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FDA Needs More Time to Decide Fate of Juul

Regulator says it has more work to do on top-selling e-cigarette brands, which are in final review stages



Juul and other e-cigarette makers had to submit their products for FDA review to keep them on the U.S. market.

PHOTO: JUSTIN LANE/EPA/SHUTTERSTOCK

By [Jennifer Maloney](#)

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The Food and Drug Administration said it needed to take more time before deciding whether e-cigarettes made by Juul Labs Inc. and other top manufacturers can remain on the U.S. market.

The FDA faced a Thursday deadline to respond to applications from Juul and other e-cigarette makers who had to submit their products for review to keep them on the U.S. market. The Wall Street Journal earlier reported that the FDA would take more time to reach a decision on Juul, the market leader.

The agency Thursday said it had acted on 93% of the applications submitted by last year's filing deadline. "However, there's more work to be done to complete our remaining

reviews and ensure that we continue taking appropriate action to protect our nation's youth from the dangers of all tobacco products," the FDA said in a statement Thursday.

Among the FDA's decisions so far, the agency ordered off the market more than 946,000 flavored products—including vaping liquids with flavors such as apple crumble, cola and cinnamon toast cereal—saying the manufacturers hadn't provided sufficient evidence that their products benefited adult smokers to an extent that outweighed their potential appeal to young people.

The agency didn't say when its review of products submitted by Juul and other large manufacturers would be complete. "We continue to work expeditiously on the remaining applications that were submitted by the court's Sept. 9, 2020, deadline, many of which are in the final stages of review," the FDA said Thursday.

More than 500 companies filed applications for some 6.5 million products. The FDA's mandate is to authorize vaping products only if their manufacturers can demonstrate that they are in the interest of public health. The FDA must weigh, among other things, the potential good of adult cigarette smokers switching to a less-harmful option against the potential harm of young people getting hooked on nicotine.

"Lots of very good people who I respect deeply and who helped thousands of smokers quit, got told by our government that their products were illegal," Amanda Wheeler, president of the American Vapor Manufacturers Association, wrote on Twitter on Wednesday. "To all of you, I am so very sorry. To your customers, I am even more sorry."

FDA officials previously had said they wouldn't be able to render decisions by Sept. 9 of this year on every product submitted, but had pledged to fast-track those with the largest market share. The biggest U.S. e-cigarette manufacturer is Juul, according to sales in stores tracked by Nielsen. Juul is followed by Reynolds American Inc., which makes Vuse e-cigarettes. NJOY Holdings Inc. holds the No. 3 spot.

"We respect the central role of the FDA and the required thorough science- and evidence-based review of our applications," a Juul spokesman said. "We remain committed to transitioning adult smokers away from combustible cigarettes while combating underage use."

The FDA's sweeping review could reshape the e-cigarette market. Agency officials have told manufacturers to expect stricter controls on the way products are marketed and sold,

once they are authorized to remain on the market. The FDA also could allow some sweet and fruity e-cigarette cartridges back on the market after temporarily restricting such products last year.

The agency is weighing whether to allow Reynolds, NJOY and others to resume selling fruit-flavored cartridges. Juul submitted only tobacco- and menthol-flavored refill pods for FDA review.

Youth vaping fell significantly in the U.S. last year after federal restrictions raised the legal purchase age for tobacco products to 21 and took fruity-flavored e-cigarette cartridges off the market.

Some lawmakers and public-health groups have called on the FDA to permanently ban all sweet and fruity e-cigarettes. Some also have asked the agency to consider a cap on nicotine concentration. Agency officials have said they would review each product individually rather than issuing blanket rules.

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