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Public Health Groups Call on FDA to Deny Authorization of Sale For JUUL E-Cigarette Products

Washington, D.C. - April 27, 2021 - Public health groups submitted a [letter](#) to the U.S. Food and Drug Administration (FDA) today urging it to deny authorization of the sale of JUUL e-cigarette products because they do not meet the required “public health standard” within the premarket review application process. Given what we already know about JUUL products, FDA must find that JUUL products are not “appropriate for the protection of the public health.” This “public health standard” is an essential criterion, one that many public health groups successfully advocated be included in the 2009 Family Smoking Prevention and Tobacco Control Act, which provided FDA the authority to regulate tobacco products.

The premarket review application process requires manufacturers of e-cigarettes and other tobacco products to apply to the FDA to sell new products. Because of delays, many tobacco products, including JUUL products, that meet the definition of “new” have been on the market for years prior to review. Manufacturers of these products had a court-mandated deadline of Sept. 9, 2020 to submit their applications to the agency or be removed from the market. FDA has one year from the date of submission to determine if a product meets the standard and, therefore, can stay on the market. If FDA determines the standard hasn’t been met or does not make a determination, manufacturers must pull their products from shelves.

FDA has said it will review the most popular products first; because JUUL’s products continue to have the largest share of the e-cigarette market, this likely means Juul’s application is undergoing expedited review.

The letter submitted by American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative, asserts that real-world evidence shows that JUUL’s marketing, use of flavors, and high nicotine concentrations have greatly contributed to the youth tobacco epidemic. There is also a lack of evidence that JUUL’s products have helped adult smokers switch completely or stop using all tobacco

products. Based on these facts, JUUL products, regardless of flavor, cannot meet the public health standard; the letter urges FDA to deny JUUL's application to continue sale of its products.

The following is a statement from the public health groups:

“Because of the FDA’s years-long delay in its oversight of JUUL and other e-cigarettes, many of these products have been on the market now for years without having undergone any pre-market review. JUUL products have caused, and are still causing, immeasurable damage to public health, particularly to the health of the nation’s children. The evidence is overwhelming that JUUL’s products, technological innovations, sleek design and marketing have led to a level of use and addiction that was previously unimaginable. JUUL changed the market and its introduction was accompanied by a massive growth in youth use, with little or no growth in the percentage of adult users, with long-term consequences of unknown proportions. We call upon the FDA to take a strong stand for public health by denying products that do not meet the statutory requirement that manufacturers prove their products are a benefit to public health.

“As the FDA considers the applications, it is critical the agency consider the wealth of data concerning the actual impact of the full range of JUUL’s products on public health during their years on the market.

“With such a substantial share of the market, JUUL’s products have been largely responsible for the surge in youth e-cigarette use and the growth in the percentage of youth who have become addicted to e-cigarettes—an epidemic which continues to this day—with no measurable public health benefit.

“Indeed, given JUUL’s disastrous real-world impact, any marketing order granted to JUUL would establish a precedent that would undermine decades of efforts to reduce youth tobacco use and pave the way for marketing orders for other e-cigarette and tobacco products that cannot meet the public health standard, causing grievous damage to public health for many years to come.”

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