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EXCLUSIVE POLICY

U.S. Regulators Plan Major Move to Speed Authorizations of Vapes, Tobacco Pouches

Move comes despite lawmakers voicing concern about recent flavor approvals

By Liz Essley Whyte and Laura Cooper
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VALERIE PLESCH/BLOOMBERG NEWS

The Trump administration is planning to smooth the way for more tobacco products such as flavored vapes to legally enter the market by changing the rules to speed up the authorization process, people familiar with the matter said.

The Food and Drug Administration is expected to announce in coming days that it will revisit a 2021 rule that outlined requirements for new tobacco applications, the people said, though the plans could still change.

The agency is looking to add more flexibility for companies to get more products authorized, the people said. One potential way to do that is by simplifying requirements for scientific studies and speeding review times, one of the people said.

These possible changes are most important for newer tobacco products, such as vapes and the increasingly popular nicotine pouches, which aren't eligible for a simplified path to market that exists for older products like cigarettes.

Tobacco companies have long complained that the FDA review process for their new products regularly takes much longer than the around six months mandated by Congress—sometimes even taking years.

The administration hopes to see products it considers less harmful for smokers, such as flavored vapes, enter the market more easily, people familiar with the matter said.

"The Trump administration is committed to keeping nicotine out of the hands of kids, getting counterfeit vaping products off the streets, and providing safer alternatives for adults who want to quit smoking cigarettes," an HHS spokeswoman said.

Tobacco companies and some policy experts have argued a more vibrant legal market, with more flavors available, would help combat the flood of illegal Chinese vapes into the U.S. that they feel are blatantly marketed to teens. Public-health groups argue those flavors appeal to children and can induce people into trying tobacco products for the first time.

In the 2021 rule, the government outlined the standards for what scientific evidence companies needed to provide to have their new tobacco products on the market in the U.S.

Frustrated with the slow pace of approvals, a group of manufacturers and retailers—including Altria-owned vape business NJOY—earlier this month sued the FDA over the rule, saying the agency's "regulatory roadblocks" led to an "insurmountable logjam" of applications that has kept new products off the market.

The move to speed new products is a contrast from Trump's first term, when the FDA banned fruit-flavored vapes in an effort to curb teen use.

The second Trump administration has taken a number of steps welcomed by tobacco companies. This year, the agency authorized a number of new nicotine pouches and allowed some to be marketed as less harmful for smokers than traditional cigarettes.

In May, the FDA issued a guidance that allowed companies to sell most tobacco products legally after they have filed applications but before they have received a complete scientific review. Public-health groups including the Campaign for Tobacco-Free Kids have sued the administration over that guidance, arguing that the agency violated federal law by not giving the public a chance to comment on the change.

Mitch Zeller, the former director of FDA's tobacco center who helped write the 2021 rule, said he was skeptical of the agency's recent moves on flavored tobacco products.

"The solution to the massive problem of illicit flavored vapes today is the right kind of enforcement action, not new policy that lowers the evidentiary bar to get more flavored products authorized," he said.

Lawmakers on both sides of the aisle have objected to the FDA's recent approvals of more flavored tobacco products, including blueberry and mango. "That only makes vaping more attractive to young people," said Sen. Susan Collins (R., Maine) in a hearing earlier this month.

Flavored vapes are already likely to be a flashpoint in Thursday's confirmation hearing for Dr. Heidi Overton, President Trump's nominee to lead the Food and Drug Administration. The previous FDA commissioner, Dr. Marty Makary, clashed with the White House over flavored tobacco products before resigning under pressure.

The 2021 rule for applications, proposed in the first Trump administration, was finalized in the Biden administration.

Liz Essley Whyte is a health policy reporter in The Wall Street Journal's D.C. bureau, with a special focus on the federal health agencies. Before joining the Journal in 2022, she was an investigative reporter at the Center for Public Integrity, a nonprofit newsroom, where for several years she covered...

Laura Cooper is a reporter covering beverage and tobacco companies for The Wall Street Journal in New York. Her coverage includes beverage makers, including Coca-Cola and PepsiCo, as well as tobacco companies, beer and spirits makers. Before joining the corporate team, she covered deals and private...

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