FDA NEWS RELEASE

FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health

Action Marks First Marketing Denial Orders for E-Cigarette Products; Products Receiving Such Orders Must be Removed from the Market or Risk Enforcement; More Marketing Decisions to Follow

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Today, the U.S. Food and Drug Administration issued the first marketing denial orders (MDOs) for electronic nicotine delivery system (ENDS) products after determining the applications for about 55,000 flavored ENDS products from three applicants lacked sufficient evidence that they have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products. The products from JD Nova Group LLC, Great American Vapes, and Vapor Salon subject to this action are non-tobacco-flavored ENDS and they include flavors such as Apple Crumble, Dr. Cola and Cinnamon Toast Cereal.

“Congress gave the FDA the authority to regulate tobacco products to protect the public from the harmful effects of tobacco use through science-based regulation,” said Acting FDA Commissioner Janet Woodcock, M.D. “Ensuring new tobacco products undergo an evaluation by the FDA is a critical part of our aim to reduce tobacco-related disease and death. We know that flavored tobacco products are very appealing to young people, therefore assessing the impact of potential or actual youth use is a critical factor in our decision-making about which products may be marketed.”

This action represents a significant step toward making progress on the unprecedented number of applications received by the Sept. 9, 2020 court-ordered deadline for submission of premarket applications for deemed new tobacco products, and addressing youth use of flavored ENDS products.

The FDA has received applications from over 500 companies covering more than 6.5 million tobacco products. Although the agency has issued other negative actions (/tobacco-products/ctp-newsroom/fda-issues-refuse-file-rtf-letter-jd-nova-group-llc) for some applications, this is the first set of MDOs the FDA has issued for applications that have reached the substantive scientific review portion of premarket review. The agency is committed to working to transition the current marketplace to one in which all ENDS products available for sale have demonstrated that they are "appropriate for the protection of the public health."

The products subject to an MDO for a premarket application may not be introduced or delivered for introduction into interstate commerce. If the product is already on the market, the product must be removed from the market or risk enforcement. The MDOs announced today do not include all ENDS products for which the companies submitted applications. Applications for the rest of the products remain under consideration. The FDA had previously notified (/tobacco-products/ctp-newsroom/fda-issues-refuse-file-rtf-letter-jd-nova-group-llc) one of the companies, JD Nova Group LLC, that their premarket tobacco product applications associated with approximately 4.5 million of their products did not meet the filing requirements for a new tobacco product seeking a marketing authorization.

"Flavored ENDS products are extremely popular among youth, with over 80 percent of e-cigarette users between ages 12 through 17 using one of these products. Companies who want to continue to market their flavored ENDS products must have robust and reliable evidence showing that their products' potential benefit for adult smokers outweighs the significant known risk to youth," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "The burden is on the applicant to provide evidence to demonstrate that the marketing of their product meets the statutory standard of 'appropriate for the protection of the public health.' If this evidence is lacking or not sufficient, the FDA intends to issue a marketing denial order, which requires the product to be taken off or not introduced to market."

The FDA's review of new tobacco products before they can be legally marketed ensures that they meet the standard Congress set in the law to protect the public health. In light of the public health threat posed by the well-documented, alarming levels of youth use of flavored ENDS, the agency has reviewed the applications subject to this action to determine whether there is sufficient product-specific scientific evidence to demonstrate enough of a benefit to adult smokers that would overcome the risk posed to youth. Based on existing scientific evidence and the agency's experience conducting premarket reviews, the evidence of benefits to adult smokers for such products would likely be in the form of a randomized controlled trial or

longitudinal cohort study, although the agency does not foreclose the possibility that other types of evidence could be adequate if sufficiently robust and reliable. Because this evidence was absent in these applications, the FDA is issuing MDOs.

The agency will continue to review other premarket tobacco applications for non-tobacco flavored ENDS to determine whether there is sufficient product-specific scientific evidence of a benefit to adult smokers to overcome the risk posed to youth. If the applications contain evidence of this type, the FDA will conduct further in-depth scientific evaluation as to whether the evidence satisfies that statutory standard for authorization. But in the absence of this evidence, the agency intends to issue an MDO.

The scientific review of menthol ENDS, as compared to other non-tobacco-flavored ENDS products, raises unique considerations. Although menthol-flavored ENDS are not included in the decisions described above, the FDA notes that its reviews will similarly examine whether the evidence in the application demonstrates a benefit to existing adult users that outweighs the known youth use of such products.

Related Information

- Submit Tobacco Product Applications for Deemed Tobacco Products (https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products)
- Update on FDA's Application Review: PMTA List Posted, Progress Metrics Updated (https://www.fda.gov/tobacco-products/ctp-newsroom/update-fdas-application-review-pmta-list-posted-progress-metrics-updated)
- National Survey Shows Encouraging Decline in Overall Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products (https://www.fda.gov/news-events/press-announcements/national-survey-shows-encouraging-decline-overall-youth-e-cigarette-use-concerning-uptick-use)
- What Happens After I Submit the Application? (https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products#What%20Happens%20After%20I%20Submit%20the%20Application?)
- Tobacco Products Marketing Orders (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Marketing%20Denial)

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