August 8, 2014

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

Re: Docket No. FDA-2014-N-0189, RIN 0910-AG38, Advanced Notice of Proposed Rulemaking seeking comments on Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations of the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Dear Sir or Madam,

I. BACKGROUND

Smoking continues to be the leading preventable cause of death and disease in the United States, killing an estimated 480,000 Americans each year, while millions more suffer from chronic disease.\(^1\) Since 1964, smoking has caused more than 20 million premature deaths; nearly 5 million in the past decade alone.\(^2\) Among Americans 35 years of age or older, smoking is responsible for 9 out of 10 lung cancer deaths, 6 out of 10 pulmonary disease deaths and 3 out of 10 coronary heart disease deaths.\(^3\) Moreover, if the existing rate of decline in smoking rates continues, an estimated 5.6 million youth (currently 0 to 17) will die prematurely from smoking related illnesses.\(^4\)

While current smoking-attributable mortality estimates only include deaths caused by cigarette smoking and exposure to secondhand smoke from cigarettes, cigars produce many of the same harmful effects. Cigars contain the same carcinogenic and toxic compounds as cigarettes – often in higher concentrations.\(^5\) Cigar smoking increases the risk of many of the same diseases as cigarette smoking, including, oral, esophageal, laryngeal, and lung cancer, coronary heart

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\(^2\) Id. at 7.
\(^3\) Id. at 675-677.
\(^4\) Id. at 12.
\(^5\) Michael B. Steinberg & Christine Delnevo, Tobacco Smoke by Any Other Name is Still as Deadly, 152 ANNALS INTERNAL MED. 259, 259 (2010).
disease, and chronic obstructive pulmonary disease (COPD). And, cigar smokers face comparable levels of risk for death and disease as cigarette smokers. In fact, the most popular cigar brands today closely resemble cigarettes and are designed to be inhaled; hence, most cigar smokers face the same risks as cigarette smokers.

That cigar smoking presents similar health risks as smoking cigarettes is of particular concern because recent data indicate youth and young adults are smoking cigars at nearly the same rate as cigarettes. Moreover, youth cigarette smoking rates continue to decrease, while cigar smoking rates have leveled off or even increased in recent years. The most logical explanation for the sustained popularity of cigars among youth despite decreasing cigarette smoking rates is simple: the tobacco industry has exploited the failure of federal, state and local governments to regulate cigars as rigorously as cigarettes. There are no federal manufacture, reporting, or sales and distribution regulations for cigars; unlike cigarettes, cigars may still be sold in candy and fruit flavors, singly, without health warnings and with no marketing restrictions. As a result, cigars remain a cheap and attractive alternative to cigarettes.

II. ACTION REQUESTED

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) of 2009 granted FDA the authority to regulate all tobacco products, including cigars. The statute expressly subjects cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco to FDA regulation; however, FDA must affirmatively assert jurisdiction over any other product meeting the statutory definition of “tobacco product,” such as cigars, before subjecting the product to regulation.

On May 9, 2011, the Legal Resource Center for Public Health Policy (formerly the Center for Tobacco Regulation, Litigation and Advocacy) led a group of fourteen public health organizations and officials in filing a Citizen Petition calling on FDA to assert jurisdiction over cigars, include cigars within its sales and distribution regulations, and prohibit the sale of flavored cigars. Nearly three years later, and five years after the passage of the Tobacco Control Act, FDA issued the Advanced Notice of Proposed Rulemaking (ANPRM), which proposes to deem all products “meeting the statutory definition of ‘tobacco product,’ except accessories of a proposed deemed tobacco product,” to be subject to Chapter IX of the Food, Drug and Cosmetic Act (FD&C Act). FDA also requested additional information and public

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7 Id.
8 See SGR 2014, supra note 1, at 707.
10 Id.
12 Tobacco Control Act, § 901, 123 Stat. at 1786 (codified at 21 U.S.C. § 387(a(b)).
13 The Petition, FDA-2011-P-0356/CP, requested additional regulation of cigars, including: imposing marketing restrictions on cigars and mandating textual and graphic warnings on cigar packages and advertisements. While the Legal Resource Center maintains that these additional regulations are critical to preventing youth access to and use of cigars, we do not address those issues in depth in this Comment. The Petition remains open and we encourage the Agency to consider all elements the Petition addresses.
comment on the proposed rule and the products subject to its provisions, including cigars. This letter is submitted in response to FDA’s ANPRM request for additional information.

The Legal Resource Center for Public Health Policy (LRC) respectfully requests that FDA deem all cigars, including premium cigars, as tobacco products subject to FDA authority under Chapter IX of the FD&C Act, as amended by the Tobacco Control Act. LRC also requests FDA draft, publish, and implement regulations prohibiting characterizing flavors in cigars, requiring direct, face-to-face transactions for the sale of cigars, and imposing minimum packaging requirements on non-premium cigars.

III. RESPONSE TO SPECIFIC QUESTIONS IN ANPRM

Question 1: As noted previously, given that different kinds of cigars may have the potential for varying effects on public health, FDA is proposing two options for the categories of cigars that would be covered by this rule. FDA is specifically seeking comment on whether all cigars should be subject to deeming and what provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars.

A. FDA should assert its jurisdiction over all cigars, including premium cigars, that meet the definition of “tobacco product” as defined by the FD&C Act

In determining whether to assert its “tobacco product” authority over additional products not specifically enumerated in the Tobacco Control Act, FDA only must ascertain whether the additional products meet the statutory definition of a tobacco product under the Food, Drug and Cosmetic Act (FD&C Act). The FD&C Act defines tobacco product as “any product made or derived from tobacco that is intended for human consumption.” All cigars, including premium cigars, meet this statutory definition of tobacco product. Therefore, FDA should deem all cigars, including premium cigars, as tobacco products subject to the Tobacco Control Act.

FDA suggests that because of the size, retail price, or frequency with which some users smoke premium cigars that these products should be exempt from federal regulation. However, irrespective of weight, the presence or absence of a filter, or retail price, cigars are addictive and may lead to serious health consequences, including cancer, COPD, and heart disease. Moreover, recent sales and use data indicate that despite a decades-long decline in total tobacco consumption, large cigar use (of which premium cigars are a subset) is increasing in prevalence. This increase in total consumption has been accompanied by a rise in youth and young adult cigar smoking rates. Although it may be appropriate to impose different restrictions on high-priced premium cigars, there is no public health rationale for excluding them from the deeming regulation. There is the real risk that if FDA fails to include premium cigars, the tobacco industry will creatively and aggressively exploit that loophole.

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14 Tobacco Control Act, § 906, 123 Stat. 1776 (codified as 21 U.S.C. 387a(b)).
17 Cigars: Health Effects and Trends, supra note 6.
Given the serious health risks associated with the use of all cigars (i.e. little cigars, cigarillos, small cigars, large cigars, and premium cigars), and the increasing prevalence of youth and young adult cigar smoking, FDA should assert jurisdiction over all cigars, and not exempt premium cigars.

i. All cigars are harmful and addictive and increasingly used by youth and young adults.

There is no question that cigar smoking presents many of the same health risks as cigarette smoking. Scientific data causally links regular cigar use to certain cancers, including oral, esophageal, and lung. Regular cigar smoking has also been found to significantly increase the risk of coronary heart disease and COPD. The 1998 National Cancer Institute (NCI) Monograph No. 9 categorically dismissed industry claims suggesting “cigar smokers experience little or no increased disease risk,” stating the assertions were not supported by scientific evidence. Rather, the larger size and longer smoking time of most cigars results in higher levels of exposure to tar, carbon monoxide, hydrocarbons, ammonia, and other toxic substances. Additionally, all cigars produce higher levels of carcinogenic nitrosamines than cigarettes. In light of these findings, NCI determined that “cigar smoke is as, or more, toxic than cigarette smoke.”

Without comprehensive regulations, like those governing the sale and distribution of cigarettes, cigar sales, including premium cigar sales, dramatically increased from 2000 to 2011. Total cigar consumption in the United States more than doubled during this period, from 6 billion to 14 billion per-cigarette equivalents. Large cigars, of which premium cigars (as defined in §1100.3 of the proposed rule) are a subset, increased from 3.8 to 12.9 billion per-cigarette equivalents, representing a sales increase of 233%. In contrast, total cigarette consumption declined each year from 2000-2011, and declined nearly one-third (32.8%) overall. The increase in total consumption of cigars, and large cigars in particular, coincided with an increase in youth and young adult cigar smoking rates. The 2012 National Youth Tobacco Survey (NYTS), a school-based questionnaire administered to U.S. middle and high school students, revealed that youth are smoking cigars at nearly the same rate as cigarettes. According to NYTS, 14% of high school students (grades 9-12) reported current use of cigarettes, compared to 12.6% for cigars. By contrast, in the 2006 survey (the last NYTS administered prior to enactment of the Tobacco Control Act), 19.7% of high school students reported current use of cigarettes, compared to 11.8% for cigars. Thus, while youth cigarette smoking rates declined by

19 Cigars: Health Effects and Trends, supra note 6.
20 Id.
21 Id.
22 Michael B. Steinberg and Christine Delnevo, Tobacco Smoke by Any Other Name is Still as Deadly, 152 Annals Internal Med. 259, 259 (2010).
23 Id. at 259.
26 Id.
27 Id.
28 Maryland Youth Tobacco & Risk Behavior Survey, Maryland Department of Health and Mental Hygiene, 1 (2013).
nearly one-third from 2006 to 2012, cigar smoking rates actually increased. Moreover, recent studies indicate that youth surveys may significantly underreport cigar smoking rates as a result of students failing to identify popular brands (i.e. Swisher Sweets, Black and Mild, etc.) as cigars.29

Young adult cigar smoking rates have experienced even more accelerated growth over the past decade. The National Adult Tobacco Survey (NATS) found that young adults (18-24) smoke cigars at a higher rate (15.9%) than a decade ago (11.2%) and at a significantly higher rate than adults age 25-44 (7.2%), 45-64 (4.9%), or 65 or older (1.8%).30 Furthermore, among 18-24 year old current cigar users, the percentage reporting premium cigar use (15.1%) exceeds the percentage reporting use of little filtered cigars.31

Youth tobacco use rates in Maryland mirror the national trend. In 2013, cigars surpassed cigarettes as the most popular tobacco product among high school youth.32 Current use of cigars was reported by 11.5% of high school youth, compared to 11.0% for cigarettes.33 In addition, nearly 2 out of 3 (63%) high school students’ using more than one tobacco product reported using cigars.34 Likewise, Maryland’s youth cigar smoking rates are at odds with continued declines in cigarette smoking and overall tobacco use. Between 2000 and 2013 the high school youth cigarette smoking rate declined from 23% to 11% and overall tobacco use declined from 29.4% to 17.7%.35 In contrast, the high school youth cigar smoking rate remained virtually unchanged between 2000 and 2013.36 In fact, several Maryland counties experienced significant increases in cigar smoking rates among underage high school youth.37

**ii. There is no justification for excluding premium cigars from the deeming provisions.**

Option 2 of the proposed regulation would exempt premium cigars from FDA authority under the Tobacco Control Act. The proposed rule defines premium cigars as any cigar: 1) wrapped in whole tobacco leaf, 2) containing 100% tobacco leaf binder and 3) primarily long filler tobacco, that 4) is made by manually combining the wrapper, filler and binder, 5) has no filter, tip or non-tobacco mouthpiece, 6) has a retail price of at least $10.00, 7) does not have a characterizing flavor other than tobacco, and 8) weighs more than 6 pounds per 1000 units.

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32 The Maryland Youth Risk Behavior Survey is given to select Maryland public schools with grades 6-8 or 9-12. The data cited here is from the 2013 Maryland Youth Risk Behavior Survey. See Maryland Youth Tobacco & Risk Behavior Survey supra, note 28.
33 Id.
34 Id.
35 Id.
36 Id.
37 Id.
The cigars subject to this exemption are large, expensive and generally sold at specialty tobacco shops, which are popular among men over the age of 18. As such, there may be valid reasons for adopting different regulations for premium cigars as opposed to youth-attractive products such as small and little cigars (i.e. minimum packaging requirements). However, there is no justification for excluding premium cigars from the modest mandatory manufacture, reporting, and sales and distribution regulations that would apply to the newly deemed covered tobacco products. Restricting free samples, prohibiting reduced risk claims without FDA approval, reporting product and ingredient listings, and preventing the sale of adulterated or misbranded products are not onerous provisions for those who manufacture and distribute premium cigars. Rather, deeming all cigars covered would create a uniform regulatory structure for all tobacco products; easing enforcement and reducing industry and consumer uncertainty over what types of products are subject to which regulations.

Conversely, as evidenced by industry measures taken after passage of the Tobacco Control Act, exempting premium cigars could lead the cigar industry to promote or market these products to youth or otherwise take advantage of the absence of regulatory oversight. Under the Tobacco Control Act, the sale of flavored cigarettes is prohibited and all cigarettes may be sold only in packages of at least twenty. In response to the Act, several cigarette manufacturers increased the weight of their products or added tobacco to the wrapper, taking the products outside the statutory definition of cigarette and circumventing the flavor ban, and minimum packaging and health warning label requirements. Subsequently, the sale of flavored and large cigars increased significantly, as did youth use rates of these products.

Manufacturers and retailers of premium cigars frequently contend that their products are primarily used by adults, who only smoke occasionally, and therefore do not present the same public health risk as cigarettes or small and little cigars. However, all cigars are potentially harmful and addictive and premium cigars generally contain more tobacco (and subsequently more toxic compounds) than small or little cigars. Also, though many premium cigar users may only smoke occasionally, the Surgeon General has conclusively determined that there is no risk free amount of exposure to tobacco smoke. Furthermore, recent data suggests that youth and young adults are increasingly using premium cigars. Regardless, the Tobacco Control Act requires FDA to weigh the risks and benefits of a proposed action to the population as a whole, including users and nonusers, and not just on youth. Applying this public health standard FDA must assert authority over premium cigars.

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41 Id.
45 Food & Drug Admin, supra note 16.
46 Tobacco Control Act, § 907, 123 Stat. 1776 (codified as 21 U.S.C. 387g(b)(1)).
FDA may regulate any product that meets the statutory definition of tobacco product. All cigars, regardless of size, meet this definition. Moreover, all cigars are addictive, cause disease and premature death, and are used increasingly by youth and young adults. No data indicate that premium cigars, as defined by the proposed rule, are less harmful than other cigars or present less of a public health problem than other cigars, and several surveys demonstrate increased premium cigar use by youth and young adults. Therefore, FDA should implement Option 1 and subject all cigars to the deeming provisions of the Tobacco Control Act.

B. All additional provisions of the proposed rule are appropriate for all cigars, including premium cigars.

All cigars, including premium cigars, meet the FD&C definition of tobacco product and therefore should be subject to the automatic “deeming provisions” of the Tobacco Control Act. In addition, FDA may invoke other authorities under the Tobacco Control Act and the proposed rule extends three additional provisions to the newly deemed tobacco products: (1) requiring a minimum age to purchase, (2) health warnings for product packages and (3) prohibiting vending machines outside of age-restricted establishments. FDA may adopt these additional restrictions on the sale and distribution of a tobacco product if “such regulation would be appropriate for the protection of the public health.” The so-called public health standard of review requires FDA to weigh the risks and benefits of the regulation on the population as a whole. Specifically, by determining whether the proposed regulation will increase or decrease the likelihood that existing users will stop using such products and that nonusers will start using the products.

Applying the public health standard FDA must extend the additional sales and distribution provisions to all cigars. Minimum purchase age requirements, health warnings for product packages and restrictions on vending machines are effective, evidence-based measures to reduce tobacco use and initiation rates. In 2009, the Tobacco Control Act adopted these provisions for cigarettes, smokeless tobacco and roll-your-own tobacco. Following enactment, youth tobacco use declined from 26% to 22% and cigarette smoking declined from 19% to 15.7%. Over the same period young adult cigarette smoking rates declined from 23.5% to 18%. Conversely, in the absence of federal sales and distribution restrictions cigar sales increased 123% between 2000 and 2011. In fact, total consumption of cigars increased nearly 20% in the three years immediately following passage of the Tobacco Control Act alone, suggesting that a lack of federal minimum age and warning label requirements may have had a direct effect on cigar sales.

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47 The FD&C Act subjects all deeming tobacco products to the following: “1) Enforcement action against products determined to be adulterated or misbranded; 2) required submission ingredient listing and reporting harmful and potentially harmful constituents (HPHCs) for all tobacco products; required registration and product listing for all tobacco products; 4) prohibition against use of modified risk indicators (i.e. “light,” “low” and “mild”) and claims unless FDA issues an order permitting their use; 5) prohibition on the distribution of free samples; and 6) premarket review requirements.” Federal Register, Vol. 79, No. 80 April 25, 2014 23143.

48 Federal Register, supra note 16 at 23144.

49 Tobacco Control Act, § 906, 123 Stat. 1776 (codified as 21 U.S.C. 387f(d)).


51 Id.

52 Id.
Moreover, all cigars are harmful and addictive; premium cigars do not present less of a public health threat because they are more expensive or used less frequently. The 2014 Report of the Surgeon General concluded that the “burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products.”

Eliminating the use of combustible tobacco products, including cigars, will greatly reduce the death and disease associated with tobacco products and increase public health. Sales and distribution restrictions are proven methods of reducing the use of all tobacco products, including combustible tobacco products such as cigars. Therefore, FDA must extend the minimum age, health warning and vending machine provisions to all cigars, including premium cigars.

**Question 2: The prohibition against characterizing flavors established in the Tobacco Control Act applies to cigarettes only. Consequently, when this regulation is finalized and other tobacco products are deemed subject to FDA’s tobacco product authority, the statutory prohibition against characterizing flavors will not apply automatically to those products. However, once they are deemed, FDA may establish a product standard prohibiting flavors in those products. FDA requests information and data that would support establishing such a standard.**

**A. FDA should extend the prohibition against characterizing flavors to all cigars.**

The Tobacco Control Act expressly prohibits the manufacture, distribution or sale of a cigarette or any of its component parts containing any characterizing flavor. Although the ban specifically applies to cigarettes, FDA may extend the ban to any tobacco product. Once this regulation is finalized and cigars are deemed subject to FDA’s tobacco product authority, the agency may prohibit flavors in cigars. FDA should take the additional step to prohibit characterizing flavors in cigars because (1) flavored cigar use is increasing, particularly among youth and young adults, (2) youth who smoke flavored cigars are more likely to become addicted to tobacco, (3) the tobacco industry is targeting young consumers with flavored brands, and (4) flavored cigars have the same harmful effects as regular tobacco products.

**i. Youth and young adults are far more likely to smoke flavored cigars.**

While cigarette consumption in the United States continues its six-decade decline, cigar consumption has increased in recent years. This growth is largely the result of surging flavored cigar sales. Between 2008 and 2011, convenience store revenue from cigar sales rose 30%, driven primarily by flavored cigar sales, which increased more than 50%. By 2011, flavored cigars made up more than half of all convenience store cigar sales. Little cigars, which are most popular among youth users, were even more closely tied to flavors, with approximately 80% of total sales comprised of flavored brands.

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53 SGR 2014, supra note 1 at 871.
54 Id.
57 Ctrs for Disease Control & Prevention, supra note 9.
59 Id.
60 Id.
Growth of the flavored cigar market is directly linked to the increasing prevalence of flavored cigar use among youth (age 12-17) and young adults (age 18-24). More than one-third (35.9%) of middle and high school youth who smoke cigars smoke flavored brands.\(^{61}\) Young adult cigar smokers report smoking flavored cigars at an even higher rate, with nearly 60% choosing flavored brands.\(^ {62}\) The prevalence of flavored cigar use, however, declines significantly with age. Young adults are three times more likely than 25-44 year olds (9.1% to 3.1%), five times more likely than 45-64 year olds (1.4%) and forty times more likely than adults 65 and older (.2%), to smoke flavored cigars.\(^{63}\)

Flavored cigar use by teens is particularly problematic in Maryland, where cigars have surpassed cigarettes as the most popular tobacco product among high school youth.\(^{64}\) Although the smoking rate (11.5%) in this demographic in Maryland is virtually identical to the national average (11.6%), flavored cigar use is significantly higher in Maryland.\(^{65}\) Nearly 75% of high school cigar users reported flavored cigar use, compared to slightly more than 33% in the most recent NYTS.\(^ {66}\) Likewise, more than half (55.5%) of Maryland middle school cigar users reported flavored cigar use, doubling the national average (21.4%).\(^ {67}\)

The percentage of youth who smoke flavored cigars is higher than either the NYTS or the Maryland Youth Tobacco & Risk Survey report. Several recent studies indicate that many students who acknowledge using popular (flavored) cigar brands such as Swisher Sweets, White Owl, and Cheyenne fail to identify these products as cigars.\(^ {68}\) For instance, the 2009 Virginia Youth Tobacco Survey found that nearly 6 out of 10 youth who smoke Black & Mild, a wildly popular line of flavored cigars, did not report current cigar use.\(^ {69}\) Supporting these findings, CDC determined that the top cigar brands preferred by youth and young adults “include flavorings, such as peach, grape, apple and chocolate.”\(^ {70}\)

**ii. Youth flavored cigar smokers are more likely to become addicted to tobacco.**

The increase in flavored cigar use by youth is especially troubling because young smokers are more sensitive to nicotine and therefore can become addicted to tobacco more quickly.\(^ {71}\) Nearly all daily tobacco users, including all flavored cigar smokers, began using tobacco before the age

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\(^{62}\) Id.

\(^{63}\) Id.

\(^{64}\) *Maryland Youth Tobacco & Risk Behavior Survey*, supra note 28 at 4.

\(^{65}\) Id.

\(^{66}\) Id.

\(^{67}\) Id.


\(^{69}\) *Cigar Use Misreporting Among Youth*, supra note 29.

\(^{70}\) SGR 2014, *supra* note 1 at 677.

of 18. Preventing a young person from initiating tobacco use prior to age 18 is the most surefire way to ensure that he will never start using tobacco during his lifetime.

Youth who smoke flavored cigars may be even more likely to become addicted than youth who smoke unflavored cigars. The fruit and candy flavored cigars “mask the natural harshness and taste of tobacco,” making these products easier for youth to use. Also, the 2011 NYTS found that among current cigar smokers, flavored cigar users were more likely to not think about quitting than regular cigar users.

iii. The cigar industry is targeting youth and young adult consumers with flavored cigar brands.

Congress recognized that tobacco manufacturers were using candy and fruit flavors to attract and addict youth users and imposed a ban on characterizing flavors in cigarettes. Yet cigars, which cause many of the same negative health effects as cigarettes, may still be sold in youth-enticing flavors such as chocolate, grape, peach, strawberry, vanilla, and watermelon. The tobacco industry, including many of the same powerhouse companies that lured kids with flavored cigarettes, has exploited this regulatory gap by targeting underage youth and young adults with inexpensive and sweetly flavored cigars.

Although a small percent of adult cigar smokers favor flavored brands, these products primarily appeal to youth. Sugar preference is strongest among youth and young adults – declining with age – meaning sweet flavors most strongly attract younger consumers. Tobacco manufacturers recognize that flavored products are more appealing to younger consumers and market products with this demographic in mind. The flavor chemicals in several popular cigar brands are structurally similar to the chemicals used in candy brands such as Jolly Rancher, Life Savers and Zotz, and drink mixes like Kool-Aid. In fact, some flavored tobacco products contain flavor chemicals at significantly higher levels per serving than candy and drink products. Since the 2009 federal ban on characterizing flavors in cigarettes, tobacco manufacturers have filled the void by marketing dozens of new flavors. Swisher Sweets – the largest cigar manufacturer in the United States – recently introduced summer twist, island madness and sticky sweet flavors to compliment the wine, grape, peach, white grape, menthol, and blueberry flavors added since 2010.

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72 Id.
73 Id.
78 Id.
iv. Flavored cigars have the same negative health effects as non-flavored tobacco products.

Cigar smoking is addictive and presents the same negative health effects as cigarette smoking. However, the perception of cigars and the negative health effects of cigar smoking vary dramatically from cigarettes. Underage youth perceive cigars in a more positive light than cigarettes.  

Cigars are viewed as more natural, less addictive, cheaper and better smelling, and cigar smoking is believed to be a safe alternative to smoking cigarettes. Despite flavor additives that assist in masking the harsh taste and odor of cigars, flavored cigars are as addictive and carry the same health risks as unflavored cigars. In fact, some flavors produce carcinogens when burned, potentially making flavored brands more harmful than unflavored brands. Moreover, youth and young adults perceive flavored cigars as less harmful than unflavored cigars.

In 2009, Congress prohibited characterizing flavors in cigarettes on the basis that they are attractive to youth and disguise the harsh taste of tobacco, yet are just as addictive and harmful as unflavored cigarettes. For these same reasons FDA should take the additional step and ban flavored cigars. Flavored cigars are as addictive and harmful as unflavored cigars, and are overwhelmingly used by youth and young adults, whose sugar preferences make these products more attractive.

Question 3: Aside from this proposed rule, what additional actions, if any, should the FDA take to address the sale of candy and/or fruit-flavored tobacco products to children and young adults?

Aside from the proposed rule, FDA should ban the sale of candy and fruit flavored cigars. As discussed above, the Tobacco Control Act authorizes FDA to adopt any tobacco product standard, including prohibiting characterizing flavors, which is “appropriate for the protection of the public health.” Flavored cigars present the same dangers as flavored cigarettes (i.e. appeal to youth, mask the harsh taste of tobacco, are as addictive as unflavored cigars, and have the same harmful effects as unflavored cigars), and therefore there is no justification for not extending the prohibition against characterizing flavors to cigars.

In addition to (or in the absence of) a ban on characterizing flavors in cigars, FDA should draft and publish regulations that would impose a minimum pack size for non-premium cigars and require direct, face-to-face exchanges for the sale or distribution of cigars.

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83 Cigar Use Misreporting Among Youth: Data from the 2009 Youth Tobacco Survey, supra note 29.
84 This comment is specifically tailored to address FDA regulation of cigars; however, LRC believes that the additional provisions discussed herein could and should also be applied to other non-cigarette tobacco products, such as smokeless tobacco and electronic cigarettes.
A. FDA must require direct face-to-face exchanges for the sale or distribution of cigars.

FDA requires tobacco retailers to sell cigarettes or smokeless tobacco in “a direct, face-to-face exchange without the assistance of any electronic or mechanical device.” The proposed rule, however, fails to extend this ban to include the sale of newly deemed tobacco products, such as cigars. Instead, the proposed rule would prohibit the sale of cigars in vending machines (with an exception for adult-only facilities) while permitting other self-service access to these products.

Direct, face-to-face transactions are central to a comprehensive tobacco regulatory scheme for two reasons. First, the retail community has repeatedly sought clarity and consistency in regulation of tobacco products. The proposed rule, however, establishes one set of regulations for cigarettes, cigarette tobacco and smokeless tobacco, and another, less stringent set of regulations for cigars, electronic cigarettes, hookah, and other covered tobacco products. This means that retailers must educate staff on two separate regulatory schemes and on which products are subject to each scheme. A difficult task, especially when many cigar brands so closely resemble cigarettes.

Likewise, state and local enforcement officials and community members that may report violations cannot reasonably be expected to effectively interpret the contradictory regulations.

Second, direct, face-to-face sales help retailers verify the customer’s age and prevent youth from shoplifting tobacco products. Preventing underage access to tobacco products is one of the prime objectives of the Tobacco Control Act and an efficient method of age verification is vital to this goal. By not requiring direct, face-to-face transactions FDA enables cigars and other tobacco products to be placed anywhere in the store, including at children’s eye level or next to candy or other children’s items. Exposure to tobacco product displays at the point of sale encourages children to see these products as harmless and increases the likelihood that children will experiment with tobacco products. These are lessons long ago learned with respect to cigarettes that are fully applicable to cigars.

In order to maximize the effectiveness of sales and distribution regulations and reduce youth access to cigars, cigarillos and little cigars FDA must require direct, face-to-face exchanges for the sale of all cigars.

B. FDA must establish minimum packaging requirements for non-premium cigars.

FDA prohibits the sale of individual cigarettes and instead requires cigarettes be sold in packages of at least twenty. Despite the growing evidence-base that concludes cigars are as addictive and harmful as cigarettes and are increasingly used by young people, the proposed rule does not...

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86 C.F.R. § 1140.14(a)(3); the regulation permits the sale of cigarettes, cigarette tobacco and smokeless tobacco through vending machines and self-service displays in adult-only facilities where no one under the age of 18 is permitted to enter.
establish any minimum packaging requirements for cigars. In order to restrict youth access to cigars, FDA must establish minimum packaging requirements for cheap, flavored brands. Premium cigars, as defined by FDA in the proposed rule, may be exempt from any packaging requirements, because the price (at least $10.00 at retail) makes it unlikely that youth will access these products.

Underage youth are extremely price sensitive and therefore attracted to cheap, single cigars. As discussed above, while cigarette sales continue to decline, the sale of cigars generally, and cheap and flavored cigars specifically, has actually increased in recent years. In Maryland, a single, flavored cigar may be sold for less than a dollar – as little as one-sixth the cost of a pack of cigarettes. The lower price point makes cigars more attractive to underage youth and has contributed to cigar smoking surpassing cigarette smoking among public high school students in Maryland. Requiring minimum pack sizes for non-premium cigars will help restrict youth access to these products while still permitting adults to lawfully purchase them at retail tobacco establishments. Accordingly, FDA should draft and publish minimum packaging requirements for non-premium cigars.

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