

[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)

[\(/ucm/groups/fdagov-public/documents/image/ucm491663.jpg\)](http://ucm/groups/fdagov-public/documents/image/ucm491663.jpg)

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://TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm)), propylene glycol, glycerin, and other ingredients. The liquid is heated into an aerosol that the user inhales.



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.

On this page, you can find:

- [Statistics about ENDS Use](#)
- [FDA Regulation of ENDS](#)
- [Manufacturing ENDS and E-Liquids](#)
- [Nicotine Warning Statement](#)
- [Retail Sales of ENDS, E-Liquids, or their Components or Parts Made or Derived from Tobacco](#)
- [Vape Shops That Mix E-Liquids or Modify Products](#)
- [Importing ENDS and E-Liquids](#)
- [Report Adverse Experiences and Product Violations](#)

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 \(CDER\) \(/Drugs/default.htm\)](http://Center for Drug Evaluation and Research (CDER) (/Drugs/default.htm)). FDA recently proposed a [rule clarifying the jurisdiction \(/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm462957.htm\)](http://TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm462957.htm) over tobacco products, drugs, and devices.

[/ucm/groups/fdagov-public/documents/image/ucm541368.jpg](https://www.fda.gov/ucm/groups/fdagov-public/documents/image/ucm541368.jpg)

"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 (<https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the#h-57>), please read the final rule 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



Battery Safety Concerns in Electronic Nicotine Delivery Systems (ENDS) Public Workshop
(/TobaccoProducts/NewsEvents/ucm535185.htm) - Deadlines:

- February 17, 2017 - **Submit request to serve as presenter or panelist at April 2017 public workshop on ENDS battery safety hazards**
(/TobaccoProducts/NewsEvents/ucm535185.htm#presenters)
- March 17, 2017 - **Register to attend the April 2017 public workshop in person or online**
(/TobaccoProducts/NewsEvents/ucm535185.htm#register)
- March 17, 2017 - **Submit request to present public comments at the April 2017 public workshop**
(/TobaccoProducts/NewsEvents/ucm535185.htm#comments)
- May 22, 2017 - **Submit public comments (https://www.federalregister.gov/documents/2017/01/04/2016-31857/meetings-battery-safety-concerns-in-electronic-nicotine-delivery-systems-public-workshop)**

At any time, interested parties with relevant scientific data may also contact the FDA directly to request an informal meeting on ENDS battery safety concerns.

Manufacturing ENDS and E-Liquids

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import ENDS, you must **comply with these requirements for manufacturers** ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm](https://www.fda.gov/ucm/groups/fdagov-public/documents/default.htm)).

CTP's Office of **Small Business Assistance** ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm](https://www.fda.gov/ucm/groups/fdagov-public/documents/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

Beginning in 2018, 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."

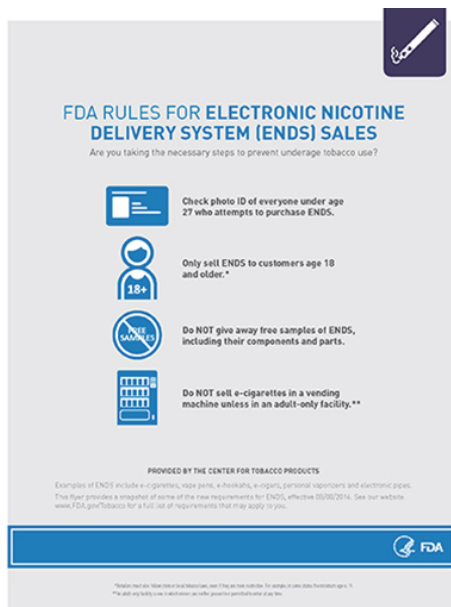
If the tobacco product manufacturer submits a self-certification statement to FDA that the newly-regulated tobacco product does not contain nicotine (and that the manufacturer has data to support this assertion), then an alternate statement must be used on product packages and advertisements:

“This product is made from tobacco.”

You can find more information about nicotine warning statements in the final rule, **Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act** (<https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to->).

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

Order FDA Rules for ENDS Sales Flyer



[\(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm284328.htm\)](https://TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm284328.htm)

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](https://TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm)).

Click on the flyer thumbnail image to order printed materials from CTP's Exchange Lab or to download a PDF to print yourself.

You can find a list of retailer responsibilities for ENDS in the final rule **Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act** (<https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to->). In addition, our website offers more information on **regulations, guidance, and webinars for retailers** ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237759.htm](https://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 may be considered a manufacturer. As a result, some vape shops may have legal **responsibilities as both manufacturers and retailers** ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm514606.htm](https://TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm514606.htm)) of tobacco products. Please also see 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** ([/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm536995.htm](https://TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm536995.htm)).

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 \(/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179264.htm\)](/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 \(/downloads/ICECI/Inspections/IOM/UCM123522.pdf\)](/downloads/ICECI/Inspections/IOM/UCM123522.pdf) (PDF - 406 KB).

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 \(/TobaccoProducts/PublicHealthScienceResearch/ucm377563.htm\)](/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 \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm330160.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm330160.htm).

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

References

Additional Resources

- [Small Business Assistance \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm)
- [Manufacturing \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm)
- [Retailer Overview of FDA Regulations for Selling Tobacco Products \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm)
- [FDA's New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products \(/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm\)](/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm)

More in Products, Ingredients & Components

[\(/TobaccoProducts/Labeling/ProductsIngredientsComponents/default.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/default.htm)

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

[Chemicals in Cigarettes: From Plant to Product to Puff \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm535235.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm535235.htm)

[Cigars, Cigarillos, Little Filtered Cigars \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482562.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482562.htm)

[Dissolvable Tobacco Products \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482569.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482569.htm)

[Flavored Tobacco \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm)

[Harmful and Potentially Harmful Constituents \(HPHCs\) \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20035927.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20035927.htm)

[Hookah Tobacco \(Shisha or Waterpipe Tobacco\) \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482575.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482575.htm)

[Menthol Cigarettes \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20038740.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20038740.htm)

[Nicotine Gels \(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482571.htm\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482571.htm)