NATO News

Critical News for Members on Tobacco Legislation, Litigation and Regulations

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FDA Statement on Enforcement of Guidance

Today, the FDA issued a statement regarding the agency's Guidance Document prioritizing enforcement actions on certain flavored cartridge-based and pod-based electronic nicotine products. The entire statement of the FDA is shown below:

Last month, FDA announced the agency's enforcement priorities for electronic nicotine delivery systems (ENDS), such as e-cigarettes, on the market without premarket authorization. Beginning today, the agency intends to prioritize enforcement against certain illegally marketed flavored e-cigarette products, focusing on products that are particularly popular with youth and are easily accessible or marketed to them – such as flavored, cartridge-based e-cigarette products (other than tobacco and menthol).

Importantly, this policy is designed to be flexible, enabling the agency to focus its priorities as warranted to address youth use. If FDA sees a product that is targeted to kids, the agency will not hesitate to target that product. For example, FDA will take action against any product—regardless of whether a product is cartridge-based, disposable, or flavored—if it is targeted to minors, its marketing is likely to promote youth use, or if the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access.

Additionally, FDA intends to issue an import alert in the near future and refuse admission of certain unauthorized e-cigarette products that are imported or offered for import into the United States where warranted and as informed by the agency's enforcement priorities.

While FDA expects that responsible members of industry will cease the manufacture, distribution, and sale of unauthorized e-cigarette products, the public may continue to see some of the types of products outlined in the priorities on the market as the agency works to hold manufacturers and retailers—both in brick-and-mortar stores and online—accountable. For example, FDA will be initiating inspections and surveillance of manufacturers and retailers. Under the policy, companies that continue to manufacture, distribute, and sell unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) risk FDA compliance and enforcement actions ranging from warning letters to injunction, seizure, and/or civil money penalty actions where warranted. Retailers and distributors are encouraged to communicate with their suppliers to discuss possible options for the unauthorized products in their inventory.

FDA's enforcement priorities are not a "ban" on flavored or cartridge-based ENDS. FDA has already accepted and begun review of several premarket applications for flavored ENDS products through the pathway that Congress established in the Tobacco Control Act. Manufacturers that wish to market any of these products—including flavored e-cigarettes or e-liquids—need to submit an application to FDA that demonstrates that the product meets the applicable standard in the law, such as whether the product is appropriate for the protection of the public health. If a company can demonstrate to FDA that a specific product meets the applicable standard set forth by Congress, including considering how the marketing of the product may affect youth initiation and use, then the agency would authorize that product for sale.

Additionally, manufacturers of *all* deemed new tobacco products will still be required to submit marketing applications for their products by May 12, 2020. After May 12, FDA intends to also prioritize enforcement against any ENDS products that continue to be sold and for which the manufacturers have not submitted a premarket application. For ENDS products other than those in the three groups described above, if premarket applications are submitted by that date, FDA intends to continue to exercise enforcement discretion for up to one year pending FDA review of the applications, unless there is a negative action by FDA on such application or the product is authorized to be marketed by FDA.