

August 2, 2022

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2021–N–1309 for “Tobacco Product Standard for Characterizing Flavors in Cigars”

Dear Commissioner Califf:

The American Lung Association appreciates the opportunity to express our strong support for the Food and Drug Administration’s (FDA) 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. These comments are intended to supplement comments the Lung Association also submitted with the broader health and medical community.

The American Lung Association is the oldest, voluntary public health organization in the United States and is committed to eliminating tobacco use and tobacco-related disease. The Lung Association has long called on FDA to end the manufacture and sale of all flavored tobacco products, including flavored cigars, waterpipe or pipe tobacco. As the National Cancer Institute, the National Academy of Medicine and other highly esteemed sources have continued to find, cigars, including flavored cigars have the same addictive, toxic and carcinogenic compounds found in cigarettes and are not a safer alternative.¹ Cigars have been linked to many of the same deadly diseases as well.² The Lung Association urges FDA to move quickly in finalizing this proposed rule by the end of 2022.

Ending the Sale of Flavored Cigars Will Promote Public Health and Advance Health Equity

Flavors play a key role in attracting youth to start using tobacco products, including cigars.³ Flavors increase the appeal of cigars and make them easier to use by improving their taste and masking the harshness of tobacco in the product.⁴ Flavors in cigars promote initiation in young people and increase the likelihood that they will become regular cigar smokers.⁵ Young people also generally perceive cigars, and more specifically flavored cigars, as less harmful.⁶ Prohibiting flavored cigars will decrease tobacco-related health disparities and advance health equity, especially among Black Americans and young people.

Flavored cigars have proliferated in recent years and are sold in hundreds of kid-friendly flavors like chocolate, cherry dynamite and tropical twist.⁷ As a result, cigars are now the second most popular tobacco product among high schoolers.⁸ Almost 81% of 12–17-year-olds who had ever used a tobacco product initiated use with a flavored product⁹ and close to half (44.4%) of youth cigar users use flavored cigars.¹⁰

The tobacco industry has aggressively targeted Black communities with marketing for cheap, flavored cigars for decades.¹¹ As a result, Black high school students smoke cigars at higher rates compared to other races or ethnicities; in 2021 the rates were 4.4% among Black high

school students vs. 2.1% among white high school students.¹² Non-Hispanic Black youth are also more likely to initiate cigarillo or little cigar use and transition to regular use at earlier ages compared to non-Hispanic white youth.¹³ Black youth are often surrounded by cigar imagery, which largely contributes to the disparity in cigar use.

In addition to youth and Black smokers, 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 groups experiencing disproportionate impact, such as youth and young adults, some racial and ethnic minority groups, those with lower household income and educational attainment, and individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+).”¹⁴

Given the disproportionate health burden experienced in some communities, FDA expects that eliminating flavored cigars will substantially decrease tobacco-related health disparities and will promote health equity across population groups.¹⁵

Given the role flavors play in attracting young people to use cigars, there is no rationale for continuing to permit any characterizing flavors in any cigar. This proposed product standard would reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use.

FDA Must Take Proactive Steps to Prevent Loopholes and Industry Manipulation

The American Lung Association urges FDA to include all flavors of all different kinds of cigars in the final rule. The tobacco industry has a long-documented history of manipulating products to take advantage of regulatory ambiguity. If any flavor is exempted from FDA's rulemaking, the tobacco industry will take undue advantage of any loophole. For example, after the passage of the *2009 Family Smoking Prevention and Tobacco Control Act*, the sale of flavored cigarettes (apart from menthol) was prohibited. Sensing an opportunity, cigar manufacturers stepped up the production and marketing of flavored little cigars that were still legal to sell.

This type of gross manipulation and exploitation of regulatory loopholes expanded the sale of flavored combustible non-cigarette products, including cigarillos. Many of these products are functionally indistinguishable from cigarettes and continue to be sold – a clear effort to circumvent the *Tobacco Control Act's* prohibition on flavored cigarettes. It has also resulted in expanding the gap in health disparities. Using data from the 1999-2013 Youth Tobacco Surveys, a 2017 study analyzed the impact of the 2009 statutory prohibition of characterizing flavors in cigarettes on youth tobacco use. The researchers found that cigarette use declined significantly after 2009, whereas cigar and pipe tobacco use significantly increased. Another study found that cigar sales increased by 29% between 2012 and 2016, driven by a 78% increase in cigarillo sales.¹⁶

In another blatant example of industry manipulation to avoid policies that could impact sales of their products, the cigar company, Cheyenne International, was caught adding sepiolite, a clay material used in kitty litter, waste treatment and industrial cleaners in an effort to increase the

weight of their 'heavy weight' cigars to avoid higher tax rates that were charged on smaller cigars and cigarettes due to the federal cigarette tax increase that took effect in 2009.¹⁷

The above examples clearly demonstrate that to maximize the public health impact of the proposed rule prohibiting characterizing flavors in cigars, FDA must prohibit the sale of menthol cigarettes concurrently using the same effective dates. Menthol cigarettes are disproportionately used by racial and ethnic minority groups, including Black Americans, and attract young people to initiate tobacco use. Issuing both rules concurrently with the same effective date will maximize the public health impact and prevent the tobacco industry from selling menthol cigarettes posing as cigars or allowing individuals who smoke flavored cigars to shift to using menthol cigarettes. FDA must also ensure there are no regulatory loopholes included in the final rule that the tobacco industry can exploit to addict another generation to harmful tobacco products.

FDA Should Include Flavored Waterpipe Tobacco and Pipe Tobacco in its Final Rule

FDA has asked for comment on whether flavored waterpipe tobacco or pipe tobacco should be included in the proposed rule on flavored cigars, and the American Lung Association urges FDA to do so. Waterpipe tobacco products, also known as hookahs, originate from Middle Eastern countries but their use in the U.S. has become more commonplace with 31.9% of adult ever users having used hookah within the past year.¹⁸ Traditionally, hookahs were used with raw tobacco, but in the 1990s flavored waterpipe tobacco was introduced leading to more young people using it.¹⁹ While nationwide data shows only 1.2% of high school students using hookah tobacco, Black high schoolers report a significantly higher rate of hookah use (3.2%). This compares to much lower rates among non-Hispanic white (0.8%) and Hispanic (1.2%) high school students.²⁰ According to the Population Assessment on Tobacco and Health (PATH) study, use of flavored tobacco is higher for users of waterpipe tobacco than for any other tobacco product and young hookah users report using waterpipe tobacco because it comes in flavors they like.²¹ Young people also say that they use hookah because they like socializing while using the product.²²

Unfortunately, youth and young adults often perceive waterpipe tobacco to be less harmful than smoking cigarettes, but studies show that the smoke contains many of the same toxic components found in cigarette smoke, such as nicotine, tar and heavy metals.²³ Due to the flavor and the smoking technique, people who smoke waterpipe tobacco are exposed to more smoke over a greater period of time than when smoking a cigarette.²⁴ There is a strong likelihood that waterpipe tobacco products lead to cigarette smoking.²⁵ Excluding flavored waterpipe tobacco from this rule would give manufacturers a big loophole to exploit.

Manufacturers can also easily re-label roll-your-own (RYO) tobacco used for cigarettes and cigars as "pipe tobacco," because there is no standard definition for pipe tobacco. Including waterpipe tobacco with characterizing flavors in the final rule will discourage young people from using these products. This would still allow adults who partake in waterpipe tobacco for cultural purposes to access unflavored waterpipe tobacco.

FDA Should Continue to Include Flavored "Premium" Cigars in the Final Rule

The Lung Association appreciates that FDA has included flavored "premium" cigars in the proposed rule and urges FDA to include all cigars in the final rule. The term "premium" cigar is one devised by the tobacco industry in an effort to achieve a different set of rules and circumvent regulations established for all tobacco products by FDA. The "premium" cigar

industry claims that their cigars are different than other smoked tobacco products because they are crafted by artisans and made by using the best, all-natural tobacco. However, the health harms from smoked tobacco products come primarily from the combustion of the tobacco leaf itself, which “premium” cigars contain. So-called “premium” cigars are not inherently less risky than regular cigars as a recently released report from the National Academies of Science, Engineering and Medicine (NASEM) found, which nullifies the argument being made by some companies that “premium” cigars should be exempted from this rule.²⁶ In addition, the definition of “premium” cigar used in the NASEM report did not include flavored products, and one of the conclusions from the report addressed the potential negative impacts of flavored “premium” cigars: “Adding flavors to “premium” cigars could result in greater appeal to nonusers and more frequent use, thereby increasing nicotine intake, addiction potential, and exposure to smoke constituents.”

FDA Should Reconsider the Proposed Loophole to Permit Flavored Cigars to Be Manufactured for Export

The Lung Association also urges FDA to extend the prohibition to include all flavored cigars including those designated for export. The proposed rule indicates that FDA intends to allow domestic manufacturers to continue to manufacture flavored cigars for export. It is unconscionable that the U.S. could allow products it has determined to be detrimental to the public health to be exported to harm citizens of other countries. While the U.S. is slowly beginning to limit the type of tobacco products that are sold domestically, the tobacco companies continue to help expand tobacco markets abroad. Tobacco companies have aggressively exploited trade and investment agreements to expand their reach in low and middle-income countries. As FDA has found time and time again, no tobacco product is safe. Further, the domestic manufacture of flavored cigars may result in illicit sales of such flavored cigars ‘designated for export’ in the United States.

Removing Flavored Cigars Will Promote Tobacco Cessation

Evidence suggests that eliminating flavors in cigars will lead many current cigar smokers to stop smoking.²⁷ As is indicated in the proposed rule, many cigar smokers state flavors are a contributing factor for their cigar use. Experimenting with flavored cigars increases the chance of someone becoming regular cigar users. There are some flavored cigar smokers who may switch to non-flavored cigars or other tobacco products; however, estimates indicate that switching is not as common as quitting.²⁸ Prohibiting the sale of flavored cigars will make cigars less appealing, will reduce the number of people experimenting and transitioning to regular use and will incentivize people who prefer flavored tobacco products to quit.

Given that priority populations disproportionately smoke flavored cigars, prohibiting the sale of flavored cigars will have a greater impact on increasing smoking cessation among these populations and help reduce health disparities. FDA estimates that 780 premature tobacco-related deaths will be avoided annually due to this product standard, with more than 25,000 deaths avoided over the next 40 years.²⁹

The United States Preventive Services Task Force has repeatedly found the seven FDA-approved cessation medications and three forms of counseling safe and effective to help smokers quit. All 10 of these treatments are considered first line in helping smokers quit. These are not only cost-effective cessation strategies, but they also increase the likelihood of successfully quitting smoking, particularly when used in combination.

Individuals who smoke in the U.S. have several opportunities to get help with quitting. Individuals can call 1-800-Quit-Now and access their state quitline. Quitlines are effective, evidence-based cessation interventions that help tobacco users quit through a variety of service offerings, including counseling and referral to other cessation resources. Some state quitlines also offer free cessation medications or provide tobacco users with vouchers or discounts to receive these medications at reduced cost. These treatments are also required to be covered without cost-sharing in most types of health insurance plans, including Medicaid expansion plans.

While these treatments are highly successful, we support more research into new medications that will eventually gain FDA-approval for cessation, especially among youth. Evidence shows individuals who use flavored cigars want to quit, not switch to a new product. After FDA finalizes this proposed rule, we urge the agency to partner with Centers for Disease Control, National Institutes of Health, states, non-profits, state quitlines and others to promote available cessation resources – the seven FDA-approved medications and three forms of counseling.

The American Lung Association stands ready to help all tobacco users quit, including people who smoke flavored cigars, with proven effective quit smoking methods. This would consist of delivering evidence-based cessation programming through our Freedom From Smoking Program.

Implications of FDA’s Proposed Rules on State and Local Flavored Tobacco Product Laws

The American Lung Association has consistently opposed any effort to preempt state and local tobacco control authority and was a strong supporter of section 916 in the *Tobacco Control Act* that preserved state and local authority to regulate sales of tobacco products and exposure to secondhand smoke. The Lung Association believes that state and local laws prohibiting sales of flavored tobacco products are complementary to FDA’s proposed rules on menthol cigarettes and flavored cigars. In addition, they, in many cases, cover flavored tobacco products, such as smokeless tobacco and e-cigarettes, that FDA’s proposed rules do not address. This proposal will remove the sale of flavored cigars nationwide and will continue to allow state and localities to proceed with stronger efforts to pass even more comprehensive flavored tobacco laws.

A related example is the federal law setting the legal age of sale for tobacco products to 21 years old and state laws that set the age of sale for tobacco products at 21 and place other regulations and restrictions on tobacco product sales. This combination of state and federal laws work in harmony and can allow for additional state enforcement of underage sale of tobacco product laws.

FDA’s Rule on Flavored Cigars if Properly Enforced is Unlikely to Create a Large Illicit Market

The tobacco industry and other organizations have argued that FDA should not impose any product standard concerning flavored tobacco products because any tobacco control measure will cause illicit sales. The Lung Association and our partners submitted [detailed comments](#) on this topic to FDA on July 18, 2018, which we resubmit to this docket now.

The tobacco industry has consistently overestimated the size and significance of illicit markets to discourage measures that would prevent and reduce tobacco use from being implemented. Their vocal opposition to effective tobacco control measures, including prohibiting the sale of

flavored cigars, comes from a fear of reduced sales and a decrease in profits. FDA should be skeptical of the tobacco industry's claims about illicit markets. Instead, the Lung Association recommends FDA rely on its own research and that of organizations who are champions for improving the public's health.

In addition, because the proposed rule applies to sales of flavored cigars from all potential locations in the United States, including the tribal lands of Indigenous Peoples, this removes a potential avenue for an illicit market in flavored cigars to develop.

The Lung Association also urges FDA to implement the track-and-trace system it is mandated to do under the Tobacco Control Act. There is currently an outstanding [citizen petition](#) that the Lung Association and several partners filed in 2013 to which FDA has yet to respond. The petition requests FDA fulfill its responsibilities to implement a track-and-trace system. Under this system, FDA and other law enforcement authorities would be able to identify the source and distribution history of product packages and increase the effectiveness of law enforcement. This would have great value in enforcing compliance with product standards, prevent any black market that does exist and maximize the public health benefits of strong oversight.

Prohibiting the manufacture of flavored cigars for export will also help prevent the illicit sale of such products "designated for export" in the United States.

The most important thing FDA could do to prevent an illicit market in flavored cigars from occurring is to vigorously enforce the final rule against cigar manufacturers and distributors.

Satisfying the Premarket Review Requirements

FDA has requested comments regarding how manufacturers that change their flavored cigars to comply with the rule might satisfy the premarket review requirements of the *Tobacco Control Act*. If a manufacturer only removes the flavored additives from a flavored cigar that was a legally marketed tobacco product prior to the effective date, then the substantial equivalence exemption pathway would be appropriate given that all other requirements of the pathway are fulfilled. Manufacturers must:

- Provide detailed accounts of the proposed modification, why it is minor and why a substantial equivalence report is not necessary, and
- provide a certification "summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors*, toxicity, addictiveness, or abuse liability," which would necessarily include a certification that no other modifications were made to the predicate tobacco product.³⁰

If these conditions are not met, a manufacturer should seek a marketing authorization through a different pathway, including the substantial equivalence or premarket tobacco product application pathways.

FDA Should Allow No More Than One Year for Effective Date

FDA has requested comments as to whether there should be a shorter effective date. The American Lung Association respects that section 907(d)(2) of the Tobacco Control Act states

* The word "minors" is directly from section 905(j)(3) of the Federal Food, Drug & Cosmetic Act; however, it is important to note that the federal minimum age for the sale of tobacco products has changed from 18 to 21.

that any regulation establishing a tobacco product standard may become effective one year after the date of publication of the final rule.³¹ The Lung Association would be strongly opposed to any attempts at extending the effective date beyond one year and urges FDA to be prepared to enforce the rule on the effective date. Additional delay, beyond one year, will increase the numbers of young people who experiment with flavored cigars and may become regular smokers, delay smoking cessation efforts by people who currently smoke cigars and worsen tobacco-related health disparities.

FDA has also requested comments on whether it should provide a sell-off period of 30 days after the effective date of a final rule. The Lung Association is firmly against authorizing a sell-off period. Retailers will have one year post publication of the final rule to sell off their inventory of flavored cigars and minimize any adverse financial impact of such removal. One year is sufficient time for retailers and thus, there is no justification for a sell-off period. Additionally, maintaining a single day for these products to no longer be manufactured, sold or distributed will reduce confusion for retailers and individuals who smoke flavored cigars.

A sell-off period will also make it harder to coordinate tobacco cessation campaigns.

Conclusion

The proposed rule to remove flavored cigars from the marketplace has the potential to save lives. Ending the sale of flavored cigars will reduce youth smoking initiation and prevent them from becoming regular smokers. It will also substantially increase smoking cessation among flavored cigar smokers. This will also help to reduce the unjust disparities in tobacco use, especially among the Black community, who have been so aggressively targeted by the tobacco industry. FDA should work with other entities noted above to help people end their addiction for good and not switch to another tobacco product.

The American Lung Association urges FDA to act by the end of 2022 to issue this lifesaving rule in final form. When finalized, we believe this product standard as well as the product standard removing menthol cigarettes from the marketplace will be the most significant actions taken by FDA in its 13-year history of regulating tobacco products.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Harold Wimmer". The signature is written in a cursive, flowing style.

Harold P. Wimmer
President and CEO

Appendix

The Lung Association submits the following documents for the docket that supplement our comments in support of the proposed rule to remove flavored cigars from the marketplace.

[Addressing Tobacco Use Among Black Communities Toolkit](#) (2022)

- A comprehensive toolkit that explores the racial injustices and health inequalities faced by the Black community concerning tobacco use, including use of menthol cigarettes.

[Lung Association's Black Men & Lung Cancer Report](#) (2010)

- This report provides a comprehensive discussion defining the impact of cancer-causing agents, primarily, but not limited to, inhaled tobacco on the development of lung cancer and its disproportional impact on the lives of Black Americans.

¹ National Cancer Institute. Smoking and Tobacco Control Monographs. Monograph 9: Cigars: Health Effects and Trends. 1998. NIH Pub No 98-4302.

² The National Academies of Sciences Engineering Medicine (2022). Health Effects of Premium Cigars. *Premium Cigars: Patterns of Use, Marketing, and Health Effects* (pp. 220).

³ Cullen, K.A., S.T. Liu, J.K. Bernat, et al., "Flavored Tobacco Product Use Among Middle and High School Students— United States, 2014–2018." *Morbidity and Mortality Weekly Report*, 68(39):839–844, 2019. Available at <http://dx.doi.org/10.15585/mmwr.mm6839a2>.

⁴ Manning, K.C., K.J. Kelly, M.L. Comello, et al., "Flavoured Cigarettes, Sensation Seeking and Adolescents' Perceptions of Cigarette Brands." *Tobacco Control*, 18(6):459–465, 2009. Available at <https://doi.org/10.1136/tc.2009.029454>

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

⁶ Huang L-L, Baker HM, Meernik C, Ranney LM, Richardson A, Goldstein AO. Impact of non-menthol flavours in tobacco products on perceptions and use among youth, young adults and adults: a systematic review. *Tobacco Control* 2016.

⁷ 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).

⁸ U.S. Centers for Disease Control (CDC), "Tobacco Product Use Among Middle and High School Students—United States, 2020," *MMWR*, 69, December 18, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf> (2020 National Youth Tobacco Survey).

⁹ Ambrose, BK, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *Journal of the American Medical Association*. 17, 1871-3, 2015, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6467270/>.

¹⁰ Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. *MMWR Surveill Summ* 2022;71(No. SS-5):1–29.

¹¹ Seidenberg, A.B., R.W. Caughey, V.W. Rees, et al., "Storefront Cigarette Advertising Differs by Community Demographic Profile." *American Journal of Health Promotion*, 24(6):e26–e31, 2010. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3086453/>.

¹² CDC, "Tobacco Product Use Among Middle and High School Students—United States, 2021," *MMWR* 71(5), March 11, 2022, <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

¹³ Chen et al. Age of Initiation of Cigarillos, Filtered Cigars and/or Traditional Cigars among Youth: Findings from the Population Assessment of Tobacco and Health (PATH) study, 2013–2017. *Plos One* 2020; <https://doi.org/10.1371/journal.pone.0243372>.

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

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

¹⁶ Gammon et al - National and State Patterns of Concept-Flavoured Cigar Sales, USA, 2012–2016 - TC 2018.

¹⁷ Edney, Anna. Tobacco Firms Save \$1 Billion with Kitty Litter in Cigars. *Bloomberg*. 1 Mar, 2013.

¹⁸ Robinson, Joelle N., et al. "Characteristics of Hookah Tobacco Smoking Sessions and Correlates of Use Frequency Among US Adults: Findings from Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study." *Nicotine & Tobacco Research: Official Journal of the Society for Research On Nicotine and Tobacco*, vol. 20, no. 6, 2018, pp. 731-740.

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- ¹⁹ World Health Organization, *Fact Sheet: Waterpipe Tobacco Smoking & Health*, 2015, https://apps.who.int/iris/bitstream/handle/10665/179523/WHO_NMH_PND_15.4_eng.pdf;jsessionid=CD4B4EF29B1513226BF554DF1700F5F7?sequence=1.
- ²⁰ Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," *MMWR* 71(5): 1-29, March 11, 2022, <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.
- ²¹ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
- ²² Ambrose BK, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014, *JAMA*; 2015, 314(17):1871-3.
- ²³ U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. 2012.
- ²⁴ CDC, "Hookahs." Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/. Accessed March 4, 2016.
- ²⁵ WHO, Advisory note: "Waterpipe tobacco smoking: health effects, research needs and recommended actions for regulators, 2nd Edition," 2015, <https://www.who.int/publications/i/item/advisory-note-waterpipe-tobacco-smoking-health-effects-research-needs-and-recommended-actions-by-regulators-2nd-ed>, at 40.
- ²⁶ The National Academies of Sciences Engineering Medicine (2022). Health Effects of Premium Cigars. *Premium Cigars: Patterns of Use, Marketing, and Health Effects* (pp. 220).
- ²⁷ L Rostron B, G Corey C, Holder-Hayes E, K Ambrose B. Estimating the Potential Public Health Impact of Prohibiting Characterizing Flavors in Cigars throughout the US. *Int J Environ Res Public Health*. 2019 Sep 4;16(18):3234. doi: 10.3390/ijerph16183234. PMID: 31487796; PMCID: PMC6765886.
- ²⁸ 87 Fed. Reg. at 26,426.
- ²⁹ FDA, *Tobacco Product Standard for Characterizing Flavors in Cigars, Docket No. FDA-2021-N-1309; Preliminary Regulatory Impact Analysis*, <https://www.fda.gov/media/158013/download>, at 36, 39.
- ³⁰ 21 C.F.R. § 1107.1(b).
- ³¹ H.R. 1256 – 111th Congress (2009-2010): Family Smoking Prevention and Tobacco Control Act. (2009, June 22). [PUBL031.PS \(congress.gov\)](https://www.congress.gov/bills/111/1256)