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Sections in green added by The Vape Bar for clarification. Sections in red are items affecting the products we are selling now.

# FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint

## *Companies that do not cease manufacture, distribution and sale of unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) within 30 days risk FDA enforcement actions*

**For Immediate Release:**

January 02, 2020

Amid the epidemic levels of youth use of e-cigarettes and the popularity of certain products among children, the U.S. Food and Drug Administration today issued a policy prioritizing enforcement against certain unauthorized flavored e-cigarette products that appeal to kids, including fruit and mint flavors. Under this policy, companies that do not cease manufacture, distribution and sale of unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) within 30 days risk FDA enforcement actions.

"The United States has never seen an epidemic of substance use arise as quickly as our current epidemic of youth use of e-cigarettes. HHS is taking a comprehensive, aggressive approach to enforcing the law passed by Congress, under which no e-cigarettes are currently on the market legally," said HHS Secretary Alex Azar. "By prioritizing enforcement against the products that are most widely used by children, our action today seeks to strike the right public health balance by maintaining e-cigarettes as a potential off-ramp for adults using combustible tobacco while ensuring these products don't provide an on-ramp to nicotine addiction for our youth. We will not stand idly by as this crisis among America's youth grows and evolves, and we will continue monitoring the situation and take further actions as necessary."

"As we work to combat the troubling epidemic of youth e-cigarette use, the enforcement policy we're issuing today confirms our commitment to dramatically limit children's access to certain flavored e-cigarette products we know are so appealing to them – so-called cartridge-based products that are both easy to use and easily concealable. We will continue to use our full regulatory authority thoughtfully and thoroughly to tackle this alarming crisis that's affecting children, families, schools and communities," said FDA Commissioner Stephen M. Hahn, M.D. "Coupled with the recently signed legislation increasing the minimum age of sale of tobacco to 21, we believe this policy balances the urgency with which we must address the public health threat of youth use of e-cigarette products with the potential role that e-cigarettes may play in helping adult smokers transition completely away from combustible tobacco to a potentially less risky form of nicotine delivery. While we expect that responsible members of industry will comply with premarket requirements, we're ready to take action against any unauthorized e-cigarette products as outlined in our priorities. We'll also closely monitor the use rates of all e-cigarette products and take additional steps to address youth use as necessary."

The final guidance outlining the agency's enforcement priorities for electronic nicotine delivery systems (ENDS), such as e-cigarettes and e-liquids, comes as the 2019 National Youth Tobacco Survey (NYTS) resultsExternal Link Disclaimer on e-cigarette use show that more than 5 million U.S. middle and high school students are current e-cigarette users (having used within the last 30 days) – with a majority reporting cartridge-based products as their usual brand.

The NYTS survey, which is conducted annually by the FDA in conjunction with the Centers for Disease Control and Prevention, also shows that of current youth e-cigarette users in 2019, approximately 1.6 million were using the product frequently (use on 20 days or more in a 30-day period), with nearly one million using e-cigarettes daily. Additional data from another federal surveyExternal Link Disclaimer further underscore that youth are particularly attracted to e-cigarette flavors such as fruit and mint, much more so than tobacco or menthol flavored e-cigarettes. These overall levels of youth e-cigarette use are particularly concerning because using e-cigarettes puts them at risk for nicotine addiction and other health consequences. In particular, evidence shows that youth exposure to nicotine can adversely affect the developing adolescent brain and that, compared with non-users, youth who use e-cigarettes are more likely to try conventional cigarettes in the future.

On Aug. 8, 2016, all e-cigarettes and other ENDS products became subject to the FDA's tobacco authorities, including the premarket authorization requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act). All e-cigarettes and other ENDS products on the market at that time needed to have authorization from the FDA to be legally marketed. However, as an exercise of its enforcement discretion, the agency had deferred enforcement of the premarket authorization requirements. To date, no ENDS products have been authorized by the FDA — meaning that all ENDS products currently on the market are considered illegally marketed and are subject to enforcement, at any time, in the FDA's discretion.

Beginning 30 days from the publication of the notice of availability of this guidance in the Federal Register**(30 days ended Feb 2nd , 2020),** the FDA intends to prioritize enforcement against these illegally marketed ENDS products by focusing on the following groups of products that do not have premarket authorization:

- Any flavored, **cartridge-based ENDS product(Prefilled disposable devices and JUUL, VUZE, and most other pre-fileld products fall under this category)** (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or likely to promote use of ENDS by minors.

Cartridge-based ENDS products are a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized when the product is used. For purposes of this policy, a cartridge or pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an ENDS product.

By not prioritizing enforcement against other flavored ENDS products in the same way as flavored cartridge-based ENDS products, the FDA has attempted to balance the public health concerns related to youth use of ENDS products with considerations regarding addicted adult cigarette smokers who may try to use ENDS products to transition away from combustible tobacco products. In addition to data showing that cartridge-based ENDS products are most commonly used among youth, important findings from the 2019 Monitoring the Future surveyExternal Link Disclaimer focusing on youth use of JUUL indicate that youth preference for menthol- and tobacco-flavored e-cigarettes is much lower than that for mint- and fruit-flavored e-cigarettes. Because of the relatively low numbers of youth using both menthol- and tobacco-flavored, cartridge-based ENDS products, these products are not among the current enforcement priorities. However, should the FDA become aware of an increase of youth using any other flavored products (both cartridge-based or otherwise), the agency will take additional steps to address youth use of those products if necessary.

For all other products (cartridge-based or otherwise), including menthol-, tobacco-, and non-flavored ENDS products, the FDA will also prioritize enforcement where the manufacturer fails to take adequate measures to prevent youth access. For example, the FDA will consider whether the manufacturer has implemented adequate programs to monitor retailer compliance with age-verification and sales restrictions or if it has established and enforced penalties against retailers that fail to comply with those programs. The agency also will consider whether the manufacturer uses adequate age-verification technology (or requires that retailers who sell its products use such technology) to prevent underage access to its website and to prevent underage sales through the internet. In addition, consideration will be given to whether the manufacturer limits (or requires retailers who sell its products to limit) the quantity of ENDS products that a customer may purchase within a given period of time.

The FDA also intends to prioritize enforcement with respect to any ENDS products that are targeted to youth or likely to promote use of ENDS by youth. Examples include: products marketed with labeling and/or advertising that resemble kid-friendly foods and drinks such as juice boxes or kid-friendly cereal; products marketed directly to minors by promoting ease of concealing the product or disguising it as another product; and products marketed with characters designed to appeal to youth.

Importantly, the FDA's enforcement priorities are not a "ban" on flavored or cartridge-based ENDS. The FDA has already accepted and begun review of several premarket applications for flavored ENDS products through the pathway that Congress established in the Tobacco Control Act. Manufacturers that wish to market any ENDS product – including flavored e-cigarettes or e-liquids – are required by law to submit an application to the FDA that demonstrates that the product meets the applicable standard in the law, such as whether the product is appropriate for the protection of the public health. If a company can demonstrate to the FDA that a specific product meets the applicable standard set forth by Congress, including considering how the marketing of the product may affect youth initiation and use, then the FDA could authorize that product for sale.

The guidance also states that, after May 12, 2020, the FDA intends to also prioritize enforcement against any ENDS products that continue to be sold and for which the manufacturers have not submitted a premarket application. For ENDS products other than those in the three groups described above, if premarket applications are submitted by that date, the FDA intends to continue to exercise enforcement discretion for up to one year pending FDA review of the applications, unless there is a negative action by the FDA on such application or the product is authorized to be marketed by the FDA.

The FDA has demonstrated a deep commitment to taking steps to prevent youth from using and becoming addicted to any tobacco product, including e-cigarettes. This enforcement policy is an important step in the agency's ongoing work to ensure these products are not marketed to, sold to, or used by kids, as outlined in the agency's Youth Tobacco Prevention Plan, including investing in public education campaigns to educate youth about the dangers of e-cigarette use, provide resources to educators, parents and community leaders to prevent youth use, as well as further explore how to help those kids who are already addicted to e-cigarettes quit.

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.