

EXHIBIT 72

FDA NEWS RELEASE

FDA Issues Decisions on Additional E-Cigarette Products

Agency Permits Marketing of Certain Tobacco-Flavored Products, Denies Other Products; Additional Decisions on Popular Products Expected Soon

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Today, the U.S. Food and Drug Administration took additional actions as part of the agency’s work to ensure any electronic nicotine delivery system (ENDS) products available for sale have demonstrated that marketing of the products is appropriate for the protection of the public health.

What You Need to Know

- The FDA authorized several tobacco-flavored ENDS products (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders) from Logic Technology Development LLC (Logic) under the Logic Vapeleaf, Logic Power and Logic Pro brands, including devices. These products were authorized after the agency’s review of the product applications concluded, among other things, that the likely benefit for adult smokers who significantly reduce their cigarette use (or who switch completely and experience cigarette use cessation) outweighs the risk to youth, provided that the company follows postmarketing requirements to reduce youth access and youth exposure to their marketing. While today’s action permits these specific products to be sold in the U.S., it does not mean these products are safe nor are they “FDA approved.” All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn’t start.
- The agency also issued marketing denial orders to Logic for multiple other ENDS products. Any of those products currently on the market must be removed or FDA may take enforcement action. Retailers should contact Logic with any questions about products in their inventory. Applications for Logic’s additional products, including menthol, remain under FDA review.
- The FDA has taken action on approximately 99% of the nearly 6.7 million ENDS products submitted for premarket authorization, including issuing marketing denial orders for more than 1 million ENDS products.
- The agency is close to making additional (/tobacco-products/market-and-distribute



popular ENDS products that account for a large part of the market. The continued marketing of these products has the potential to have a substantial public health impact—either positively or negatively—as they hold an overall large market share and are used by a lot of people.

“As a cardiologist, I’ve personally seen the devastating health effects of tobacco use, so I’m highly motivated for the FDA to help reduce death and disability caused by these products,” said FDA Commissioner Robert M. Califf, M.D. **“We know that there is a demand among adult smokers to use e-cigarette products to try to switch from more harmful combusted cigarettes, but millions of youth are using these products and getting addicted to nicotine. The balance of these issues was considered by the agency’s career scientists when evaluating the potential marketing of e-cigarette products. They have made great progress and I know they will use the best available evidence with the most robust methods to ensure that products that continue to be marketed are appropriate for the protection of the public health.”**

Under the Premarket Tobacco Product Application (PMTA) pathway (</tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>), manufacturers or importers must demonstrate to the agency, among other things, that marketing of a new tobacco product would be appropriate for the protection of the public health. That statutory standard requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products. The FDA must also consider the likely impact of the products on people’s behavior—specifically, the likelihood that existing users will stop using such products and the likelihood that those who do not use tobacco products will start using such products. This is especially important for youth. Before a product is authorized under the PMTA pathway, the agency reviews a tobacco product’s components, ingredients, additives, constituents and health risks, as well as how the product is manufactured, packaged and labeled.

“Ensuring new tobacco products undergo premarket evaluation by the FDA is a critical part of our work to reduce tobacco-related disease and death,” said Mitch Zeller, J.D., director of the FDA’s Center for Tobacco Products. **“For the authorized products, the manufacturer demonstrated that possible benefits to adult smokers outweigh the risk of youth possibly initiating. We are making progress in our review of flavored ENDS, and we will continue to deny marketing of products where the applicant hasn’t provided enough evidence to show that the potential benefit to adult smokers outweighs the considerable risk to youth. We are committed to continuing to take the appropriate actions to protect our nation’s youth from the dangers of all tobacco products, including e-cigarettes, which** ^

Logic Authorizations

The FDA's review of the applications for the products authorized today determined that the marketing of the tobacco-flavored products and associated components is appropriate for the protection of the public health. The FDA authorized these tobacco-flavored ENDS products because, among several key considerations, the data submitted by the company and the available evidence show that marketing these products may help addicted adult smokers transition away from combusted cigarettes and reduce their risk of exposure to harmful and potentially harmful toxins compared to combusted cigarettes. At the same time, the data showed there was low risk for non-users, including youth, to use the products. The risk was also low for non-users, including youth, to progress to regular use of the products.

Specifically, available data showed that current tobacco users who used these tobacco-flavored products were more likely to significantly decrease their use of combusted cigarettes and that those who don't smoke are unlikely to start using these products. Most study subjects decreased the number of combusted cigarettes they smoked each day by greater than 80%, from an average of 13-16 cigarettes per day at screening to 1-2 by day 59. The data also showed that the products produce fewer or lower levels of some toxins, like carbon monoxide, than combustible cigarettes and the products' abuse liability, or their ability to encourage continued tobacco use, addiction or dependence, was lower than combusted cigarettes.

Additionally, today's authorization imposes strict marketing restrictions on the company to greatly reduce the potential for youth exposure to tobacco advertising for these products. The FDA will closely monitor how these ENDS products are marketed and will act as necessary if the company fails to comply with any applicable statutory or regulatory requirements, or if there is a notable increase in the number of non-smokers—including youth—using these products.

As evidenced through data collected via the [National Youth Tobacco Survey \(/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic\)](#), compared to users of non-tobacco-flavored ENDS products, young people are less likely to start using tobacco-flavored ENDS products. The data also suggest that most youth and young adults who use ENDS begin with flavors such as fruit, candy or mint, and not tobacco flavors. These data reinforce the FDA's decision today, consistent with past decisions, to authorize the marketing of the tobacco-flavored ENDS products in part because they are not significantly appealing to youth and authorizing these products may be beneficial for individual adult combusted cigarette users who completely switch to ENDS or significantly reduce their cigarette consumption.

The FDA may suspend or withdraw a marketing order issued under the PMTA pathway for a variety of reasons, including if the agency determines the continued marketing of a product is no longer "appropriate for the protection of the public health," such as if there is a notable increase

in youth initiation.

Related Information

- [Premarket Tobacco Product Marketing Orders \(/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders\)](/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders)
- [Premarket Tobacco Product Applications \(/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications\)](/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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