

September 27, 2012

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comment to Citizen Petition FDA-2011-P-0356

Dear Sir or Madam:

The Tobacco Control Legal Consortium is a non-profit organization of law and policy experts that serves as a respected legal resource for local, state, national and international health organizations and others. We appreciate the opportunity to comment on Petition No. FDA-2011-P-0356.

The Tobacco Control Legal Consortium supports the recommendations of this Citizen Petition to expand the FDA's jurisdiction over cigars. The Family Smoking Prevention and Tobacco Control Act of 2009 (the Act) gave the FDA broad regulatory authority over all tobacco products – including the authority to affirmatively assert jurisdiction over tobacco products not explicitly listed in the Act. The FDA's failure to assert jurisdiction over cigars and extend cigarette regulations to cigars has created a distinction between these products that has no logical public health justification. As the Petition explained, cigar smoke contains many of the same carcinogens and other disease-causing agents as cigarette smoke – posing risks of oral and throat cancers even in those cigar smokers who do not inhale and risks of disease to nonsmokers from exposure to secondhand smoke.¹ These characteristics, combined with the market shift that has occurred over the past couple of decades toward adolescent use of cigars,² make the continued exclusion of cigars from FDA regulation contrary to the goals of the Act.³

¹ Citizen Petition FDA-2011-P-0356-0014 (hereafter "Petition") at 6-7.

² *Preventing Tobacco Use Among Youth and Young Adults*, A Report of the Surgeon General, chapter 3, page 203 (2012) (hereafter Surgeon General Report 2012) (noting that "Historically, cigar smoking in the United States has been a behavior of older men, but the industry's increased marketing of cigars during the 1990s to targeted groups increased the prevalence of use among adolescents. Thus, the rise in the prevalence of cigar use during the mid-1990s was not limited to adults; instead, as documented by numerous local, state, and national surveys, cigar use and experimentation with this product have been widespread among both male and female adolescents.").

³ 111 P.L. 31 §3(1) (2009) ("The purposes of this division are -- [...] to ensure the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco.").

While national surveys conducted in the late 1980s and early 1990s observed the greatest prevalence of current cigar smoking among men in age groups between 35 and 65 and the lowest prevalence among men age 18-24,⁴ cigar smoking is now a behavior that skews younger, with young adults smoking cigars at a significantly higher rate (15.9%) than adults age 25-44 (7.2%), age 45-64 (4.9%), and age 65 or older (1.8%).⁵ Cigars are now the second most commonly used tobacco product among middle and high school students, with 3.5% of middle school students and 11.6% of high school students reporting cigar use in 2011.⁶ The prevalence of cigar use among high school males is now comparable to the prevalence of cigarette use, with 15.7% reporting use of cigars and 17.7% reporting use of cigarettes.⁷ This upward trend in youth cigar use is particularly striking for non-Hispanic black males, with cigar use increasing among middle and high school students in this subpopulation from 7.1% to 11.7% between 2009 and 2011.⁸

Effectively, the FDA's failure to regulate cigars creates a gaping loophole that is particularly troublesome in light of the tobacco industry's established practice of exploiting distinctions between tobacco products to avoid restrictions or taxes. In 2009, Congress passed an increase in the excise tax on small cigars, but not large cigars, in effort to address the issue of tobacco companies making cigarette-like small cigars to avoid the higher taxation of cigarettes.⁹ There is evidence that manufacturers, in response, engineered their cigars to be slightly heavier in order to pass over the weight threshold into the large cigar category and be subject to a lower tax scheme.¹⁰ Specifically, after the passage of the tax increase on small cigars, the cigar market dramatically shifted toward large cigars, with a 116% increase in the number of large cigars sold from 2008 to 2011, and a concomitant 85% decline in the number of small cigars sold.¹¹

Similarly, after the Act prohibited cigarettes with characterizing flavorings, at least some flavored cigarettes reemerged as flavored cigars. For example, Djarum clove cigarettes transitioned to clove cigars, and Sweet Dreams flavored cigarettes, to Sweet Dreams flavored cigars.¹² Such maneuvering is particularly concerning in light of a recently published report from the CDC that a substantial proportion, 42.8%, of adult cigar smokers report using flavored cigars. Even more troubling is the CDC's findings that there is a clear age gradient of flavored

⁴ National Cancer Institute, *Cigars: Health Effects and Trends*, Smoking and Tobacco Control Monograph No. 9., NIH Publication No. 98-4302 at 33, tab. 5 (1998) (*available at* http://www.cancercontrol.cancer.gov/tcrb/monographs/9/m9_2.PDF).

⁵ Brian A. King, Shanta R. Dube, & Michael A. Tynan, *Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009-2010 National Adult Tobacco Survey*, NICOTINE & TOBACCO RES. doi: 10.1093/ntr/nts178, 3, tab.1 (2012) (hereafter "King").

⁶ Centers for Disease Control and Prevention, *Current Tobacco Use Among Middle and High School Students – United States, 2011*, 61(31) MORBIDITY AND MORTALITY WKLY REP., 581, 582 (2012).

⁷ *Id.* at 584.

⁸ *Id.* at 582.

⁹ United States Government Accountability Office, *Tobacco Taxes: Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes*, 19-20 (April 2012) *available at* <http://www.gao.gov/assets/600/590192.pdf> (hereafter Government Accountability Office 2012).

¹⁰ Government Accountability Office 2012 at 20.

¹¹ Government Accountability Office 2012 at 19-20.

¹² Surgeon General Report 2012 at chapter 3, page 205.

cigars use, with 57.1% of 18-24 year old smokers reporting use of flavored cigars in comparison to 43.2% of smokers age 25-44, 28.9% of smokers age 45-64, and 13.4% of smokers over age 65.¹³ The CDC's findings that the prevalence of flavored cigar use among smokers decreases with age suggest that the tobacco industry is targeting its marketing of flavored cigars to younger persons,¹⁴ raising concerns regarding rates of cigar smoking not only among young adults, but also among youth. Moreover, the CDC report found that there are notable disparities in flavored cigar use across subpopulations of cigar smokers, with flavored cigar use higher among female than male cigar smokers (60.8% vs. 39.2%), higher among Hispanic than non-Hispanic white cigar smokers (61.7% vs. 37.9%), and higher among LGBT than heterosexual/straight cigar smokers (67.0% vs. 41.8%).¹⁵ These data illustrate that by failing to regulate cigars, the FDA is losing an opportunity to maximize the benefit from the regulations prohibiting flavored cigarettes – particularly among younger people and minority subpopulations.

To prevent similar circumvention, the FDA should regulate cigars without exception – extending the sales and distribution restrictions, flavoring requirements, warning label requirements, and other marketing restrictions to all cigars, regardless of labeling as small/little cigar, cigarillo, large cigar, or premium cigar. Just as the increasingly arbitrary distinction between cigarettes and cigars “creates confusion for tobacco retailers, consumers, and enforcement officials, misleads the public with regard to the health effects...and fails to reduce youth access to popular and dangerous tobacco products,”¹⁶ so too would a distinction between the various cigar products, which evade universal definition. To avoid confusion and the creation of further loopholes that would circumvent the stated goals of the Act and FDA's regulations, the FDA should quickly act to adopt the recommendations of the Petition for all cigar products.

The Tobacco Control Legal Consortium respectfully asks that the FDA consider these comments as it reviews Citizen Petition FDA-2011-P-0356.

Respectfully,



Maggie Mahoney, J.D.
Deputy Director
Tobacco Control Legal Consortium



Mike Freiberg, J.D.
Staff Attorney
Tobacco Control Legal Consortium

¹³ King at 3, tab.1.

¹⁴ King at 5 (noting that the variations in flavored cigar use by age are “consistent with research suggesting that the tobacco industry has selectively marketed flavored tobacco products to young adults”).

¹⁵ King at 3, Table 1; *id.* at 4-5 (in text).

¹⁶Petition at 2.