CENTER FOR TOBACCO PRODUCTS

# FDA'S ENFORCEMENT PRIORITIES FOR E-CIGARETTES AND OTHER ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

On January 2, 2020, FDA announced the agency's enforcement priorities for ENDS and other deemed tobacco products on the market without premarket authorization.

## Why did FDA take this action?

This action was prompted by alarming results from the National Youth Tobacco Survey (NYTS) that show over 5 million U.S. middle and high school students were current (having used in the last 30 days) e-cigarette users in 2019, with about 1.6 million of these students using these products on 20 or more of the past 30 days, and nearly one million reporting daily use. This is particularly concerning, as using e-cigarettes puts kids at risk for nicotine addiction, and nicotine exposure during adolescence could harm brain development.

## What types of ENDS products will FDA prioritize enforcement against?

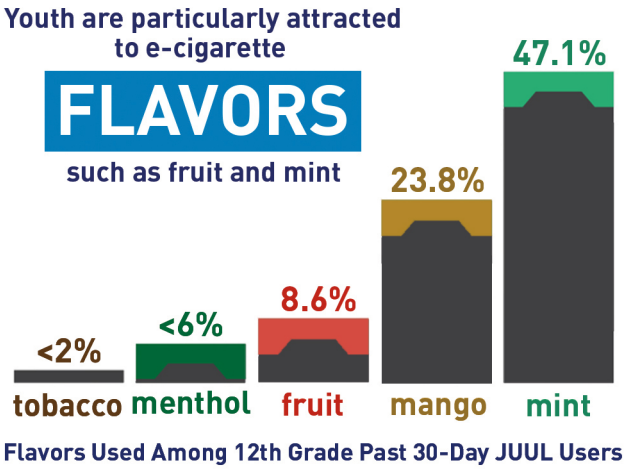
Beginning February 6, 2020, FDA will prioritize enforcement against illegally marketed ENDS products by focusing on the following groups that do not have premarket authorization:

- **Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product)**
  - Cartridge-based ENDS products consist of, includes, or involves a cartridge or pod containing 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.
- **All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access**
  - For example, FDA will consider whether manufacturers have implemented adequate programs and retailer penalties to ensure retailers comply with age and sales restrictions, as well as whether the manufacturer uses—or requires retailers to use—adequate age-verification technology to prevent underage access to its website and/or underage sales through the internet. Consideration will also be given to whether manufacturers limit and/or require retailers that sell its products to limit the quantity of ENDS products that a customer may purchase within a given period of time.
- **Any ENDS product that is targeted to minors or likely to promote use of ENDS by minors**
  - 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.

After the May 12, 2020, premarket application deadline for all deemed new tobacco products such as ENDS—regardless of whether they are pod- or cartridge-based—FDA also intends to prioritize enforcement against any ENDS that continue to be sold and for which the manufacturer has not submitted a premarket application. For ENDS products other than those in the three groups described above, if applications are submitted by May 12, 2020, 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 FDA on the application or the product is authorized to be marketed by the FDA.

## Why is FDA prioritizing enforcement against certain flavored cartridge-based ENDS?

The NYTS data also showed that among current youth e-cigarette users, the majority of youth reported cartridge-based products—such as JUUL—as their usual brand. Further, additional data from the 2019 Monitoring the Future survey found that youth are particularly attracted to e-cigarette flavors such as fruit and mint—much more so than tobacco or menthol flavored e-cigarettes.



Flavors Used Among 12th Grade Past 30-Day JUUL Users

By prioritizing enforcement against the products that are most widely used by youth, the agency aims to strike the right public health balance by maintaining e-cigarettes as a potential off-ramp for addicted adult smokers to transition away from combustible tobacco while ensuring these products do not provide an on-ramp to nicotine addiction for youth. FDA will closely monitor the use rates of all types of e-cigarette products among youth— including tobacco and menthol flavored e-cigarettes— and will take additional steps to address youth use of those products if necessary.

Since August 2016, all ENDS products have been subject to the FDA's tobacco authorities, including premarket authorization requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act). All 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, FDA deferred enforcement of the premarket authorization requirements for any products on the market at that time. To date, no ENDS products have been authorized by FDA—meaning all ENDS products currently on the market are considered illegally marketed and are subject to enforcement, at any time, at FDA's discretion.

## What are ENDS retailers and manufacturers expected to do?

FDA expects industry to comply with premarket requirements, but is ready to take action against any unauthorized e-cigarette products as outlined in the agency's priorities.

Manufacturers can apply for marketing authorization for any tobacco product, including flavored e-cigarettes described in this guidance at any time. Retailers bear responsibility to ensure the products they sell are lawfully on the market. A retailer that continues to sell these products may be subject to enforcement actions by the FDA. Retailers and distributors are encouraged to communicate with their suppliers to discuss options for ENDS described in this guidance that they have in their inventory.

## CONTACT CTP

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