

FDA Gives Certain Electronic Cigarette Manufacturers 60 Days to Address Youth Vaping

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On September 12, 2018, Food & Drug Administration Commissioner Scott Gottlieb, M.D., addressed the epidemic of youth e-cigarette use, indicating that the FDA will halt sales of certain flavored e-cigarettes if the major manufacturers cannot show the agency that they are doing enough to keep them out of the hands of children and teens. More than two million middle school, high school, and college students use the e-cigarette device to heat liquid-based nicotine into an inhalable vapor, prompting the FDA to declare youth vaping an “epidemic.”

The FDA finds there is an important interest in regulating these new products when it comes to children and the effects that nicotine has on a developing brain, and is now reconsidering its “overall approach” to e-cigarettes. As part of stepping up their efforts to prevent youth use of e-cigarettes, the FDA sent warning letters to e-cigarette manufactures Juul, Vuse, MarkTen XL, Blu, and Logic, giving them sixty days to submit “robust” plans to address e-cigarette use by minors. These five brands make up more than 97% of the U.S. market for e-cigarettes; failure by these companies to convince the agency of how they intend to curtail the “widespread use of their products by minors” may result in FDA enforcement action for these products that are already on the market. Further, the FDA will also be investigating marketing and sales practices, how the different products are being used by kids, and other policies that would allow adjustment for different product use between adults and children. In short, the FDA is taking actions to support its statement that it is refusing to “tolerate a whole generation of young people becoming addicted to nicotine....”

A copy of the recent statement can be found here:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>.