

# FDA Orders Juul E-Cigarettes Off the Market: Youth Vaping and Safety Concerns

Juul, the once-booming Silicon Valley start-up widely blamed for igniting the youth vaping epidemic, faced a major setback as federal regulators ordered all of its e-cigarette products off the market. The move was a response to “inconsistent and conflicting data” on safety concerns. The Food and Drug Administration (FDA) denied Juul’s applications to continue selling their e-cigarette device and prefilled cartridges in menthol and tobacco flavors, highlighting the company’s failure to provide sufficient evidence of safety for users of all ages.

## Safety Concerns and Study Findings

---

The FDA raised concerns about potential DNA damage and the leaching of harmful chemicals from Juul’s prefilled cartridges, which contain liquid nicotine, flavorings, and other chemicals. The agency emphasized that the safety issues were not limited to youth use but extended to anyone who might use the product. Mitch Zeller, the former director of the FDA’s Center for Tobacco Products, stated that the agency had significant questions regarding Juul’s safety claims that remained unanswered.

Michele Mital, the acting director of the FDA tobacco center, confirmed that Juul had the opportunity to respond to the agency’s questions but failed to provide satisfactory data, leading to the issuance of marketing denial orders. In response, Joe Murillo, Juul’s chief regulatory officer, expressed disagreement with the FDA’s decision and announced the company’s intention to appeal. Murillo claimed that Juul had provided comprehensive information and data based on high-quality research to address the concerns raised by the agency.

## Options for Juul and FDA Monitoring

---

Juul has several options to respond to the FDA’s decision. They can file an appeal within the agency, requesting a stay while the matter is pending, or potentially sue the FDA in federal appeals court. Meanwhile, the FDA stated its intention to closely monitor Juul distributors and retailers to ensure compliance with the sales halt. If the products are not promptly removed from the market, the agency has the authority to issue warning letters, impose fines, or even conduct seizures.

## Campaign for the Protection of Public Health

---

The FDA’s decisions regarding Juul are part of a broader campaign to review e-cigarettes for their impact on public health. The agency aims to ensure that e-cigarette products are more likely to assist adults in quitting smoking rather than attracting young people and potentially causing nicotine addiction. While the focus has been primarily on youth vaping, the FDA’s reviews also aim to ensure the overall safety of these products for adults.

Mitch Zeller noted that there were unresolved questions and concerns in the FDA’s assessment of Juul, contributing to the rejection of their applications. Although Juul experienced tremendous popularity with its sleek vaping device and flavored nicotine pods, the company faced significant backlash from parents and regulators who held it responsible for the surge in teenage vaping. In response to the criticism, Juul voluntarily removed all flavored prefilled pods from the market, except for tobacco and menthol flavors.

## Reactions and Controversies

---

Anti-vaping advocates praised the FDA’s ruling, considering it the most significant action taken to address the youth e-cigarette epidemic. Matthew L. Myers, president of the Campaign for Tobacco-Free Kids, credited Juul as the primary driver behind the youth e-cigarette epidemic. However, he pointed out that the FDA’s decision, based on safety reasons, did not fully address Juul’s role in the ongoing issue of youth vaping sustained by flavored e-cigarettes, including menthol-flavored products.

Gregory Conley, president of the American Vaping Association, criticized the FDA’s decision on Twitter, claiming that it was manufactured and complete nonsense. On the other hand, some anti-tobacco advocates questioned whether the FDA’s actions against Juul went too far. Clifford E. Douglas, director of the University of Michigan’s Tobacco Research Network, acknowledged Juul’s negative reputation but argued that the decision might have been politically influenced rather than solely based on safety concerns.

## FDA’s Review Process and Recent Actions

---

The FDA has faced criticism from both parties for its slow pace in banning flavored e-cigarettes, including those produced by Juul. Lawmakers, including senators Richard J. Durbin and Mitt Romney, have urged the agency to expedite the review process to protect public health. The FDA has ruled on applications for millions of e-cigarette products in recent months, rejecting requests from vape manufacturers seeking to reintroduce

sweet and fruity vapes.

In response to concerns about youth vaping, the FDA banned the sales of sweet and fruity e-cigarette pods in 2020, a step that Juul had already taken voluntarily. Juul and other companies were allowed to continue selling tobacco and menthol-flavored cartridges only while the FDA reviewed their marketing applications. Juul submitted their applications two years ago, presenting scientific studies and other evidence to support their claims of helping adults quit smoking without attracting young users.

## Juul's History and Industry Impact

---

Juul's problems with the FDA began in 2018 when data revealed a significant increase in teenage vaping, leading to regulatory backlash. The then-FDA commissioner, Scott Gottlieb, publicly held Juul responsible for initiating a youth vaping epidemic. Gottlieb expressed frustration when tobacco giant Altria acquired a 35 percent stake in Juul later that year.

In 2019, facing lawsuits and investigations, Juul announced a "reset" to regain public trust and implemented measures to prevent underage sales. The company ceased television, print, and digital advertising and removed all sweet and fruity flavors from the market, except for tobacco and menthol. Although Juul's sales declined following these actions, the company still holds a significant share of the market.

## FDA's Tobacco Regulation and Recent Development

---

The FDA's decision regarding Juul came shortly after another significant tobacco-related action: the agency's plan to develop a rule requiring tobacco companies to reduce nicotine levels in cigarettes sold in the United States to minimally or nonaddictive levels. This initiative could have a groundbreaking impact on reducing smoking-related deaths and potentially pose a threat to the powerful tobacco industry.

Vuse Alto e-cigarettes, owned by Reynolds American tobacco company, have recently surpassed Juul in terms of market share among cartridge-based brands in the United States. Juul's annual revenue declined from approximately \$2 billion in 2019 to \$1.3 billion in 2021, reflecting the company's challenges. However, the most recent survey by the FDA and the Centers for Disease Control and Prevention indicates a decline in youth vaping since its peak in 2019. While progress has been made, e-cigarette use among middle and high school students remains a concern.

The popularity of disposable e-cigarettes like Puff Bar, which offers a variety of flavors and was not subject to the restrictions imposed on cartridges, has made it the most popular vaping brand among young people, surpassing Juul.

### FAQs:

- Q:** Why did the FDA order Juul e-cigarettes off the market? **A:** The FDA ordered Juul e-cigarettes off the market due to safety concerns and the company's failure to provide sufficient evidence of product safety.
- Q:** Did Juul target young people with their products? **A:** Juul has repeatedly denied targeting young people, but their marketing tactics and flavored nicotine pods fueled a surge in teenage vaping, leading to regulatory scrutiny.
- Q:** Can Juul appeal the FDA's decision? **A:** Yes, Juul has the option to file an appeal within the FDA or potentially sue the agency in federal appeals court.
- Q:** What happens if Juul's products are not removed from the market? **A:** If Juul's products are not promptly removed, the FDA can issue warning letters, impose fines, or conduct seizures to ensure compliance.
- Q:** What impact does this decision have on the e-cigarette industry? **A:** The FDA's decision reflects its ongoing campaign to review e-

cigarettes for public health protection. It highlights the need for products to assist adults in quitting smoking without enticing young people to start vaping.