatory authority to cover all tobacco products, including vaporizers, vape pens, hookah pens, electronic cigarettes (E-Cigarettes), e-pipes, and all other ENDS. FDA now regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS. This includes components and parts of ENDS* but excludes accessories.

However, products marketed for therapeutic purposes (for example, marketed as a product to help people quit smoking) are regulated by the FDA through the [Center for Drug Evaluation and Research \(CDER\) \(/Drugs/default.htm\)](#). FDA recently proposed a [rule clarifying the jurisdiction \(/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm462957.htm\)](#) over tobacco products, drugs, and devices.

Components



*“Components” or “parts” include, among other things, software or an assembly of materials intended or reasonably expected alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or to be used with or for the human consumption of a tobacco product. For a full definition of ENDS components, parts, and accessories, please read the Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act. Examples of components and parts of ENDS include, but are not limited to:

- 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

Manufacturing ENDS and E-Liquids

If you manufacture ENDS, these are some requirements that apply to you:

- Submit an application and obtain FDA authorization to market a new tobacco product (for timelines and more details please see Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act)

- Register establishment(s) and submit product listing to FDA by December 31, 2016 (this currently only applies to domestic manufacturers)
- Submit listing of ingredients
- Submit information on **[harmful and potentially harmful constituents \(HPHCs\) \(/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm297786.htm\)](#)**
- Submit tobacco health documents
- Do not introduce into interstate commerce modified risk tobacco products (e.g., products with label, labeling, or advertising representing that they reduce risk or are less harmful compared to other tobacco products on the market) without an FDA order
- Manufacture your tobacco product with the required warning statement on packaging and advertisements
- Market your tobacco product in compliance with other applicable statutory requirements, rules and regulations

[CTP's Office of Small Business Assistance \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm\)](#) 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.

Nicotine Warning Statement

The product packages and advertisements of all newly-regulated covered tobacco products must bear the following warning statement:

“WARNING: This product contains nicotine. Nicotine is an addictive chemical.”

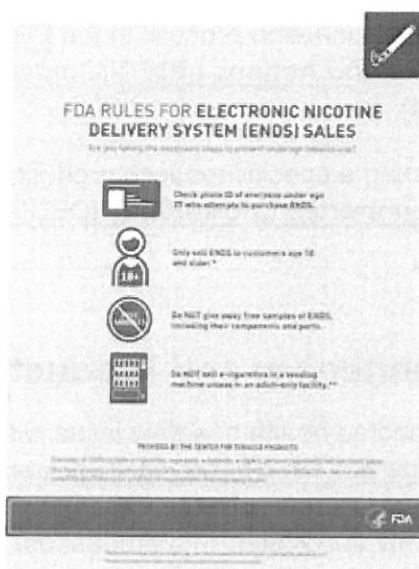
If the tobacco product manufacturer submits a self-certification statement to FDA that the newly-regulated tobacco product does not contain nicotine (and that the manufacturer has data to support this assertion), then an alternate statement must be used on product packages and advertisements:

“This product is made from tobacco.”

You can find more information about nicotine warning statements in Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act.

Retail Sales of ENDS, E-Liquids, or their Components or Parts Made or Derived from Tobacco

Federal Rules for ENDS Sales Flyer



</downloads/TobaccoProducts/Labeling/ProductsIngredientsComponents/UCM499168.pdf>

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 \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm)**.

You may also share the fact sheet below with your staff and post it in your store.

You can find a list of retailer responsibilities for ENDS in 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 \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237759.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237759.htm)**.

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 are considered a manufacturer and **[must comply with all of the legal requirements for tobacco product manufacturers \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm)**. As a result, some vape shops may have legal responsibilities as both manufacturers and retailers of tobacco products.

Importing ENDS 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 find more information on the **[Importing and Exporting webpage \(/TobaccoProducts/Labeling/ucm290823.htm\)](/TobaccoProducts/Labeling/ucm290823.htm)**.

You can also learn more about the importation process in the [FDA Regulatory Procedures Manual, Chapter 9, Import Operations and Actions \(/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179264.htm\)](#).

If you have questions about importing a specific tobacco product, please [contact the FDA district into which your product will be imported \(/downloads/ICECI/Inspections/IOM/UCM123522.pdf\)](#).

Reporting Adverse Experiences and Product Violations

If you have experienced an unexpected health or safety issue with a specific tobacco product, you can [report an adverse experience to FDA \(/TobaccoProducts/PublicHealthScienceResearch/ucm377563.htm\)](#). Knowledge about adverse experiences can help 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 \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm330160.htm\)](#).

You can [read the adverse event reports for ENDS that were voluntarily reported \(/TobaccoProducts/AboutCTP/ucm221165.htm\)](#) to FDA at the FOIA Electronic Reading Room.



Additional Resources

- [Small Business Assistance \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm\)](#) ↻
- [Tobacco Product Manufacturing \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm\)](#) ↻
- [Tobacco Retailer Overview of Federal Laws \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm\)](#) ↻
- [Extending Authorities to All Tobacco Products, Including E-Cigarettes, Cigars, and Hookah \(/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm388395.htm\)](#) ↻

References



More in Products, Ingredients & Components
[\(/TobaccoProducts/Labeling/ProductsIngredientsComponents/default.htm\)](#)

[Cigarettes \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482563.htm\)](#)

Cigars, Cigarillos, Little Filtered Cigars

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482562.htm)

Dissolvable Tobacco Products

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482569.htm)

Hookah Tobacco (also known as Shisha or Waterpipe Tobacco)

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482575.htm)

Nicotine Gels (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482571.htm)

Pipe Tobacco (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482580.htm)

Roll-Your-Own Tobacco Products

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482581.htm)

Smokeless Tobacco Products

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482582.htm)

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

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm)

Flavored Tobacco (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm)

Menthol Cigarettes

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20038740.htm)

Harmful and Potentially Harmful Constituents (HPHCs)

(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20035927.htm)

