FDA Takes First Enforcement Moves Against Tobacco-Free Vape Makers

The tobacco-free vape industry is facing its first enforcement actions by the U.S. Food and Drug Administration (FDA) as the agency cracks down on the illegal sale of synthetic nicotine products to underage Americans. This move marks a significant step towards regulating a sector that has operated without federal oversight for a long time.

FDA Warns Over 100 Retailers

Late on Wednesday, the FDA announced that it had issued 107 warning letters to convenience stores and tobacco shops across the country. These retailers were found to be selling non-tobacco nicotine products, including certain e-cigarettes, to customers under the age of 21. Additionally, two synthetic nicotine manufacturers, AZ Swagg Sauce LLC and Electric Smoke Vapor House, received warning letters for failing to submit pre-market applications for a combined total of 10,000 products by the May 14 deadline.

Crackdown on Non-Tobacco Nicotine Products

The FDA's actions reflect the approach it plans to take regarding products from companies like Puff Bar, which have gained popularity among young people. According to the agency, any new non-tobacco nicotine product that does not receive premarket authorization will be deemed illegal and subject to enforcement action. This move is aimed at curbing the accessibility and appeal of these products to underage individuals.

Mixed Reactions from Industry and Advocates

While the FDA's enforcement actions have been praised by some anti-tobacco groups, the vaping industry and consumer advocates have expressed concerns. They argue that the FDA did not provide companies with sufficient time to complete the application process and that the agency is succumbing to political pressure to crack down on the tobacco industry. On the other hand, anti-tobacco groups believe that the FDA's actions fall short in swiftly removing the most popular products among young people from the market.

Regulatory Authority Granted

The authority to regulate synthetic nicotine was granted to the FDA through a government spending package for fiscal year 2022. This closed a loophole that had allowed certain companies to avoid federal oversight. According to the law, companies had until May 14 to submit their applications, and all existing products that did not receive authorization must be removed from the market by the specified deadline.

Brian King, the newly appointed director of the FDA's Center for Tobacco Products, emphasized the agency's commitment to actively implementing this new law. The warning letters sent to retailers and vape ecig manufacturers are just the initial steps in the FDA's compliance and enforcement actions.

Application Submissions and Review Process

The FDA stated that approximately 200 manufacturers submitted around one million applications for synthetic nicotine products by the May 14 deadline. The agency is currently preparing to issue "refuse-to-accept" letters for applications that do not meet the necessary requirements for FDA review.

While the FDA did not provide a specific timeline for the review process of non-tobacco derived nicotine applications, Brian King assured that the agency is diligently working on processing them. Marketing decisions will be based on the best available science, and compliance and enforcement actions will be pursued as warranted.

Rise in Synthetic Nicotine Use Among Youth

In recent years, the use of synthetic nicotine products among young people has increased. This is partially attributed to the availability of fruit and candy flavors that were previously banned by the FDA for tobacco-based e-cigarettes. According to an annual survey conducted by the Centers for Disease Control and Prevention, approximately 39% of middle and high school tobacco users reported using e-cigarettes in 2021, with Puff Bar being the most commonly reported brand at nearly 27%.

Industry and Consumer Backlash

Members of the vaping industry view the FDA's recent actions as part of an unfair and targeted regulatory approach. They argue that e-cigarettes offer less harmful alternatives for adult smokers who are trying to quit traditional combustible cigarettes. In its e-cigarette reviews, the FDA considers whether the benefits of a product for adult smokers outweigh the risk of new smoking initiation, particularly among youth.

Alex Clark, CEO of the Consumer Advocates for Smoke-free Alternatives Association, criticized the seemingly impossible application deadline for synthetic nicotine products. He believes that removing these products will have minimal impact on reducing demand among curious youth and will make it more challenging for people to quit smoking.

Advocacy Groups Call for Stronger Measures

Anti-tobacco advocacy groups have voiced their concerns about the FDA's compliance with the deadlines set by Congress, highlighting that a significant number of synthetic nicotine products remain on the market despite their illegality. Matthew Myers, president of the Campaign for Tobacco-Free Kids, called for immediate action to remove these products while the FDA reviews the applications. Erika Sward, national assistant vice president of advocacy for the American Lung Association, expressed particular concern about the lack of action taken against Puff Bar.

Congressional Pressure

Lawmakers have consistently urged the FDA to act swiftly in regulating synthetic nicotine products. Senate Majority Whip Dick Durbin (D-Ill.) and Sen. Susan Collins (R-Maine) recently sent a letter to the FDA instructing the agency to clear the market of all unauthorized e-cigarettes that use synthetic nicotine by July 13. They emphasized that Congress had taken bipartisan action to provide the FDA with the necessary tools for proper regulation and expressed disappointment in the agency's potential failure to protect the nation's children from the dangers of nicotine addiction.

FAQs

1. What actions did the FDA take against retailers selling synthetic nicotine products to underage individuals? The FDA issued warning letters to over 100 retailers, including convenience stores and tobacco shops, for selling non-tobacco nicotine products to customers under 21. The agency aims to enforce regulations in an area that has long lacked federal oversight.

2. Which synthetic nicotine manufacturers received warning letters from the FDA? AZ Swagg Sauce LLC and Electric Smoke Vapor House were the two manufacturers that received warning letters from the FDA for failing to submit pre-market applications for a combined total of 10,000 products by the May 14 deadline.

3. What is the FDA's stance on non-tobacco nicotine products that lack premarket authorization? Any new non-tobacco nicotine product that has not received premarket authorization from the FDA will be considered illegal and subject to enforcement action, according to the agency's statement.

4. What concerns have been raised by the vaping industry and consumer advocates? The vaping industry and consumer advocates argue that the FDA did not allow sufficient time for companies to complete the application process and that the agency is bowing to political pressure to crack down on the tobacco industry.

5. How has the rise in synthetic nicotine use among youth been attributed? The availability of fruit and candy flavors in synthetic nicotine products, which were previously banned in tobacco-based e-cigarettes, has contributed to the increased use among young people. According to a survey, Puff Bar is the most commonly reported brand among middle and high school tobacco users.