

Practice Update

FDA Orders JUUL E-Cigarettes Off The Market Over Safety Concerns

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The U.S. Food and Drug Administration (the FDA) issued marketing denial orders (MDOs) to JUUL Labs for all of its products currently marketed in the United States. As a result of this MDO, JUUL must stop selling and distributing all products in the U.S. In addition, JUUL products currently on shelves in the U.S. market must be removed.

In issuing this MDO, FDA Commissioner Robert M. Califf, M.D. stated that “[t]oday’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.” Califf went on to say that “[t]he 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.”

The Agency noted that the MDOs only pertain to the commercial distribution, importation, and retail sales of these products, and do not restrict individual consumer possession or use, as FDA cannot and will not enforce against individual consumer possession or use of JUUL products (or any other tobacco products).

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After reviewing Juul's applications seeking marketing authorization for its products, the FDA stated that it determined that the applications lacked "sufficient evidence" regarding the toxicological profile of the products in order to demonstrate that marketing of the products would be appropriate for the protection of the public health. In other words, the FDA determined that JUUL's e-cigarettes and pods were not safe for consumers.

While this sweeping decision is surprising, it is not completely unexpected. However, it does raise significant concerns for both the ENDS (electronic nicotine delivery systems) market, as well as the future of the vape market. Many in the cannabis industry believe the federal illegality of marijuana will hopefully keep the industry safe from FDA interference for the time being. However, if the FDA believes the vape industry, and not just e-cigarettes, are a cause for consumer safety, it could significantly impact the cannabis market.

In response to the MDO, JUUL said it intended to seek a stay of the MDO and was exploring all its options under the law, including appealing the decision.

Akerman is closely following this development and will provide an update as new information becomes available.

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