FOR IMMEDIATE RELEASE: September 28, 2021
CONTACTS:
Dave Lemmon, Campaign for Tobacco-Free Kids, 202-738-7983
Devin Miller, American Academy of Pediatrics, 202-724-3308
Allison Miller, American Cancer Society Cancer Action Network, 202-585-3241
Steve Weiss, American Heart Association, 202-607-0911
Jill Dale, American Lung Association, 312-940-7001
Dorian Fuhrman, Parents Against Vaping e-Cigarettes, 917-860-3935
Nicole Dueffert, Truth Initiative, 202-997-1470

Leading Health Groups Urge FDA to Promptly Deny Marketing Applications for All Flavored E-Cigarettes, including Menthol

WASHINGTON, D.C. – Seven leading public health, medical and parent organizations are urging the U.S. Food and Drug Administration (FDA) to expedite decisions on remaining marketing applications for e-cigarettes and promptly deny applications for all flavored e-cigarettes, including menthol-flavored products, because of their appeal to youth and adverse impact on public health. In a letter to Acting FDA Commissioner Janet Woodcock, the groups also urged the FDA to prioritize enforcement against unauthorized flavored e-cigarettes with the largest market shares and products with the highest prevalence of youth use.

The groups sending the letter are the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Parents Against Vaping e-cigarettes (PAVe) and Truth Initiative.

The FDA on September 9 announced that it has denied marketing applications for more than 946,000 flavored e-cigarette products (and it has since announced additional marketing denial orders for flavored e-cigarettes). However, the FDA has yet to issue decisions about e-cigarette brands with the highest market shares (such as Juul, Vuse, NJOY and blu, which make up over 78% of the market, according to Nielsen data) or for products that are most commonly used by high school e-cigarette users (such as Juul, NJOY, SMOK, Suorin and Vuse). All of these products come in flavors, or can be used with flavors, that appeal to young people.

The health groups expressed particular concern that the FDA is still considering whether to authorize any menthol-flavored e-cigarettes and urged the FDA not to do so given the clear evidence that menthol is a flavor that appeals to and is widely used by kids.

“Contrary to the FDA’s August 26 statement that menthol e-cigarette products raise ‘unique considerations’ for purposes of FDA review, we do not believe there is anything ‘unique’ about menthol flavoring that would justify issuance of a marketing order. Indeed, there is no question that when FDA decided to prioritize enforcement against cartridge-based e-cigarettes in flavors other than menthol and tobacco, youth shifted to using menthol-flavored products. According to the latest data, over one million youth use menthol-flavored e-cigarettes. In 2020, 37% of high school users of flavored e-cigarettes, including 45% of users of flavored refillable cartridge systems like Juul, reported using menthol products,” the letter states.

The letter urges the FDA to take the following actions:

- Complete review of all e-cigarette products without further delay.

- Issue marketing denial orders for non-tobacco-flavored products, including menthol-flavored products, based on the continuing adverse impact of these products on public health, and particularly their impact on youth.
- Immediately revise the enforcement policy announced on September 9 to include prioritized enforcement against e-cigarette products that continue to be sold without marketing authorization if they are (a) flavored products with the highest market shares or (b) products with the highest prevalence of youth usage.
- Identify on an ongoing basis the products, and their flavors, that receive marketing denial orders, including menthol-flavored products.

Six of the groups sending the letter (all except for PAVe, which did not exist at the time) sued the FDA in 2018 after the FDA suspended, for several years, a legal requirement that e-cigarette manufacturers apply to the FDA and demonstrate that their products are "appropriate for the protection of the public health" in order to market them. A federal judge ruled that the FDA's action was unlawful and played a role in the youth e-cigarette epidemic. The judge subsequently set a deadline of September 9, 2020, for e-cigarette manufacturers to submit marketing applications to the FDA and allowed products that were the subject of timely applications to stay on the market for up to one year, until September 9, 2021, while the FDA reviewed the applications. Now that the September 9, 2021, deadline has passed, all unauthorized e-cigarette products on the market are subject to FDA enforcement action.