FDA News Release

FDA advances investigation into whether more than 40 e-cigarette products are being illegally marketed and outside agency's compliance policy

Agency seeks more information from companies as it continues to pursue its Youth Tobacco Prevention Plan amid evidence of sharply rising e-cigarette use among kids

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For Immediate Release

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Release

Today, the U.S. Food and Drug Administration **sent letters (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm)** to 21 e-cigarette companies, including the manufacturers and importers of Vuse Alto, myblu, Myle, Rubi and STIG, seeking information about whether more than 40 products – including some flavored e-cigarette products – are being illegally marketed and outside the agency's current compliance policy. These new actions build on those taken by the FDA in recent weeks as part of its **Youth Tobacco Prevention Plan (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm)** to address the epidemic of youth e-cigarette use, including **cracking down (/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm)** on the sale and marketing of e-cigarettes to kids and **educating youth (/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm)** about the dangers of using these products.

"Companies are on notice – the FDA will not allow the proliferation of e-cigarettes or other tobacco products potentially being marketed illegally and outside of the agency's compliance policy, and we will take swift action when companies are skirting the law. Given the explosive growth of e-cigarette use by kids, we're committed to taking whatever measures are appropriate to stem these troubling use trends. We're going to address issues related to the access kids have to e-cigarettes, as well as the youth appeal of these products. If products are being unlawfully marketed and outside the FDA's compliance policy, we'll act to remove them. This includes revisiting our compliance policy that has resulted in certain e-cigarettes, including flavored e-cigarettes, remaining on the market until 2022 while their manufacturers submit applications for premarket authorization. Further, many of these products pose particular concerns given their use of flavors. We know flavors are one of the principal drivers of the youth appeal of e-cigarettes and we're looking carefully at this," said FDA Commissioner Scott Gottlieb, M.D. "The FDA remains committed to the potential opportunity for e-cigarettes to help adult smokers transition away from combustible cigarettes. But we cannot allow that opportunity to come at the expense of addicting a whole new generation of kids to nicotine. We'll take forceful steps to stem the youth use, even if our actions have the unwelcome effect of impeding some opportunities for adults. These are the hard tradeoffs we now need to make. We've been warning the e-cigarette manufacturers for more than a year that they need to do more to stem the youth use. No reasonable person wants to see these products reaching epidemic use among kids. Retailers and manufacturers of e-cigarettes know that the FDA is aggressively enforcing the law to ensure they are complying with prohibitions against marketing and selling to kids. Through these actions – and with more to come in the weeks and months ahead – we're committed to doing all we can to reverse the disturbing trends of youth tobacco use, especially e-cigarettes. I'll do everything I can to curb the epidemic of youth use."

As part of the FDA's **comprehensive plan on tobacco and nicotine regulation (/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm)**, the agency implemented a new compliance policy related to the deadline for companies to submit tobacco product review applications for "deemed" tobacco products that were on the market as of Aug. 8, 2016 – the effective date of the final deeming rule that extended the FDA's authority to additional tobacco products such as e-cigarettes. The compliance policy provided manufacturers additional time to develop higher quality, more complete applications. The extension of the compliance date also aimed to give the agency more time to explore clear and meaningful measures to make tobacco products less toxic, appealing and addictive. These measures, which will focus on protecting youth, could include an examination of flavors/designs that appeal to children, child-resistant packaging and product labeling to prevent accidental child exposure to liquid nicotine.

Since this extension, the FDA has received complaints that some companies may be marketing new products that do not meet the Food Drug and Cosmetic Act's (FD&C Act) premarket requirements and that were introduced or modified after the deeming rule's Aug. 8, 2016, effective date. Such modifications could include the introduction of new product features, formulations or flavors. The letters issued today ask companies to provide information about the products in question, including evidence that the product is a deemed product that was on the market as of Aug. 8, 2016 and has not been modified since that date. JUUL Labs Inc. did not receive such a letter, as the company was separately subject to a recent unannounced on-site inspection of its corporate headquarters, which sought similar information about its marketing practices. Any product that does not comply with the premarket requirements of the FD&C Act is adulterated and misbranded and may not be marketed without authorization from the FDA. The agency has several tools to enforce the requirements of the FD&C Act and regulations, including pursuing administrative actions such as civil money penalty complaints (fines) or judicial actions such as seizures or injunctions.

Although it may appear that a deemed tobacco product, such as an e-cigarette, was not on the market as of Aug. 8, 2016, there are situations where this may not be the case. In some instances, it could be that products are, in fact, in compliance with the FDA's current policy. For example, a product may have been commercially available and on the market as of Aug. 8, 2016, but the company may not have publicly announced or advertised its product until recently. Additionally, a company may have been selling the same tobacco product under a different name as of Aug. 8, 2016, but is now promoting it as "new" because of its re-branding, or it may have been purchased from another company and re-released with a different name by the new company. In order to more easily clarify these situations, manufacturers may want to consider maintaining easily accessible evidence on the marketing status of each of their products at their facility. Doing so would benefit all parties at the time of an inspection and could also be included in future correspondence with the FDA.

The 21 letters announced today are part of series of actions over the past several months to target the illegal sales of e-cigarettes to youth more immediately, as well as to target the kid-friendly marketing and appeal of these products. In particular, the FDA recently **announced (/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm)** a series of critical and historic enforcement actions that included issuing more than 1,300 warning letters and fines to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores this summer – the largest coordinated enforcement effort in the FDA's history. Moving forward, the FDA is indefinitely stepping up enforcement actions with a sustained campaign to monitor, penalize and prevent e-cigarette sales to minors in retail locations including manufacturers' own internet storefronts. The agency is currently exploring action under both its civil and criminal enforcement tools to target potentially violative sales and marketing practices by manufacturers as well as retailers.

The agency also recently **issued letters (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm)** to five major e-cigarette manufacturers whose products – JUUL, Vuse, MarkTen, blu e-cigs and Logic – comprise more than 97 percent of the market share for closed system ENDS products. These letters asked the firms to submit to the FDA within 60 days plans describing how each firm will address the widespread youth access and use of its products.

In addition, the FDA also recently stated it will consider whether it would be appropriate to revisit the current policy that results in certain deemed products remaining on the market without a marketing order from the agency. This could mean

requiring companies to remove some or all of their flavored products, which may be contributing to the rise in youth use, from the market, until they receive premarket authorization and otherwise meet all of their obligations under the law.

The agency also recently **launched (/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm)** "The Real Cost" Youth E-Cigarette Prevention Campaign. This is a new, comprehensive effort targeting nearly 10.7 million youth, aged 12-17, who have used e-cigarettes or are open to trying them. The new campaign features hard-hitting advertising on digital and social media sites popular among teens, as well as posters with e-cigarette prevention messages in high schools across the nation.

As part of the FDA's comprehensive plan on tobacco and nicotine regulation, the agency also issued an **advance notice of proposed rulemaking (/NewsEvents/Newsroom/PressAnnouncements/ucm601690.htm)** in March to seek public comment on the role that flavors in tobacco products play in attracting youth. The FDA intends to expedite the review and analysis of the comments so it can leverage the information into policy as quickly as possible, should the science support further action. Additionally, the agency plans to explore additional restrictions on the sale and promotion of electronic nicotine delivery systems to further reduce youth exposure and access to these products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Michael Felberbaum (mailto:megan.michael.felberbaum@fda.hhs.gov)
240-402-9548

Consumers

888-INFO-FDA

Related Information

- **CTP Letters to Industry (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm)**
- **Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use (/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm)**
- **FDA takes new 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 (/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm)**
- **FDA's Youth Tobacco Prevention Plan (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm)**

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