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In Yet Another Delay that Leaves Kids at Risk, FDA Tells Court It Won't Finish Reviewing E-Cigarette Marketing Applications Until June 2023

Statement of American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative

WASHINGTON, D.C. – In yet another delay that leaves America's kids at risk, [the FDA has told a federal court](#) that it won't finish its review of marketing applications for the most popular e-cigarette products until June 2023 – nearly two years after the September 9, 2021, court-ordered deadline to do so. The FDA's continued delays are unacceptable and harmful to our nation's kids and public health. Every day the FDA fails to act, it allows tobacco companies to continue targeting and addicting our kids with flavored, nicotine-loaded e-cigarettes. The FDA has the power and responsibility to end this public health crisis, but once again it is failing to do so.

To protect our kids and truly end the youth e-cigarette epidemic, the FDA must swiftly complete its review of e-cigarette marketing applications and deny applications for all flavored e-cigarettes, including menthol-flavored products, given the clear evidence that flavored products have fueled youth use. If the FDA cannot complete these reviews by the end of June 2022, it should remove all unauthorized products from the market until it does complete its reviews.

In a court-ordered status report filed last week, the FDA stated that it will not finish reviewing marketing applications for the leading e-cigarette brands until June 30, 2023, and it will finish reviewing only 56% of these applications by the end of 2022. That means that some of the most popular youth brands – including flavored products that have driven the youth e-cigarette epidemic – could remain on the market for yet another year without FDA authorization. These delays fly in the face of the FDA's own public statements that it would prioritize review of applications for products with the largest market share, and they undermine the intent of the court's order to prevent e-cigarette products – especially those appealing to kids – from remaining on the market without FDA review. As [U.S. District Court Judge Paul W. Grimm stated on April 15](#) when he ordered the FDA to file quarterly status reports, “the popular products used by young people remain on the market unreviewed, which is inconsistent with the purpose of the Court's judgment.”

This is the latest in a long string of regulatory delays by the FDA that allowed e-cigarettes – including thousands of flavored products that appeal to kids – to stay on the market for years without FDA review and authorization and set the stage for the youth e-cigarette epidemic. In response to these delays and as a result of a successful lawsuit filed by our organizations, Judge Grimm set a deadline of September 9, 2020, for e-cigarette manufacturers to submit marketing applications to the FDA and allowed products with timely applications to stay on the market for up to one year while the FDA reviewed the applications – a period that ended on September 9, 2021. All unauthorized e-cigarette products are now subject to FDA enforcement action to take them off the market.

Eight months after this court-ordered deadline, the FDA has yet to finish its review of e-cigarette marketing applications. While it is a positive step that the FDA has denied marketing applications for over one million flavored e-cigarette products, the FDA has yet to issue decisions about many of the e-

cigarette brands that have the largest market share or are most commonly used by youth. In addition, the FDA is still considering whether to authorize any menthol-flavored e-cigarettes despite the clear evidence that menthol products are widely used by kids.

To protect our kids, the FDA must deny marketing applications for all flavored e-cigarettes – including menthol-flavored products – without further delay. Youth e-cigarette use remains a serious public health problem in the United States, with the [2021 National Youth Tobacco Survey](#) (2021 NYTS) showing that over 2 million middle and high school students use e-cigarettes. Flavored products have driven youth use, with 85% of youth e-cigarette users reporting using flavored products. The evidence is also clear that menthol is a flavor that appeals to and is widely used by kids. According to the 2021 NYTS, nearly 30% of youth who use flavored e-cigarettes reported using menthol-flavored products, including 46% of youth who use flavored cartridge-based products. Until the FDA completes its review of e-cigarette marketing applications and clears the market of all flavored e-cigarettes, our kids will remain at risk.