

## New FDA rules aim to keep kids from flavored e-cigarettes (Update)

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(HealthDay)—Responding to the steep, recent rise in the use of



addictive e-cigarettes among kids, the U.S. Food and Drug Administration on Wednesday announced it would go ahead with efforts to restrict sales of some types of flavored vaping products to minors.

The new restrictions were first announced in November. Under the rules, most forms of flavored e-cigarettes would only be sold in stores that verify a customer's age when he or she enters the store, or the store should have a special age-restricted area set aside for vaping products.

As for online sales, companies would be required to use third-party identity-verification services before selling e-cigarettes, the FDA said. Federal law currently bans use of e-cigarettes by people under the age of 18.

Companies that fail to comply with the new rules could see their products pulled from the market, outgoing FDA Commissioner Dr. Scott Gottlieb said in a statement.

Because of the new restrictions, "we expect that some flavored ecigarette products will no longer be sold at all," Gottlieb added.

In one more move, the FDA moved its deadline for companies to submit new vaping products for health and safety review to 2021. That's a year earlier than the 2022 deadline set previously, but still much later than the 2018 deadline mandated under the Obama administration.

## Millions of kids now vaping

Gottlieb, who announced his retirement as agency head just last week, has made curbing youth addiction to nicotine a top priority during his tenure at the FDA.

Sales of some flavors of cigars will face new restrictions, also, because



"youth continue to use these dangerous combusted tobacco products due, in part, to the availability and appeal of fruit and other flavors," Gottlieb said.

In all cases, it's thought that berry, candy and other flavorings added to cigars and e-cigarettes lure kids and youth to vaping and smoking.

Gottlieb said his agency is responding to a rapid surge in vaping rates among youth.

"The most recent data show more than 3.6 million middle and high school students across the country were current (past 30 day) e-cigarette users in 2018," Gottlieb noted. "This is a dramatic increase of 1.5 million children since the previous year."

Not only that, but the data showed that when kids were vaping, they were doing so more frequently than in the past and were increasingly turning to flavored products.

All of this "is particularly troubling given that research shows that kids using e-cigarettes are more likely to take up [traditional] combustible cigarettes," Gottlieb said.

## 'Enticing' flavors

Studies do seem to back up the FDA's concerns. For example, one recent study from Dartmouth University researchers, published in *Public Health Reports*, highlighted the danger.

"We found that adolescent and young adult vapers were not only more likely than older adult vapers to use fruit- and candy-flavored ecigarettes, but were more likely to concurrently use multiple flavor types," lead researcher Samir Soneji said in a university news release.



Because kids are more attracted to flavored versions of e-cigarettes than adults, "stricter regulation or banning of flavored e-cigarettes, such as fruit and candy, can achieve the dual goal of reducing youth vaping while not burdening older adult cigarette smokers who use e-cigarettes to help quit," Soneji said.

One anti-smoking expert agreed.

Sales data "inform us that the younger user of these products is enticed by the wide array of flavors," said Andrea Spatarella, of the Center for Tobacco Control at Northwell Health in Great Neck, N.Y. "The new recommendations address this issue," she believes.

Not included in the tougher new rules are tobacco-, mint- and mentholflavored e-cigarettes, Gottlieb said. That decision stems from data showing that those flavors are preferred by adult smokers who are using vaping as a means to help them quit smoking, he said.

So for now, those flavors have looser rules around their sales, although "we won't ignore [any forthcoming] data regarding the popularity of mint- and menthol-flavored [vaping products] among kids, should the concern arise," Gottlieb said.

The FDA head also announced that, "this summer, we'll unveil the first television advertisement aimed at educating children about the risks of ecigarettes."

## Rules 'inadequate,' critics say

Juul—by far the leading brand of e-cigarette, with about 70 percent of the market —announced in November that it was already withdrawing many flavored versions of its popular e-cigarettes from the market.



At the time, Juul CEO Kevin Burns said in a statement that, "Our intent was never to have youth use Juul. But intent is not enough. The numbers are what matter, and the numbers tell us underage use of e-cigarettes is a problem."

The non-profit advocacy group Campaign for Tobacco-Free Kids applauded the new FDA move, but said it still falls short.

"It does not apply to menthol and mint flavors despite recent data (from the 2018 National Youth Tobacco Survey, conducted by the FDA and the CDC) showing that over half (51 percent) of high school students who currently use e-cigarettes use menthol or mint products," the group's president, Matthew Myers, said in a statement.

"The FDA inexplicably ignores the evidence from its own survey in exempting mint and menthol flavors from its new policy," he noted.

"Today's announcement also does little to limit the availability of Juul or Juul pods that deliver as much nicotine as a pack of 20 cigarettes, despite the fact that Juul is the main driver of the youth e-cigarette epidemic," Myers said. "The Juul device itself and high-nicotine Juul pods in menthol and mint flavors will continue to be widely sold in convenience stores and gas stations accessible to kids."

The bottom line, according to Myers, is that the FDA's actions are so far "inadequate to reverse the youth e-cigarette epidemic."

With soaring uptake of vaping by kids, "the FDA must do more and do so quickly," Myers believes. "It should prohibit all flavored e-cigarettes that have not been subject to public health review by the agency, halt online sales of e-cigarettes until stronger safeguards are in place to prevent sales to kids, restrict marketing that attracts kids, and enforce rules prohibiting the sale of new products without FDA authorization."



An expert in respiratory health said there's still too little data on how vaped chemicals might affect health.

"E-cigarettes are also providing more than nicotine, with other propellants and organic compounds in the 'vaping' process," said pulmonologist Dr. Len Horovitz, of Lenox Hill Hospital in New York City. "We don't know the safety of some of these organic compounds used in the vaping process," he added.

For his part, Gottlieb stressed that the new FDA rules may help reverse current trends and "dramatically limit the ability of kids to access tobacco products we know are both appealing and addicting."

**More information:** March 13, 2019, news releases, U.S. Food and Drug Administration, Campaign for Tobacco-Free Kids, Dartmouth University; Andrea Spatarella, DNP, Center for Tobacco Control, Northwell Health, Great Neck, N.Y.; Len Horovitz, M.D., Lenox Hill Hospital, New York City

The U.S. National Institute on Drug Abuse has more about e-cigarettes.

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