FDA News Release

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

Warning letters and civil money penalty complaints to retailers are largest coordinated enforcement effort in agency history; FDA requests manufacturers provide plan for mitigating youth sales within 60 days; warns it may restrict flavored e-cigarettes to address youth epidemic

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For Immediate Release

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Release

The U.S. Food and Drug Administration today announced a series of critical and historic enforcement actions related to the sale and marketing of e-cigarettes to kids. In the largest coordinated enforcement effort in the FDA's history, the agency **issued (/TobaccoProducts/NewsEvents/ucm605278.htm)** more than 1,300 warning letters and civil money penalty complaints (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. As a result of these violations of the law – and other indications that e-cigarette use among youth has hit epidemic proportions – FDA Commissioner Scott Gottlieb, M.D., signaled that the agency intends to take new and significant steps to address this challenge in a speech at the agency's headquarters.

"We're committed to the comprehensive approach to address addiction to nicotine that we announced last year. But at the same time, we see clear signs that youth use of electronic cigarettes has reached an epidemic proportion, and we must adjust certain aspects of our comprehensive strategy to stem this clear and present danger. This starts with the actions we're taking today to crack down on retail sales of e-cigarettes to minors. We will also revisit our compliance policy that extended the dates for manufacturers of certain flavored e-cigarettes to submit applications for premarket authorization. I believe certain flavors are one of the principal drivers of the youth appeal of these products. While we remain committed to advancing policies that promote the potential of e-cigarettes to help adult smokers move away from combustible cigarettes, that work can't come at the expense of kids. We cannot allow a whole new generation to become addicted to nicotine. In the coming weeks, we'll take additional action under our Youth Tobacco Prevention Plan to immediately address the youth access to, and the appeal of, these products," said FDA Commissioner Gottlieb. "Today, we asked five e-cigarette manufacturers to put forward plans to immediately and substantially reverse these trends, or face a potential decision by the FDA to reconsider extending the compliance dates for submission of

premarket applications. Our comprehensive plan on nicotine and tobacco regulation remains intact and we remain committed to its goals to reduce tobacco-related disease and death, including our efforts to reduce the nicotine in combustible products to render cigarettes minimally or non-addictive. We're also fully committed to the concept that products that deliver nicotine exist on a continuum of risk, with combustible products representing the highest risk, and electronic nicotine delivery systems perhaps presenting an alternative for adult smokers who still seek access to satisfying levels of nicotine, but without all of the harmful effects that come from combustion. But in enabling a path for e-cigarettes to offer a potentially lower risk alternative for adult smokers, we won't allow the current trends in youth access and use to continue, even if it means putting limits in place that reduce adult uptake of these products."

FDA undertakes aggressive enforcement strategy targeting illegal sales to youth and kid-friendly marketing

As part of the agency's **Youth Tobacco Prevention Plan (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm)** and ongoing work to protect youth from the dangers of tobacco products, the FDA has taken a series of actions over the past several months to more immediately target the illegal sales of e-cigarettes to youth, as well as the kid-friendly marketing and appeal of these products.

The FDA is stepping up those efforts indefinitely.

One aspect of the agency's plan will entail increased enforcement. The more than 1,300 warning letters and fines to retailers announced today were part of a large-scale, undercover nationwide blitz to crack down on the sale of e-cigarettes to minors at both brick-and-mortar and online retailers, which was conducted from June through the end of August. The vast majority of the violations were for the illegal sale of five e-cigarette products – Vuse, Blu, JUUL, MarkTen XL, and Logic. These five brands currently comprise over 97 percent of the U.S. market for e-cigarettes.

In addition, today the FDA also **issued 12 warning letters (/ICECI/EnforcementActions/WarningLetters/default.htm)** to other online retailers that are selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly food products such as candy and cookies. These products were the subject of **agency action in May (/TobaccoProducts/NewsEvents/ucm605729.htm)** and, subsequently, are **no longer being sold (/NewsEvents/Newsroom/PressAnnouncements/ucm618169.htm)** with the offending labeling and advertising by the companies that received the May warning letters. However, the retailers receiving the warning letters today are still advertising and selling the violative products. Several of these retailers were also cited for illegally selling the products to minors. The agency will continue to monitor and take action against companies that sell tobacco products that might mislead a young child into thinking the product is appropriate for them to consume as food. The FDA has more compliance actions underway.

In addition to these new actions, the FDA had **previously issued (/TobaccoProducts/NewsEvents/ucm605278.htm)** more than 60 warning letters and fines to businesses that sold JUUL brand products to minors stemming from another enforcement blitz this past spring. The agency also recently sent letters to **JUUL Labs (/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm)** and **several other companies (/NewsEvents/Newsroom/PressAnnouncements/ucm607935.htm)** requiring them to submit important documents to better understand the reportedly high rates of youth use and the particular youth appeal of their products. The FDA is currently investigating whether manufacturers introduced certain e-cigarette products to the market after Aug. 8, 2016, and may be subject to enforcement for marketing those products without premarket authorization.

The FDA also continues to conduct checks of retail establishments that sell tobacco products to ensure compliance with federal laws. In total, the FDA has conducted 978,290 retail inspections, issued 77,180 warning letters to retailers for violating the law and initiated approximately 18,560 civil money penalty cases, as of Sept. 1, 2018. There is a clear need for strong federal enforcement of youth access restrictions and the FDA will continue to hold retailers accountable by vigorously enforcing the law with the help of the agency's state partners.

The agency also has issued more than 135 No-Tobacco-Sale Order Complaints, which can result in retailers being prohibited from selling tobacco products for specified periods of time.

FDA warns youth use of e-cigarettes is reaching epidemic proportions, signals new, aggressive steps to address challenge, including re-examining FDA's compliance policy regarding flavored e-cigarettes

Over the past several years, e-cigarettes were the most commonly used tobacco product by youth. In fact, **more than 2 million middle and high school students (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm405173.htm)** were current users of e-cigarettes in 2017.

This use by children and teens is especially concerning to the FDA because the developing adolescent brain is particularly vulnerable to nicotine addiction. That's why combating youth use of nicotine-containing products is a core priority and the guiding principle behind the FDA's Youth Tobacco Prevention Plan.

The FDA now believes that youth use of e-cigarettes is reaching epidemic proportions. This belief is based on not just the results of the agency's enforcement actions, but also recent sales trends, news coverage, increased concerns among kids, parents and educators, as well as preliminary data that will be finalized and released in the coming months.

To address these trends, and as another part of the agency's effort, the FDA is re-examining its compliance policy dates for the submission of premarket tobacco applications to the FDA for certain e-cigarettes. Toward these goals, and recognizing the critical role manufacturers must play in curtailing youth use of their products, the FDA today **issued letters (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm)** to the manufacturers of the five top-selling national brands. All of these brands – JUUL, Vuse, MarkTen XL, blu e-cigs, and Logic – made up a vast majority of the products illegally sold to minors as part of the blitz this summer. The agency is asking each company to submit to FDA within 60 days plans describing how they will address the widespread youth access and use of their products. If they fail to do so, or if the plans do not appropriately address this issue, the FDA will consider whether it would be appropriate to revisit the current policy that results in these products remaining on the market without a marketing order from the agency. This could mean requiring these brands to remove some or all of their flavored products that 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.

Today, the agency has also committed to taking even stronger measures to stem these troubling trends of youth use:

- Looking at, and potentially changing, the FDA's current compliance policy to determine whether it can better account for manufacturers that are not successfully preventing widespread youth use of their products. This means re-examining all aspects of the enforcement discretion that the FDA exercised when it extended the compliance dates for premarket authorization for certain newly deemed tobacco products. This could also mean revising the overall policy that applies to all manufacturers, which would go beyond the requests that were sent with respect to certain individual products today, and address the entire category of cartridge based e-cigarettes.
- Indefinitely stepping up FDA enforcement actions with a sustained campaign to monitor, penalize and prevent e-cigarette sales in convenience stores and other retail sites.
- Closely evaluating manufacturers' own internet storefronts and distribution practices and taking appropriate enforcement actions if we find violations of the restrictions on sales to minors. The FDA has at its disposal both civil and criminal remedies to address demonstrated violations of the law.
- Investigating whether manufacturers of certain e-cigarette products may be marketing new products that were not on the market as of Aug. 8, 2016, thus falling outside of the FDA's compliance policy, and have not gone through premarket review.

The FDA will also be developing an overall policy roadmap, designed to both address these trends and remain true to the goals of the **comprehensive plan on nicotine and tobacco regulation (/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm)** announced in July 2017, which aims to render cigarettes minimally or non-addictive and encourage the development of innovative tobacco products that could help currently addicted adult smokers switch to potentially less harmful forms of nicotine delivery. This also includes new steps that the FDA will announce in the coming weeks to promote wider access to nicotine replacement therapy marketed as new drugs as a way to help more adult smokers quit cigarettes.

As part of the FDA's comprehensive plan, the agency also continues to explore clear and meaningful measures to make tobacco products less toxic, appealing and addictive with an intense focus on youth. This could include measures on flavors/designs that appeal to youth, child-resistant packaging and product labeling to prevent accidental child exposure to liquid nicotine. The FDA 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. Additionally, the agency plans to explore additional restrictions on the sale and promotion of ENDS to further reduce youth exposure and access to these products.

The FDA has also **expanded "The Real Cost" public education campaign (/NewsEvents/Newsroom/FDAInBrief/ucm581312.htm)** with messages focused on preventing youth use of e-cigarettes. The FDA will launch a new, full-scale e-cigarette campaign targeted to youth next week.

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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Related Information

- **FDA's Youth Tobacco Prevention Plan (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm)**
- **Warning Letters and Civil Money Penalties Issued to Retailers for Selling JUUL and Other E-Cigarettes to Minors (/TobaccoProducts/NewsEvents/ucm605278.htm)**
- **CTP Letters to Industry (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm)**
- **Public Health Education Campaigns (/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/default.htm)**

- **Retailer Education Program, "This is Our Watch" (/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237741.htm)**

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