The US Food and Drug Administration (FDA) is delaying a long-awaited ruling about whether the largest manufacturers of e-cigarettes will be permitted to remain on the market, while claiming “significant progress” in rejecting marketing applications for e-cigarettes and a vast array of flavorings from small and medium-sized companies.

In a statement announcing the action, acting FDA commissioner Janet Woodcock, MD, highlighted the agency’s rejection of applications from more than 500 companies affecting more than 6 million e-cigarettes, e-liquids, and related products, many of which already had been available to the public. But she noted that the agency would miss the September 9 court-ordered deadline in deciding whether to ban products from the largest players in the vaping market, including leaders Juul, Vuse, and NJOY—a delay that was harshly criticized by antivaping groups.

In September 2020, under a federal court order, the FDA required all US manufacturers of e-cigarettes and related products to remove these products from the market or apply to have the agency review them. That court order also set a September 9, 2021, deadline for the agency to review those applications and applications for similar products that had not yet become available.

The FDA said that the court order presented the agency with “the unprecedented task” of reviewing applications for more than 6.5 million new tobacco products—mostly “electronic nicotine delivery systems (ENDS) products, such as e-cigarettes and e-liquids, which had never been through the FDA review process.”

At the heart of the agency’s decision-making for these products is weighing data on the potential benefits to adult cigarette smokers who switch to e-cigarettes against “the public health threat posed by the well-documented, alarming levels of youth use of such products.”

Critics of e-cigarettes view them as nicotine-delivery systems that entice young people to become nicotine-dependent and that increase the likelihood they will take up smoking. According to a 2018 report from the National Academies of Sciences, Engineering, and Medicine on the public health consequence of e-cigarettes, there is substantial evidence that e-cigarette use “results in symptoms of dependence on e-cigarettes” and “increases risk of ever using combustible tobacco cigarettes among youth and young adults.”

According to the Centers for Disease Control and Prevention (CDC), e-cigarettes are the most commonly used tobacco product among young people, used by 27.5% of high school students (4.1 million) and 10.5% of middle school students (1.2 million) in 2019—erasing past progress in reducing use of tobacco products by young people. In 2020, about 19.6% of high school students and 4.7% of middle school students used e-cigarettes during the COVID-19 pandemic. The reasons behind the decline are unknown, but closure of vape and smoke shops and reduced socialization and access to e-cigarettes from friends might have been factors.

Proponents of e-cigarettes say the products are useful for helping smokers to reduce exposure to tobacco-associated toxins and to quit the habit. According to the CDC, e-cigarettes “have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products,” but also notes that e-cigarettes are not currently approved by the FDA as a smoking-cessation aid and that “the few studies on the issue are mixed.”

On August 26, the FDA issued its first marketing denial orders (MDOs) for ENDS products. The products, which feature flavors such as Apple Crumble, Dr Cola, and Cinnamon Toast Cereal, are...
extremely popular among youth, with over 80% of e-cigarette users ages 12 through 17 using them," the agency noted.

Those initial MDOs and subsequent ones bring the total number of MDOs issued by the agency to 132, affecting more than 946,000 flavored ENDS products. The companies “failed to provide sufficient evidence that those products will benefit adult smokers to an extent sufficient to justify their documented risks to youth,” the FDA said.

In addition, the FDA said it refused to file one company’s application for approximately 4.5 million products because of the company’s application was incomplete.

However, most of the companies that have been issued MDOs have been small and medium-sized players, and critics of e-cigarettes expressed disappointment in the agency’s delay in acting on applications from the vaping industry’s largest companies. According to the Wall Street Journal, sales in stores tracked by the marketing research firm Nielsen indicate that Juul leads the US e-cigarette market, followed by Vuse (made by Reynolds American Tobacco), and NJoy.

“Despite publicly committing to prioritize action against the largest companies that sell e-cigarettes, the result of the agency’s inaction means that the most widely used flavored e-cigarette products—such as JUUL—will remain on the market, where they will continue to addict children and teens,” Lee Savio Beers, MD, President of the American Academy of Pediatrics, said in a statement. “Flavored JUUL products, and other products like them, are responsible for fueling a youth nicotine epidemic.”

The FDA “will leave our kids at risk unless it acts quickly on the remaining applications, including for products like Juul that have driven the youth e-cigarette epidemic, and eliminates all flavored e-cigarettes, including menthol-flavored products that are widely used by kids,” Matthew L. Myers, president of the Campaign for Tobacco-Free Kids, said in a statement.

“While we were encouraged by FDA’s previous announcement that it would require tens of thousands of flavored e-cigarettes to be removed from the marketplace, the delay of decisions on products with such a high percentage of market share among kids is very troubling,” American Lung Association president and CEO Harold Wimmer said in a statement. Ending the sale of all flavored e-cigarettes products, including menthol, “is the clear path to end the youth vaping epidemic,” he said.

Although the FDA said it is continuing to review the products, it did not give a date by which it expected to complete its review.

“The FDA is committed to completing the review of the remaining products as quickly as possible to provide regulatory certainty and will continue to keep the public informed of our progress,” the agency said.