

# Vaporizadores, cigarros eletrônicos e outros sistemas eletrônicos de entrega de nicotina (ENDS)

Vapes, vaporizadores, canetas vaporizadores, canetas narguilé, cigarros eletrônicos (e-cigarros ou e-cigs) e e-cachimbos são alguns dos muitos termos usados para descrever os sistemas eletrônicos de entrega de nicotina (ENDS). ENDS são produtos de tabaco **não combustíveis**.

Esses produtos usam um “e-líquido” que pode conter nicotina, bem como composições variadas de aromas, propilenoglicol, glicerina vegetal e outros ingredientes. O líquido é aquecido para criar um aerossol que o usuário inala.

ENDS podem ser fabricados para se parecerem com cigarros, charutos ou cachimbos convencionais. Alguns se parecem com canetas ou unidades flash USB. Dispositivos maiores, como sistemas de tanque ou mods, têm pouca ou nenhuma semelhança com cigarros.

## Doenças respiratórias associadas ao uso de produtos de vaporização

Tanto a Food and Drug Administration quanto os Centros para Controle e Prevenção de Doenças dos EUA estão trabalhando incansavelmente para investigar os incidentes angustiantes de doenças respiratórias graves associadas ao uso de produtos de vaporização.

Saiba mais sobre as ações e recomendações da FDA para o público (</news-events/public-health-focus/lung-injuries-associated-use-vaping-products>).



## Campanha de prevenção do cigarro eletrônico "O custo real" A (/real-cost-campaign)

premiada campanha de prevenção do tabaco para jovens da FDA, "O custo real", se expande para educar os jovens sobre os perigos dos cigarros eletrônicos.

## Estatísticas sobre o uso de cigarros eletrônicos entre jovens dos EUA

- Entre os alunos do ensino fundamental e médio, 3,6 milhões eram usuários atuais de cigarros eletrônicos em 2020 (</tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>).<sup>1</sup>
- Mais de 8 em cada 10 jovens usuários atuais de cigarros eletrônicos usam cigarros eletrônicos com sabor, com os sabores de frutas, menta, doces e mentol entre os mais comumente usados.<sup>1</sup>
- De acordo com uma pesquisa de 2013-2014, 81 por cento dos jovens usuários de cigarros eletrônicos citaram a disponibilidade de sabores atraentes como a principal razão para o uso.<sup>2</sup>





## Regulamentação da FDA para Sistemas Eletrônicos de Entrega de Nicotina

Em 2016, o FDA finalizou uma regra estendendo a autoridade regulatória do CTP para cobrir todos os produtos de tabaco (/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products) , incluindo sistemas eletrônicos de entrega de nicotina (ENDS) que atendem à definição de produto de tabaco. A FDA regula a fabricação, importação, embalagem, rotulagem, publicidade, promoção, venda e distribuição de ENDS, incluindo componentes e peças de ENDS, mas excluindo acessórios. Exemplos de componentes e partes do ENDS incluem:

- E-líquidos
- Um frasco de vidro ou plástico com e-líquido
- Cartuchos
- Atomizadores
- Certas baterias
- Cartomizadores e claromizadores
- Display digital ou luzes para ajustar as configurações
- Sistemas de tanque
- Dicas de gotejamento
- Aromas para ENDS
- Software programável



Products marketed for therapeutic purposes (for example, marketed as a product to help people quit smoking) are regulated by FDA Center for Drug Evaluation and Research (CDER). FDA published a rule clarifying when products made or derived from tobacco are regulated as tobacco products, drugs, and/ or devices (<https://www.federalregister.gov/documents/2017/01/09/2016-31950/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or>).

In January 2020, FDA issued an enforcement policy on unauthorized flavored cartridge-based e-cigarette products, including fruit and mint flavors, that appeal to kids. For more information, see the final guidance: Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market).

## Manufacturing Electronic Nicotine Delivery Systems and E-Liquids

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import ENDS, you must comply with the requirements for manufacturers (/tobacco-products/compliance-enforcement-training/manufacturing).

CTP's Office of Small Business Assistance (/tobacco-products/compliance-enforcement-training/small-business-assistance-tobacco-product-industry) 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.

Beginning in 2018, all "covered" tobacco products\* must bear the required nicotine addictiveness warning statement ([/tobacco-products/labeling-and-warning-statements-tobacco-products/covered-tobacco-products-and-roll-your-own-cigarette-tobacco-labeling-and-warning-statement](#)) on product packages and advertisements. \***Note:** Cigars ([/tobacco-products/products-ingredients-components/cigars-cigarillos-little-filtered-cigars](#)), which are also "covered" tobacco products, have additional required warning statements.

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## Retail Sales of Electronic Nicotine Delivery Systems and, E-Liquids

**Note:** On December 20, 2019, the President signed legislation to amend the Federal Food, Drug, and Cosmetic Act, and raise the federal minimum age of sale of tobacco products from 18 to 21 years. It is now illegal for a retailer to sell any tobacco product – including cigarettes, cigars and e-cigarettes – to anyone under 21. FDA will provide additional details on this issue as they become available, and the information on this page will be updated accordingly in a timely manner.

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 ([/tobacco-products/retail/summary-federal-rules-tobacco-retailers](#)).

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 ([/tobacco-products/retail/retailer-regulations-and-guidance](#)).

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## 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 ([/tobacco-products/compliance-enforcement-training/pipe-cigar-and-vape-shops-are-regulated-both-retailers-and-manufacturers](#)) of tobacco products. Please also see the Guidance: Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops ([/tobacco-products/rules-regulations-guidance/interpretation-and-compliance-policy-certain-label-requirement-applicability-certain-federal-food](#)).

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## Importing Electronic Nicotine Delivery Systems and E-Liquids

Tobacco products imported or offered for import ([/tobacco-products/products-guidance-regulations/importing-and-exporting](#)) into the United States must comply with all the applicable requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

You can also learn more about the importation process in the FDA Regulatory Procedures Manual, Chapter 9, Import Operations and Actions.

If you have questions about importing a specific tobacco product, please contact the FDA district into which your product will be imported ([/media/75281/download](#)).

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## Report a Problem with a Tobacco Product or Potential Tobacco Product Violations

If you have experienced undesired health or quality problems with a specific tobacco product, you can report a problem ([/tobacco-products/science-research/safety-reporting-portal-tobacco-products](#)) with any tobacco product, including vapes, to the FDA. Knowledge about adverse experiences can help the FDA identify health or quality problems beyond those normally associated with tobacco 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 ([/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation](#)).

You can read the adverse experience reports for tobacco on the Tobacco Product Problem Reports ([/tobacco-products/tobacco-science-research/tobacco-product-problem-reports](#)) page.

### 1. Consider using vapes with safety features

such as firing button locks, vent holes, and protection against overcharging.



### 2. Keep your vape covered.

Don't let it come into contact with coins or loose batteries in your pocket.

### 3. Never charge your vape with a phone or tablet charger.

Always use the charger that came with it.

### 4. Don't charge your vape overnight

or leave it charging unattended.

### 5. Replace the batteries if they get damaged or wet.

If your vape gets damaged and the batteries are not replaceable, contact the manufacturer.

## Additional Resources

- FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint ([/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children](#))
- FDA takes steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access ([/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more](#))
- Small Business Assistance for Tobacco Product Industry ([/tobacco-products/compliance-enforcement-training/small-business-assistance-tobacco-product-industry](#))
- Manufacturing ([/tobacco-products/compliance-enforcement-training/manufacturing](#))
- Selling Tobacco Products in Retail Stores ([/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores](#))
- Tips to Help Avoid "Vape" Battery Explosions ([/tobacco-products/products-ingredients-components/tips-help-avoid-vape-battery-explosions](#))
- Regulamentações do FDA para cigarros eletrônicos, charutos e todos os outros produtos de tabaco ([/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products](#))
- Orientação: Aplicações de Produtos de Tabaco de Pré-comercialização para Sistemas Eletrônicos de Entrega de Nicotina (ENDS) ([/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends](#))
- Orientação: Interpretação e Política de Conformidade para Certos Requisitos de Etiqueta; Aplicabilidade de certos requisitos da lei federal de alimentos, medicamentos e cosméticos para lojas Vape ([/regulatory-information/search-fda-guidance-documents/interpretation-and-compliance-policy-certain-label-requirement-applicability-certain-federal-food](#))
- Administração Federal de Aviação: Kit de Marketing Vapes On a Plane ([https://www.faa.gov/hazmat/packsafe/resources/vapes\\_marketing\\_kit/](https://www.faa.gov/hazmat/packsafe/resources/vapes_marketing_kit/))

## Referências

1. Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA, King BA. E-cigarette Use Among Middle and High School Students — United States, 2020. MMWR Morb Mortal Wkly Rep. ePub: 9 September 2020.
  2. Villanti AC, Johnson AL, Ambrose BK, et al. Use of flavored tobacco products among U.S. youth and adults; findings from the first wave of the PATH Study (2013-2014)
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