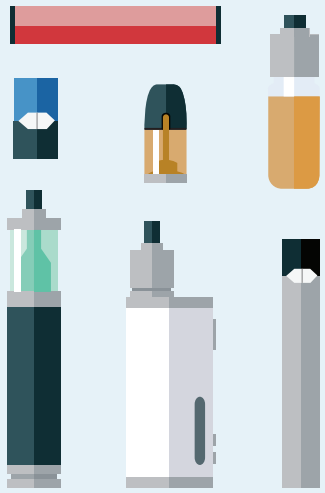
CENTER FOR TOBACCO PRODUCTS

HOW FDA REGULATES VAPES

Vapes, e-cigarettes, e-cigs, vape pens, and vaporizers are among many names for electronic nicotine delivery systems (ENDS). Over the last decade, ENDS have become popular among both adults and teens. Sadly, youth e-cigarette use is now a public health concern affecting children, families, schools, and communities.

FDA PREVENTS YOUTH ACCESS TO VAPES.

The U.S. Food and Drug Administration (FDA) is addressing this challenge through its regulatory activity under the **Family Smoking Prevention and Tobacco Control Act** (Tobacco Control Act). (See https://bit.ly/3mAQ0iP for more information.) This fact sheet explains how FDA regulates ENDS, enforces federal tobacco laws, and helps prevent youth access to tobacco products.



FDA REGULATES ENDS AND ALL OTHER TOBACCO PRODUCTS.

FDA began regulating ENDS in August 2016, when the **"Deeming Rule"** went into effect. (See https://bit.ly/3GIpcEw for more information.) This rule gives FDA regulatory authority over all ENDS and other tobacco products in ways the agency already was regulating cigarettes, smokeless tobacco, and roll-your-own tobacco. For example, it became illegal to distribute free samples of e-cigarettes.

FDA regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS and their components. This includes e-liquids, vials that contain e-liquid, cartridges, flavors, certain batteries, and even software. FDA does not regulate ENDS accessories, such as lanyards or decorative cases for vapes.

CONSUMERS MUST BE 21 OR OLDER TO BUY TOBACCO PRODUCTS.

Under federal law, the minimum age to purchase tobacco products is 21. This law took effect on December 20, 2019. It is now illegal for retailers to sell any tobacco product—including ENDS and cigarettes—to anyone under age 21. The law applies to all retailers and stores, with no exceptions.

VAPE MANUFACTURERS CANNOT MARKET PRODUCTS WITHOUT FDA AUTHORIZATION.

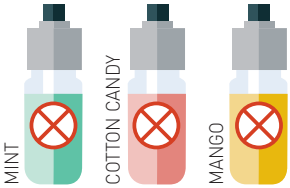
ENDS products have been on the market for a while, but FDA did not have the authority to regulate them until August 8, 2016. A court decision later required ENDS manufacturers to submit product applications to FDA for agency review by September 9, 2020. FDA received applications for more than 6.7 million tobacco products, the majority of which were for ENDS products submitted near the deadline's end. Since then, FDA has made tremendous progress in reviewing these applications: The agency has taken action on more than 99 percent of these products, including denying the marketing of more than 1 million flavored ENDS products. FDA also has authorized some ENDS products after determining that they meet the public health standards in the law, which includes an assessment of the risk of their use by youth.

The premarket review of these products is a major milestone for ensuring that new tobacco products, including popular ENDS products, undergo robust scientific evaluation by FDA—an important way in which the agency protects public health. For a list of authorized tobacco products and information about products that have been denied, visit **FDA's Tobacco Product Marketing Orders webpage.** (See https://bit.ly/3G6fM5u for more information.)

FDA PRIORITIZES ENFORCEMENT AGAINST CERTAIN ILLEGALLY MARKETED ENDS.

FDA's scientific review of vaping products ensures they are appropriate for the protection of public health. The agency continues to monitor the marketplace to protect youth from certain illegally marketed ENDS products.

In January 2020, FDA issued a guidance (revised in April 2020) describing some of the agency's enforcement priorities when it comes to illegally marketed ENDS. Consistent with that guidance, FDA continues to make enforcement decisions on a case-by-case basis, recognizing that the agency is unable—as a practical matter—to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of its resources.



As described in FDA's enforcement guidance, the agency has identified flavored products that appeal to youth as enforcement priorities.

Products for which no application is pending—for example, those with a Marketing Denial Order and those for which no application was submitted—are also among FDA's highest enforcement priorities.

If such products are not removed from the market, FDA will generally issue a warning letter and allow the recipient an opportunity to respond before initiating enforcement action (such as civil money penalties, seizure, or injunction). FDA is committed to working quickly to transition the current marketplace to one in which all tobacco products have undergone a careful, science-based review by the agency and have met the statutory standard.

A Note About Cannabis in Vapes

FDA supports sound, scientifically based research into the medicinal uses of drug products containing cannabis or cannabis-derived compounds and will continue to work with companies interested in bringing safe, effective, and quality products to market. More information about products containing cannabis or cannabis-derived compounds, including cannabidiol (CBD), can be found at **https://bit.ly/3DcMqRD.**

FDA REGULATIONS HELP PREVENT USE OF TOBACCO PRODUCTS BY YOUTH.

FDA works hard to prevent youth from using and becoming addicted to tobacco products. The agency's aggressive and ongoing enforcement of ENDS products that are appealing to youth is an important part of this work. FDA will continue working to ensure e-cigarettes are not marketed to, sold to, or used by youth.

CENTER FOR TOBACCO PRODUCTS

MORE INFORMATION ABOUT VAPING AND REGULATION OF TOBACCO PRODUCTS

Vaping Facts, Statistics, Health Risks, Safety Information, and Federal Regulation

Check out FDA's Center for Tobacco Products (CTP) website for a wide range of information about ENDS, including facts, research, and legal and regulatory information. Find tips on how people can keep themselves, their families, and the environment safe and healthy. **Visit CTP's ENDS webpage at https://bit.ly/3zejJ4A**

FDA Resources

Order and download FREE materials at FDA's CTP Tobacco Education Resource Library. The website contains many items for public health professionals and the public about tobacco products, e-cigarettes, and related information. Posters, fact sheets, flyers, and syndicated web content are available. **Visit digitalmedia.hhs.gov/tobacco**

Request a CTP Speaker

Want to hear more about vapes from a CTP expert? Find out how to request a CTP speaker for your next event. **Visit https://bit.ly/3jk1x45**

FDA Tobacco Product Marketing Orders

See a list of authorized tobacco products and information that can be disclosed about those that have been denied. **Visit FDA's Tobacco Product Marketing Orders webpage at https://bit.ly/3G6fM5u**

Tobacco Retailer Warning Letters

Learn more about FDA warning letters to retailers. **Visit https://bit.ly/3KsA1vT**