

Summary of FDA's January 2020 Guidance on Flavored E-cigarettes



On January 6, 2020 the U.S. Food and Drug Administration (FDA) released a new tobacco industry guidance on certain flavored e-cigarettes. The *"Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization"* states that the FDA will prioritize enforcement of only certain flavored e-cigarette products starting February 6, 2020 by removing these products from the market.

Under the Family Smoking Prevention and Tobacco Control Act (TCA), all *new* tobacco products that are currently on the market without FDA authorization are considered illegally marketed products. FDA may use its enforcement authority to order the removal from the market of all illegally marketed products. A new tobacco product is defined in the TCA that was not commercially marketed in the United States as of February 15, 2007. Almost all e-cigarette products and many cigars, hookah tobacco and smokeless products meet the definition of a new tobacco product.

Prohibited Flavored Products

FDA will use its enforcement authority to remove from the market some flavored cartridge-based e-cigarettes except for tobacco- and menthol-flavored products. Cartridge-based e-cigarettes are defined as those that consist of, include, or involve a cartridge or pod that holds liquid to be aerosolized. A cartridge or pod is any small, enclosed unit designed to fit with an e-cigarette. It can be sealed or unsealed.

In addition, the guidance states FDA will use its enforcement authority to order removal of products that target youth and young adults and products for which the manufacturer has failed to prevent youth access to the products. The guidance does not provide any specificity on how these provisions would be enforced and there is little certainty of their impact.

Flavored Products Still Permitted

FDA will not use its enforcement authority to remove from the market other kinds of e-cigarettes, including self-contained disposable products, and open, refillable systems, and e-liquids used to fill them. Nor will FDA use its enforcement authority to remove from the market other flavored new tobacco products, including flavored cigars, hookah tobacco, and smokeless. Therefore, e-liquids, open, refillable e-cigarette products, self contained disposable e-cigarette products, cigars, hookah tobacco, and smokeless tobacco in any flavor will still be permitted to be on the market. Tobacco- and menthol-flavored cartridge-based e-cigarettes will also still be permitted.

In addition, the guidance does not place any restrictions on where these products can be sold (for example, in "vape shops" or by retailers that only permit entry to individuals over the age of 21 at all times).

Menthol cigarettes are not and could not be addressed through guidance because they are not a new tobacco product illegally on the market. FDA would have to use other authorities, such as a product standard, to address menthol cigarettes.

FDA Authorization of New Tobacco Products

This guidance on the removal from market of only certain flavored e-cigarettes does not change the federal requirement that any new product must receive marketing authorization from the FDA. As a reminder, all

new tobacco products that are currently on the market without FDA authorization are illegally marketed products. As a result of a lawsuit brought by the American Cancer Society Cancer Action Network (ACS CAN) and other tobacco control organizations, the court has mandated deadlines for the marketing authorization process. Manufacturers of new products must submit their marketing authorization applications to FDA by May 12, 2020. If an application is not submitted, the product should be removed. If the application is submitted, the product can remain on the market for up to one year or until FDA determines whether to authorize the product; whichever date is earlier.

FDA states in this guidance that it will prioritize enforcement of the premarket review requirements for e-cigarettes prior to the May 12, 2020 deadline, but importantly, it is still up to individual manufacturers to submit their applications prior to the deadline. FDA also acknowledges it may not have the resources to remove every illegally marketed new tobacco product and therefore will use its enforcement discretion on a case-by-case basis after the May 12, 2020 deadline. Factors FDA could consider in prioritizing enforcement of market availability could include youth and young adult use of certain tobacco products, including the use of flavor products.

ACS CAN's Position:

The aggressive use of flavors and marketing tactics by the tobacco industry, the rapid increased use of flavored tobacco products by youth and young adults, and under-regulation of these products requires the public health community to take action to protect youth and young adults, and the public health at-large. The FDA's guidance on certain flavored e-cigarettes is woefully insufficient to address the current youth tobacco epidemic. ACS CAN supports several strategies:

- ❖ **Federal Restrictions:** Congress or the FDA should prohibit the use of characterizing flavors, including menthol, in all tobacco products. A manufacturer of a new tobacco product, as defined by law, should be required, through premarket review, to prove that the use of a flavor is appropriate for the protection of public health.
- ❖ **State and Local Sales Restrictions:** Many states and localities are moving forward and enacting restrictions on the sale of flavored tobacco products and winning legal challenges to its laws. The TCA does not permit a state or locality from requiring a product standard, such as the removal of a flavor, but the law does preserve the ability for states and localities to regulate the sales of tobacco products. States and localities should pursue policy options including restrictions or a complete prohibition of the sale of flavored tobacco products, including menthol cigarettes, while taking into consideration what is permitted in a specific jurisdiction.