

## E-cigs using synthetic nicotine come under FDA oversight

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In this Jan. 31, 2020 photo a woman holds a Puff Bar flavored disposable vape device in New York. The Food and Drug Administration says it will soon begin cracking down on vaping companies that have used a now-closed loophole to escape federal oversight, including the company behind a line of fruit-flavored e-cigarettes that have become the top choice among teenagers. Under a new law taking effect Thursday, April 14, 2022, the FDA can regulate e-cigarettes and similar products that use synthetic nicotine. Credit: AP Photo/Marshall Ritzel



U.S. regulators will soon begin cracking down on vaping companies using a now-closed loophole, including a line of fruit-flavored ecigarettes that have become teenagers' top choice.

Under a law taking effect Thursday, the Food and Drug Administration can regulate e-cigarettes and similar products that use synthetic nicotine.

The action targets Puff Bar and several other vaping companies that recently switched their formulas to laboratory-made nicotine to skirt FDA oversight.

The change will allow the FDA to "hold e-cigarette companies using synthetic nicotine to the same public health standards we've implemented for other tobacco products," FDA Commissioner Robert Califf said in a <u>tweet</u> Wednesday. Companies must now register with the FDA and submit their products for review within 30 days.

Puff Bar did not immediately respond to a request for comment Thursday.

The FDA's action does not automatically ban Puff Bar and similar products. Instead it brings them under the same regulatory scheme as older e-cigarettes that derive their nicotine from tobacco.

"The synthetic nicotine products do not necessarily just disappear on their own," Robin Koval, chief executive of the Truth Initiative, an advocacy group that runs anti-tobacco ads. "The FDA will have to decide how they want to enforce the law and hopefully they will."

The FDA has been reviewing applications for a vast array of vaping devices, formulas and flavors—rejecting more than 1 million, usually because of their potential appeal to youngsters. Anti-tobacco advocates hope the agency will quickly do the same for any applications submitted



by Puff Bar and other manufacturers.

Nicotine, the chemical the makes smoking and vaping addictive, occurs naturally in tobacco plants.

The 2009 law that first gave the FDA oversight of cigarettes and related products only referred to tobacco-based nicotine. That left an opening for artificial nicotine, which is being used in e-cigarette liquids, nicotine pouches and other products.

Last month, Congress passed language clarifying that the FDA can regulate any form of nicotine, regardless of the source.

After appearing in 2019, Puff Bar has grown to become the most popular e-cigarette among teenagers, by far, sold in flavors like blueberry, strawberry banana and mango. Under FDA pressure, the company said it was halting sales in 2020, pulling its disposable vaping devices out of convenience stores, gas stations and vape shops.

Last February, the company announced a "fresh launch" of its colorful devices using synthetic nicotine. In marketing language, the company said its products "do not contain tobacco or anything derived from tobacco." That put Puff Bar in a legal gray area, because federal, state and local restrictions nearly always apply to tobacco-based products, not nicotine itself.

Stanford researchers last year found synthetic nicotine products for sale via online platforms that prohibit tobacco sales, such as Amazon, eBay and Target. Under the new law, synthetic nicotine will be subject to the same federal age limit and sales restrictions as other tobacco products.

Using synthetic nicotine is not a new idea. Tobacco companies experimented with chemically derived nicotine as early as the 1960s, but



deemed it too expensive for mass production. Manufacturing advances in recent years finally made it a viable alternative to tobacco-derived nicotine.

A large government survey last year showed Puff Bar had leapfrogged over better-known brands to become the top choice among high schoolers who vape. Juul—which is widely blamed for initially sparking the teen vaping trend—was the fourth most popular brand.

In 2020, the FDA restricted flavors in cartridge-based e-cigarettes like Juul to just menthol and tobacco, which are generally preferred by adults. But the flavor ban didn't apply to disposable e-cigarettes like Puff Bar and other types of vaping devices.

Anti-tobacco groups worry that the FDA seems to consistently be one or two steps behind whichever products are making inroads among kids.

"The lesson we can all take away from this is that when the FDA's actions are incomplete and happen after the fact—which has often been the case with e-cigarettes—you will always be playing whack-a-mole and catch-up," said Koval.

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