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Dockets Management Staff (HFA-305) Food and Drug Administration 5630 Fishers Lane, rm. 1061 Rockville, MD 20852

<u>Re: Docket No. FDA–2021–N–1309 for "Tobacco Product Standard for</u> <u>Characterizing Flavors in Cigars"</u>

The American Association for Respiratory Care (AARC) appreciates the opportunity to express our strong support for the Food and Drug Administration's proposed rule to prohibit all characterizing flavors in cigars. The FDA's proposed rule systematically lays out the evidence showing that prohibiting flavored cigars will protect our children, reduce health disparities, and save lives.

The AARC is a national professional organization with a membership of 40,000 respiratory therapists who specialize in providing pulmonary diagnostics and treatment for patients who suffer from respiratory conditions like chronic obstructive pulmonary disease (COPD), asthma, pneumonia, lung trauma and other respiratory-related diagnoses. Respiratory therapists are educated and trained in all aspects of pulmonary medicine and are acutely aware of the devastating impact of tobacco use.

Prohibiting flavored cigars will reduce initiation and use of cigars, especially among young **people.** Flavors play a key role in attracting youth to start using tobacco products, including cigars.¹ Flavors increase the appeal of cigars and make them easier to use by improving their taste and masking the harshness of tobacco products.² Flavors in cigars promote initiation in young people and increase the likelihood that they will become regular cigar smokers.³ Flavored cigars have proliferated in recent years⁴ and are sold in hundreds of kid-friendly flavors like wild berry, brownie and tropical twist. According to the National Cancer Institute, cigars contain the same addictive, toxic and carcinogenic compounds found in cigarettes and are not a safe alternative to them. Those who smoke cigars heavily or inhale deeply also increase their risk of developing chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema [NIH Pub No 98-4302]. COPD is a leading cause of death in the United States and accounts for increased hospital readmission rates due to acute exacerbations of the disease. As experts in pulmonary medicine, respiratory therapists are acutely aware of the devasting effects of COPD on quality of life. Reducing characterizing flavors in cigars that are popular among today's youth can go a long way to prevent years of respiratory disease that may result as they approach adulthood.

Prohibiting flavored cigars will reduce tobacco-caused disease and death. Cigars are addictive and harmful.⁵ As is well documented in the proposed rule, flavored cigar smokers, like all cigar smokers, are at increased risk for developing cancers of the mouth and throat, lung cancer, heart and lung diseases, and many other negative health consequences.⁶ The FDA has

previously concluded that "all cigars pose serious negative health risks" and that "all cigar use is harmful and potentially addictive."⁷ Indeed, each year about 9,000 Americans die prematurely from regular cigar use.⁸ Removing flavors from cigars will substantially reduce initiation and use and subsequently tobacco-related disease and death.⁹ Pipe and cigar smoking have also been linked to COPD; thus, it is imperative that the FDA act as swiftly as possible to finalize this product standard to reduce the chance of future cases of decreased lung function and death as a result of this debilitating disease.

Prohibiting flavored cigars will decrease tobacco-related health disparities and advance health equity, especially among Black Americans. The tobacco industry has targeted Black communities with marketing for cheap, flavored cigars for decades.¹⁰ As a result, Black high school students smoke cigars at higher rates compared to other races or ethnicities.¹¹ In addition to youth and Black smokers, the FDA's proposed rule recognizes the disproportionate burden that cigar use – including flavored cigar use – has on members of many underserved communities, stating, "Such disparities in cigar use contribute to higher rates of observed tobacco-related morbidity and mortality among underserved communities and vulnerable populations, such as youth and young adults, some racial and ethnic populations, those with lower household income and educational attainment, and individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+)."¹² Given the disproportionate health burden experienced in some communities, the FDA expects that eliminating flavored cigars will substantially decrease tobacco-related health disparities and will promote health equity across population groups.¹³

The AARC urges the FDA to move quickly to finalize this lifesaving rule to prohibit all flavored cigars without exceptions as well as extend it to cover other combustible tobacco products, including hookah and pipe tobacco. Implementing this rule will protect our health and promote health equity nationwide.

Respectfully submitted,

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- ⁹ 87 Fed. Reg. 26396, 26406 (May 4, 2022).
- ¹⁰ 87 Fed. Reg. 26396, 26412 (May 4, 2022).

¹ 87 Fed. Reg. 26396, 26405 (May 4, 2022).

² 87 Fed. Reg. 26396, 26405 (May 4, 2022).

³ 87 Fed. Reg. 26396, 26397 (May 4, 2022).

⁴ Delnevo, CD, et al. "Cigar Sales in Convenience Stores in the US, 2009-2020," *JAMA* 326(23):2429-2432. 87 Fed. Reg. 26396, 26403 (May 4, 2022).

⁵ 87 Fed. Reg. 26396, 26413 (May 4, 2022).

⁶ 87 Fed. Reg. 26396, 26418 (May 4, 2022).

⁷ 81 Fed Reg 29020, 29022 (May 10, 2016).

⁸ 87 Fed. Reg. 26397, 26399 (May 4, 2022).

¹¹ CDC, "Tobacco Product Use Among Middle and High School Students—United States, 2021," *MMWR* 71(5), March 11, 2022, <u>https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf</u>

¹² 87 Fed. Reg. 26396, 26401 (May 4, 2022).

¹³ 87 Fed. Reg. 26396, 26397 (May 4, 2022).