US Food and Drug Administration FDA Denies Authorization to Market JUUL Products

The U.S. Food and Drug Administration issued marketing denial orders (MDOs) to JUUL Labs Inc. for all of their products currently marketed in the United States. As a result, the company must stop selling and distributing these products. In addition, those currently on the U.S. market must be removed, or risk enforcement action. The products include the JUUL device and four types of JUULpods: Virginia tobacco flavored pods at nicotine concentrations of 5.0% and 3.0% and menthol flavored pods at nicotine concentrations of 5.0% and 3.0%. Retailers should contact JUUL with any questions about products in their inventory.

“Today’s action is further progress on the FDA’s commitment to ensuring that all e-cigarette and electronic nicotine delivery system products currently being marketed to consumers meet our public health standards,” said FDA Commissioner Robert M. Califf, M.D. “The agency has dedicated significant resources to review products from the companies that account for most of the U.S. market. We recognize these make up a significant part of the available products and many have played a disproportionate role in the rise in youth vaping.”

These MDOs only pertain to the commercial distribution, importation and retail sales of these products, and do not restrict individual consumer possession or use—the FDA cannot and will not enforce against individual consumer possession or use of JUUL products or any other tobacco products.

After reviewing the company’s premarket tobacco product

applications (PMTAs), the FDA determined that the applications lacked sufficient evidence regarding the toxicological profile of the products to demonstrate that marketing of the products would be appropriate for the protection of the public health. In particular, some of the company's study findings raised concerns due to insufficient and conflicting data – including regarding genotoxicity and potentially harmful chemicals leaching from the company's proprietary e-liquid pods – that have not been adequately addressed and precluded the FDA from completing a full toxicological risk assessment of the products named in the company's applications.

To date, the FDA has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUULpods. However, the MDOs issued today reflect FDA's determination that there is insufficient evidence to assess the potential toxicological risks of using the JUUL products. There is also no way to know the potential harms from using other authorized or unauthorized third-party e-liquid pods with the JUUL device or using JUULpods with a non-JUUL device. The FDA recommends against modifying or adding substances to tobacco products. JUUL users are encouraged to report any unexpected health problems or product problems to the FDA through the Safety Reporting Portal and to seek medical attention as necessary.

"The FDA is tasked with ensuring that tobacco products sold in this country meet the standard set by the law, but the responsibility to demonstrate that a product meets those standards ultimately falls on the shoulders of the company," said Michele Mital, acting director of the FDA's Center for Tobacco Products. "As with all manufacturers, JUUL had the opportunity to provide evidence demonstrating that the marketing of their products meets these standards. However, the company did not provide that evidence and instead left us with significant questions. Without the data needed to determine relevant health risks, the FDA is issuing these

marketing denial orders."

Any products subject to an MDO may not be offered for sale or distributed in the United States, or the FDA may take enforcement action.

In addition to ensuring that JUUL complies with this order, as with unauthorized products generally, the FDA intends to ensure compliance by distributors and retailers. Specifically, the FDA notes that all new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action.

As the FDA has stated in the past, unauthorized electronic nicotine delivery system (ENDS) products for which no application is pending, including for example, those with an MDO, are among our highest enforcement priorities. Therefore, the FDA encourages retailers to discuss products in their inventory with their suppliers including the current status of any particular tobacco product's marketing application or marketing authorization. Manufacturers will be the best source of that information and retailers should rely on manufacturers directly to inform decisions about which products to continue selling.

There are many resources to help smokers who want to quit. Quitting all tobacco products is the best possible path to good health. Some current JUUL users who will not have access to JUUL products following this action or current smokers who want to transition away from cigarettes and cigars may decide to switch to other ENDS products that have been reviewed and authorized by the FDA based on their potential to benefit adult smokers.

To date, the FDA has authorized 23 ENDS products. Under the PMTA pathway, applicants must demonstrate to the agency, among other things, that permitting the marketing of the new tobacco product would be appropriate for the protection of the public

health.

The FDA continues to work to complete its review of the remaining pending applications for deemed products submitted by the Sept. 9, 2020, deadline.