IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, PREMIUM CIGAR ASSOCIATION, and CIGAR RIGHTS OF AMERICA	)
Plaintiffs	)
v.	) Civ.Action No.1:16-cv-1460-APM
UNITED STATES FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX AZAR, in his official capacity as Secretary of Health and Human Services Office of the Secretary, and STEPHEN HAHN, M.D., in his official capacity as Commissioner of Food and Drugs	)
Defendants	)

MOTION OF AMICI CURIAE PUBLIC HEALTH ORGANIZATIONS FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF IN OPPOSITION TO THE PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT OR A PRELIMINARY INJUNCTION AND IN SUPPORT OF THE MOTION OF THE DEFENDANTS FOR PARTIAL SUMMARY JUDGMENT

Pursuant to D.C. District Court Rule 7(c) the American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids and Truth Initiative (collectively, "Public Health Organizations" or "Amici Curiae") seek leave to file the attached amicus curiae brief. Amici Curiae are non-profit organizations working to protect the public from the devastating harms caused by tobacco products, the leading cause of preventable death in America. Each of the Public Health Organizations works to educate children and adults about the health hazards of cigars and regularly engages with the U.S. Food and Drug Administration ("FDA) to ensure that its regulation of the tobacco industry, including manufacturers and sellers of all cigars, promotes public health and adheres to the requirements of law.

The Public Health Organizations have long been engaged in efforts to require the FDA to fulfill its statutory obligation to require cigar manufacturers to file premarket applications pursuant to the Tobacco Control Act as a condition of being permitted to continuing market cigars that are New Tobacco Products. To accomplish this objective, Public Health Organizations, together with several pediatricians who regularly treat adolescents suffering from the effects of exposure to tobacco products, and advise their patients regarding the consequences of the use of these products, brought suit in the United States District Court for the District of Maryland (*American Academy of Pediatrics v. FDA,* Civ. Action No. 18-883) and obtained orders from that court that would require cigar manufacturers to file premarket applications for cigars that are new tobacco products by May 12, 2020 as a condition of being permitted to market such cigars. 379 F. Supp. 3d 461, 399 F. Supp. 3d 479 (D. Md. 2019) Those orders are the subject of a pending appeal before the United States Court of Appeals for the Fourth Circuit that is currently being briefed and is scheduled for oral argument on March 18, 2020. (Case. No. 19-2130). The Public Health Organizations have a strong interest in the Motions pending before this Court because the relief Plaintiffs in this case seek would conflict with the orders granted by the U.S. District Court for the District of Maryland. Amici Curiae have previously been granted leave to file amicus curiae briefs in this case but have not briefed the issues currently before this Court.[1]

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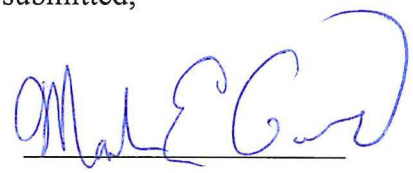
[1] Amici filed a brief supporting summary judgment dismissing plaintiffs' claims that the disclosure requirements imposed by the deeming rule on cigars violate the First Amendment (October 31, 2017), ECF 76; and a brief opposing the amendment of the Complaint to add a claim for declaratory relief seeking to exempt cigars from the remedial order entered by the federal court in *AAP v. FDA* (July 26, 2019), ECF 141-1. The Amici Organizations also filed an amicus brief in the U.S. Court of Appeals for the D.C. Circuit in support of Appellees in the pending appeal of this Court's order upholding application of the warning labels in the deeming rule to cigars as consistent with the APA, the Tobacco Control Act and the First Amendment (May 6, 2019), Document #1786306.

The Amici Curiae have a perspective distinct from that of Defendants, who were the opposing party in the litigation in the U.S. District Court for the District of Maryland and who have appealed from the judgment of that Court.

The Defendants have consented to the filing of this Amicus Curiae Brief. Counsel for Amici Curiae requested the consent of the Plaintiffs but Plaintiffs' Counsel did not reply.

Accordingly, the Public Health Organizations hereby request leave to file the attached Amicus Curiae Brief. A proposed order granting leave to file is attached.

Respectfully submitted,



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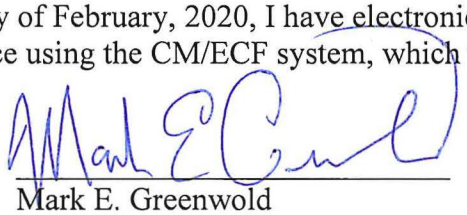
February 10, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this tenth day of February, 2020, I have electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF system, which will send a notice of filing to all counsel of record.



Mark E. Greenwold
Counsel for Amici Curiae

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, PREMIUM CIGAR ASSOCIATION, and CIGAR RIGHTS OF AMERICA	)	
Plaintiffs	)	
v.	)	Civ.Action No.1:16-cv-1460-APM
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Defendants	)	

ORDER

It is hereby ordered that the Motion of Public Health Organizations to file a brief Amicus Curiae in Opposition to the Plaintiffs' Motion for Partial Summary Judgment or a Preliminary Injunction and in Support of the Motion of the Defendants for Partial Summary Judgment.

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AMIT P. MEHTA

United States District Court Judge

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, PREMIUM CIGAR ASSOCIATION, and CIGAR RIGHTS OF AMERICA	)	
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BRIEF OF AMICI CURIAE PUBLIC HEALTH ORGANIZATIONS IN OPPOSITION TO THE PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT OR A PRELIMINARY INJUNCTION AND IN SUPPORT OF THE MOTION OF THE DEFENDANTS FOR PARTIAL SUMMARY JUDGMENT

CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Amici curiae are non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 19(a)(4)(E) AND LOCAL CIVIL RULE 7(o)(5)

Counsel for amici curiae hereby states that no counsel for any party to this litigation authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund, or did fund, the preparation or submissions of this brief; and no person, other than amici curiae, contributed money that was intended to fund, or did fund, the preparation or submission of this brief.

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IDENTITY AND INTEREST OF THE AMICI

The *Amici* are the American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids and Truth Initiative,[1] (collectively "*Amici*"), non-profit organizations working to protect the public from the devastating harms caused by tobacco products, the leading cause of preventable death in America. Amici work to eradicate tobacco addiction and to prevent the creation of new generations of addicted children and adults. Their work includes educating children and adults about the health hazards of cigars and engaging with the U.S. Food and Drug Administration ("FDA") to ensure that its regulation of the tobacco industry, including manufacturers and sellers of all cigars, promotes the public health and complies with law. Amici have an interest in ensuring the proper functioning of the mandatory statutory process for premarket review of new tobacco products, including substantial equivalence review, to ensure that such new products do not exacerbate the health risks of tobacco products. Amici also are plaintiffs in *American Academy of Pediatrics v. FDA* ("*AAP v. FDA*"), in which they obtained a federal court order vacating the FDA's 2017 Guidance suspending the operation of premarket review for several years for cigars and e-cigarettes and a remedial order establishing new deadlines for submission of premarket applications and for FDA review of those applications.[2] Amici have a strong interest in opposing the relief sought by the plaintiffs here, which would effectively nullify the orders entered by the Maryland federal court.

INTRODUCTION AND SUMMARY OF ARGUMENT

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[1] A description of the amicus organizations is provided in the Appendix to this amicus brief.
[2] *American Academy of Pediatrics v. FDA,* 379 F. Supp. 3d 461, 399 F. Supp. 3d 479 (D. Md. 2019), *appeal docketed*, No. 19-2130 (4th Cir. Oct. 18, 2019).

Plaintiffs ask this Court to invalidate the Final Deeming Rule promulgated nearly four years ago pursuant to the Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. 111-31, codified at 21 U.S.C. § 387-387u ("Tobacco Control Act" or "TCA") after an extensive notice-and-comment rulemaking, and to enjoin the enforcement of the premarket review and substantial equivalence process against cigars and pipe tobacco. The remedy Plaintiffs seek would postpone for many more years the implementation of the premarket review provisions Congress found necessary to protect the public health in 2009 and would consign untold thousands of young people to nicotine addiction and tobacco-related disease. As Congress found in enacting the Tobacco Control Act, "[i]t is essential that manufacturers prior to the marketing of [tobacco] products, be required to demonstrate that such products will meet a series of rigorous criteria..." 123 Stat. at1779, § 2 (36). In the more than ten years since enactment of the TCA, FDA's inaction has allowed a flood of cheap, flavored cigars virtually indistinguishable from cigarettes and marketed to children without the premarket review required by the TCA, resulting in a proliferation of cigar use by youth to the detriment of public health. The May 12 deadline for premarket applications set by a coordinate federal court in *AAP v. FDA* and FDA's Guidance of January 2, 2020 (ECF 179-1) recognizing the applicability of that deadline to cigars would finally provide the long-delayed public health protection envisioned by the statute. This Court should not prevent these important public health provisions from becoming effective.

Today's cigars are designed to attract young people: they bear little resemblance to traditional cigars and many are almost indistinguishable from cigarettes.[3] They come in youth-

[3] See, Campaign for Tobacco-Free Kids, *Not Your Grandfather's Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids* (Mar. 13, 2013), A.R. 154,646-154,679https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf.

friendly flavors and they are advertised and marketed to attract youth. They are every bit as addictive as cigarettes and the tobacco they contain has the same carcinogens and toxins as cigarette tobacco. Today more high school students use cigars than cigarettes[4] and unless and until FDA implements premarket review, as the TCA requires, this scourge will continue.

Unless a cigar was commercially marketed on February 15, 2007 (the "grandfather date"), it is a "new tobacco product" under the TCA and cannot be marketed unless FDA grants an application for a marketing order upon a finding that the new product is "substantially equivalent" to a product marketed on the grandfather date.[5] The large majority of the most egregiously kid-oriented cigars were introduced after February 15, 2007 and are unlikely to be found substantially equivalent to grandfathered products.

Although cigars have been subject to FDA jurisdiction since August 2016 and the original deadline for submission of premarket review applications of February 2018 is long past, manufacturers have been permitted to keep new products on the market without applying for marketing orders. After years of delay, cigar manufacturers now will have to submit applications for premarket review by May 12, 2020 in order to continue marketing non-grandfathered cigars. Requiring manufacturers to file premarket applications will provide FDA, for the first time, with detailed information about new cigar products and enable it to allow market access only to those products that do not increase the risk of addiction and disease.

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[4] U.S. Dep't of Health and Human Services, Center for Disease Control and Prevention, Tobacco Product Use and Associated Facts Among Middle and High School Students in the U.S. Morbidity and Mortality Weekly Reports, Dec. 6, 2019. https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm. ("CDC, Tobacco Product Use 2019").

[5] The other principal pathway to market is through a finding that the product is "appropriate for the protection of the public health" and all parties concede that no cigars or other combusted tobacco products are likely meet this standard.

This Brief will establish that cigar smoking is a significant public health concern. (Sec. I) Next, it will argue that the relief sought by Plaintiffs should be denied because it would conflict with and require FDA to disobey the orders of a coordinate federal district court. (Sec. II) It will then demonstrate that the FDA's Deeming Rule asserting jurisdiction over all cigars was a valid exercise of its authority under the TCA and the Administrative Procedure Act ("APA"). (Sec. III) It will also explain why the FDA's issuance of an Advanced Notice of Proposed Rule Making ("ANPRM") regarding premium cigars does not provide a basis for delaying the enforcement of premarket review for all new cigars beyond May 12, 2020 (Sec. IV) and that the reasons underlying this Court's orders enjoining the requirement of warning labels on premium cigars have no bearing on the enforcement of premarket review as to all cigars as of that date. (Sec. V)

I. Cigar Smoking Is a Significant Public Health Concern.

A. Cigar Smoking Has Serious Adverse Health Impacts for Both Adults and Youth.

As the Supreme Court has observed, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). This observation is no less true of cigars than other tobacco products. In promulgating the Deeming Rule, FDA cited extensive evidence and numerous scientific studies establishing that cigar smoking presents a significant public health risk to both minors and adults. 81 Fed. Reg. at 29,020-27 and notes 68-83, May 10, 2016. As FDA found, "[all] cigars pose serious negative health risks." 81 Fed. Reg. at 29,020. In 2010 alone, regular cigar smoking was responsible for "approximately 9,000 premature deaths." *Id.* Furthermore, as FDA found, "all cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users" as well as other adverse health effects, such as "increased risk of heart and pulmonary

disease," "a marked increase in risk for chronic obstructive pulmonary disease (COPD)," a higher risk of death from COPD, and "a higher risk of fatal and nonfatal stroke." *Id.*

Cigar smoke also contains the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds. *Id.* Cigars also produce significantly more secondhand smoke than cigarettes, which causes heart disease and cancer in nonsmokers.[6] Compared to a cigarette, a large cigar emits 20 times the carbon monoxide, five times the respirable particles, and twice the amount of carcinogenic polycyclic aromatic hydrocarbons.[7]

Cigars also deliver powerfully addictive doses of nicotine. *Id.* at 29022. "[A] cigar can contain as much tobacco as an entire pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette" and can cause dependence even if the smoke does not inhale. *Id.*

Use of cigars by children raises particular public health problems. As the FDA explained, while it "remains concerned about the use of all tobacco products, particularly combusted products like cigars and cigarettes... [it] remains most concerned about use by youth and young adults given their unique susceptibility to the addictiveness of nicotine." *Id.* at 29,023. ("[N]icotine exposure during adolescence may have lasting adverse consequences for brain development.") 81 Fed. Reg. at 28,981, 29033. In fact, according to the U.S. Surgeon General, tobacco product use is started and established primarily during adolescence[8] and Congress found,

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[6] HHS, *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*, HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2006, p.11, 484, 532; National Cancer Institute, *Cigars: Health Effects and Trends*. Smoking and Tobacco Control Monograph No. 9., National Institutes of Health, National Cancer Institute, 1998, p.87-93, 97

[7] Baker, F, et al., "Health Risks Associated With Cigar Smoking," *Journal of the American Medical Association* 284(6):735-740, 2000, at 738.

[8] U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, 2012.

in enacting the TCA that "virtually all new users of tobacco products are under the minimum legal age to purchase such products." Pub. L. 11-31, §2(4).

B. The Long History of Misleading Tobacco Product Marketing and Marketing to Children.

The high prevalence of cigar smoking among youth is no accident. When Congress enacted the TCA, it found that "advertising, marketing and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of these products by youth." *Id.* at § 2(15). Cigars, like cigarettes and other tobacco products, have been the subject and beneficiary of decades of misinformation, both by affirmative deception and misleading omission. As the FDA noted when seeking comments on the proposed Deeming Rule, the Federal Trade Commission has found numerous cigar manufacturers to have engaged in deceptive and unfair marketing practices. 79 Fed. Reg. 23,143, 23,164 (Apr. 25, 2014) (citing seven "consent orders resolving allegations that failure to disclose the adverse consequences of cigar use was deceptive and unfair.")

As a result of this long history of consumer deception, "many people inaccurately think cigars are safe alternatives to cigarettes." 79 Fed. Reg. 23,158. As the FDA explained:

> Research suggests that youth perceive cigars in a more positive light than cigarettes and believe cigars are more natural and less harmful; and some do not realize that cigars contain nicotine. In addition, in a focus group of African-American youth aged 14 to 18, researchers found that the participants were not well versed in the harms caused by smoking cigars... In fact, the study found that youth had received very little cigar-specific health education...
>
> Use of cigar products by youth and young adults is no longer an alternative to cigarette use, but rather is now the primary tobacco product of choice in certain urban and suburban areas. One study also showed that adult cigar smokers believe, mistakenly, that switching from cigarettes to cigars reduces a smoker's chance of illness, with former cigarette smokers most likely among cigar smokers to believe that cigars are a safer alternative.

Id. (citations omitted)

C. The Tobacco Industry's Recent Focus on Kid-Friendly Cigars and Youth Marketing.

Under the TCA, the essential difference between a cigarette and a cigar is that a cigar contains tobacco in the wrapper, while a cigarette does not. *See* 15 U.S.C. 1332(1)(a) (defining "cigarette"); 21 CFR 1143.1 (defining "cigar"). The tobacco industry has a long history of reformulating cigars or changing their marketing to allow sale of cigarette-like products in the wake of regulation. To circumvent the FDA's ban on fruit- and candy-flavored cigarettes that appealed to kids, some cigarette makers added tobacco to the wrapper and weight to their products so that they meet the definition of small or large cigars, despite being sold in packs of 20 like cigarettes.[9] And some flavored cigarettes were simply remarketed after the TCA as cigars: the product marketed as "Sweet Dreams" clove flavored cigarettes before the TCA was enacted re-emerged as "Sweet Dreams" cigars afterwards.[10] To illustrate the nature of these products, a picture showing Cheyenne brand "cigarettes" and "cigars" is attached as Exhibit 1.

The TCA prohibited the marketing of flavored cigarettes other than menthol. 21 U.S.C. 387g(a)(1). Cigar manufacturers responded by dramatically increasing the production of flavored cigars, transforming the cigar market. Today, cigar manufacturers produce flavored cigars by the billions, lacing them with sugary flavors from candy to chocolate to lemonade and giving them names like "Purple Haze," "Hush Honey," or "Banana Split."[11] As FDA found, young people are far more likely than older smokers to prefer flavored cigars. *See* 79 Fed. Reg. at 23,146 ("Research has shown that sugar preference is strongest among youth and youth adults and declines with age.") As one cigar manufacturer has acknowledged, "it is mainly new recruits to cigar smoking who take to the new flavors," and it has long been the case that "new recruits" are

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[9] "Not Your Grandfather's Cigar, supra, note 3 at iii.
[10] Report of the Surgeon General, *supra,* note 9 at 205 (2012).
[11] "Not Your Grandfather's Cigar," supra, note 3 at 19.

disproportionately minors.[12] *See, e.g.* 79 Fed. Reg. at 23,155 ("Virtually all new users of most tobacco products are youth...") *See supra* note 3 at 7 (quoting a tobacco industry publication acknowledging, "While different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers.") One study cited by the FDA found that according to a focus group of 14 to18-year-olds, "cigars were easy to obtain," "new brands were targeting youth," and "the products were prominent in rap videos." 79 Fed. Reg. at 23,158.

As the cigar industry shifted toward the youth market cigar sales skyrocketed, Overall cigar sales in 2018 were more than twice the 2000 level.[13] And dollar sales of flavored cigar products increased by nearly 50 percent between 2008 and 2015, increasing flavored cigars' share of the overall cigar market to 52.1 percent in 2015.[14] That time also witnessed an explosive growth in kid-friendly flavors such as "Berry Fusion," "Maui Pineapple," "Banana Smash," and strawberry kiwi. The number of unique cigar flavor names more than doubled, from 108 to 250, during this period.[15] Spurred by flavors, cigar usage among high school students now exceeds cigarette usage.[16] According to the 2014 National Survey on Drug Use and Health, more than 2,500 persons under the age of 18 smoke their first cigar each day. 81 Fed. Reg. at 28,985 (*see also* 79 Fed. Reg. at 23,156 (reporting that more than one million people between the ages of 12 and 18 initiated cigar use in 2010)).

D. Subjecting Cigars to Premarket Review is Critical to Curbing the Public Health Impact of Cigars, Particularly Among Youth.

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[12] See Comments of J.C. Newman Cigar Company to the Proposed Deeming Rule (Dkt. No. FDA-214-N-01898) (Aug. 8, 2014) at 52.
[13] US Alcohol, Tobacco Tax and Trade Bureau ("TTB"), Tobacco Statistics.
[14] Delnevo, CD et al., Changes in the Mass Merchandise Cigar Market Since the Tobacco Control Act, Tobacco Regulatory Science 3 (2 Suppl. 1):S8-S16 (2017)
[15] *Id.*
[16] U.S. Dep't of Health and Human Services, CDC, *supra*, note 4.

Contrary to plaintiffs' unsupported speculation (Pl. Br. at 4) there is no indication in the Tobacco Control Act that mandatory premarket review was intended by Congress to respond only to the public health risks of new types of cigarettes. Indeed, Congress explicitly gave FDA authority to extend its jurisdiction to "any other tobacco products that the Secretary by regulation deems to be subject to this chapter," 21 U.S.C. 387a(b), and provided that "new tobacco products," meaning "(A) any tobacco product ... that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, ... or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified produce was commercially marketed in the United States after February 15, 2007," are subject to FDA pre-market review. 21 U.S.C. 387j(a). Congress thus recognized that new versions of other tobacco products, including cigars, could cause similar risks.

FDA deemed cigars subject to the Tobacco Control Act by issuing the Deeming Rule pursuant to an extensive notice-and-comment rulemaking. 81 Fed. Reg. 28,974, May 10, 2016. Cigars introduced or modified after the grandfather date of February 15, 2007 are "new tobacco products" and manufacturers are required to submit reports demonstrating that their products are "substantially equivalent" to products that were on the market on the grandfather date.[17] The statute defines "Substantial equivalence" and sets forth the procedure for establishing substantial equivalence. 21 U.S.C. § 387e(j), 387j(a)(3). In order to have a product found "substantially equivalent" a manufacturer must demonstrate that the product has "the same characteristics" as a grandfathered product or, if it has different characteristics, that it nevertheless does not "raise

[17] Plaintiffs themselves recognize that "the primary pathway" to a marketing order for cigars is the substantial equivalence process. Pl. Br. at 1.

different questions of public health." *Id.* § 21 U.S.C. j(a)(3)(A). The purpose of the substantial equivalence process is to prevent changes in tobacco products that increase the appeal, addictiveness or toxicity of tobacco products so as to create new risks to public health. As the D.C. Circuit recently observed in *Nicopure Labs, LLC. v. FDA,* "Congress...took the then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health." 944 F.3d 267 at 271 (D.C. Cir. 2019).

A large number of cigar products introduced subsequent to February 15, 2007 are the cheap flavored cigars similar to cigarettes that are driving cigar smoking among youth. These products are unlikely to have the "same characteristics" as grandfathered cigars or raise no new questions of public health. However, the injunction sought by the plaintiffs would continue the regulatory "holiday" enjoyed by cigar manufacturers, *AAP v. FDA,* 379 F. Supp. 3d at 493, allowing the continues sale of cigars that could not survive the scrutiny mandated by Congress.

II. The Relief Plaintiffs Seek Would Conflict With and Require FDA to Disobey the Order of a Coordinate Federal Court.

FDA's January 2, 2020 Guidance makes it clear that cigar manufacturers will be required to submit marketing applications by the May 12 application deadline set by order of the U.S. District Court for the District of Maryland or be subject to FDA enforcement actions. Any order of this Court prohibiting the enforcement of the May 12 deadline would place FDA in conflict with its obligation to obey that order. This Court has previously rejected plaintiffs' request for declaratory relief to accomplish the very same objective on the ground that

> "an order granting the relief plaintiffs seek would be tantamount to permitting a collateral attack on the AAP court's order, which this court cannot do. FDA remains bound by the AAP court's decision unless and until an appeal overturns the decision and this court cannot issue a declaration that alters that reality. . . .Because Plaintiffs delayed in raising their issues before the AAP court, their conduct weighs against granting the extraordinary relief they now seek."

Order of October 18, 2019, ECF-158 at 2-3.

The order Plaintiffs seek would have precisely the same impermissible effect as the order this Court declined to issue on October 18, 2019 and should be rejected for the same reasons.

III. FDA's Application of the Tobacco Control Act's Premarket Review Requirements to All Cigars Is Consistent with Both the TCA and the APA.

Plaintiffs ask this Court to invalidate the Deeming Rule so that they can continue to market their lethal and addictive products with no effective regulatory control. Perhaps not surprisingly, their brief is devoid of any recognition that the purpose of the TCA is to protect the public health against products such as cigars that are both addictive and lethal. Yet the extensive statements of purpose in the TCA make it clear that the purposes of the Act were to protect the public health from the harm caused not only by cigarettes, but by all tobacco products.[18] Congress gave FDA broad authority to deem tobacco products subject to the Act, and as early as mid- 2010, FDA announced that it would do just that.[19] Thus, years before the Deeming Rule was promulgated manufacturers were made aware of FDA's intention. When FDA eventually proposed the Deeming Rule and again when it issued the Final Deeming Rule, FDA provided extensive documentation supporting its jurisdiction over cigars. 79 Fed. Reg. 23,150-59, (2014), 81 Fed. Reg. at 29,020-27. In upholding the validity of the Deeming Rule against a challenge by e-cigarette manufacturers, the U.S. District Court for the District of Columbia held that FDA's decision to subject tobacco products to the TCA should be treated with great deference. *Nicopure Labs LLC. v. FDA,* 266 F. Supp. 3d 360 at 368, 393 (D.D.C. 2017), *aff'd*, 944 F.3d 267

[18] "A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious health effects." Pub. L. 111-31.

[19] Office of Management and Budget, Unified Regulatory Calendar, showing FDA's intention to issue a proposed rule deeming cigars subject to the TCA. Exhibit 2.

(D.C. Cir. 2019). The same deference is due to the FDA's decision to subject new cigar products to the TCA.

A. The Premarket Review Provisions of the Deeming Rule are Consistent with the Tobacco Control Act and the Administrative Procedure Act

Plaintiffs argue that application of the premarket review provisions of the TCA to cigars is inconsistent with the TCA and the Administrative Procedure Act ("APA"). To the contrary, as D.C. Circuit has held, the premarket review provisions of the TCA are mandatory for all products subject to the TCA. 944 F.3d at 281 ("It was Congress, not the FDA, that imposed [the premarket review] requirement on new tobacco products…") Once the Secretary of HHS makes the decision to deem a tobacco product subject to the Act "the requirement of premarket review is established by statute." 266 F. Supp. 3d at 396. As the D.C. Circuit observed, "the industry's …objection is to Congress' design, not to any arbitrariness in FDA's part in carrying it out." 944 F.3d at 281.

Plaintiffs argue that use of the statutory February 15, 2007 date in determining whether a product is grandfathered was arbitrary and capricious in violation of the APA, 5 USC 701. Pl. Br. at 27. On the contrary, as FDA concluded after extensive discussion in the Deeming Rule, the date is unambiguously prescribed by statute and any deviation from it would have violated the law. 81 Fed. Reg. 28,999. As the district court explained in *Nicopure*, "the statute unambiguously specifies a date – February 15, 2007 – and it contains no exceptions for items deemed to be tobacco products in the future." 266 F.Supp.3d at 398-99.

Plaintiffs point to other regulatory authorities given FDA by the TCA, such as the authority to issue product standards or to regulate advertising and marketing, as reasons for curtailing premarket review. Pl. Br. at 30. However, nothing in the statute suggests that these authorities were intended as substitutes for premarket review or that they render premarket

review optional. The premarket review provisions of the statute are intended to limit introduction of new tobacco products to those that FDA determines are appropriate for the protection of the public health or substantially equivalent to products already on the market as of the date specified in the statute. Product standards, advertising restrictions and other statutory provisions are designed to meet different regulatory needs and to function in addition to—not instead of—the requirement that no new product can be introduced in the absence of FDA review.

B. Application of the Substantial Equivalence Requirement Would Prohibit the Marketing of Many of the Most Egregiously Child-Oriented Cigars Introduced After the Grandfather Date.

Incredibly, Plaintiffs argue that FDA "did not identify a practice or problem in the cigar industry that premarket review would detect and cure." Pl. Br. at 5. On the contrary, the extensive discussion in both the proposed and final deeming rules of the reasons why FDA asserted jurisdiction over cigars demonstrates that premarket review is essential to identify and eliminate the new generation of cigars introduced since the enactment of the statute in 2009 that have addicted millions of young people and made cigar smoking more prevalent than cigarette smoking among high school students nationwide. *See, e.g.,* 81 Fed. Reg. at 29,020-27. As noted above, after the TCA prohibited the marketing of flavored cigarettes other than menthol, cigar manufacturers filled the unregulated gap created by the prohibition on flavored cigarettes by introducing massive numbers of cigars, virtually indistinguishable from cigarettes, with youth-friendly flavors such as "Sweet Dreams or "Da Bomb Blueberry". *See supra* note 3 at 9, 14. The Deeming Rule specifically addressed this practice of the cigar industry. In the introduction to the proposed Deeming Rule, FDA noted

> "young adults often mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes....Further, many of the products proposed to be covered by this rule are offered in fruit and candy flavors, such as chocolate and grape flavors, making them especially attractive to children and young adults. For example, from 2010 to 2012, one

> cigar company introduced grape, white grape and blueberry flavors to its line of little cigars and cigarillos."

79 Fed. Reg. at 23,146. FDA expressed its "concern[] that manufacturers may be ...representing tobacco products that are, in fact, cigarettes to be little cigars, cigarillos or similar products in order to evade the prohibition against characterizing flavors in cigarettes." 79 Fed. Reg. at 23,147.

Strategies such as this—which have resulted in cigar usage by high school students in excess of their cigarette usage—were precisely the kinds of product changes Congress sought to prevent by making them subject to premarket review. The premarket review requirement was not intended just to eliminate nicotine manipulation in cigarettes, but also to prevent manufacturers of all tobacco products from changing their products in significant ways without prior FDA review. The purpose of substantial equivalence review is to prevent the marketing of new products that, because of changes in the product, raise different questions of public health. As FDA stated when it promulgated the Deeming Rule and applied it to *all* cigars, "premarket review...will allow FDA to monitor product development and to prevent more harmful or addictive products from reaching the market." 81 Fed. Reg. at 29,020.

Plaintiffs complain that FDA's delay in promulgating the Deeming Rule has made it harder to establish substantial equivalence because the passage of time has made it more difficult to document the characteristics of products that were marketed before the grandfather date. Pl. Br. at. 8. In fact, however, FDA's delay in implementing premarket review permitted cigar manufacturers to introduce thousands of new products without any regulatory review, all the while increasing the attractiveness of their products to youth and filling gaps created by the elimination of flavored cigarettes.

If cigar manufacturers lack the ability to demonstrate that their new tobacco products are substantially equivalent to grandfathered products, they have only themselves to blame. Cigar manufacturers have been aware since the enactment of the TCA in 2009 that they could be subject to premarket review under the statute and they have been aware since 2010 of FDA's intention to subject them to the Act and to premarket review.[20] A prudent cigar manufacturer planning to introduce new products would have taken care in 2010 at the latest to define the characteristics of any potential predicate product and would never have put a new cigar on the market in the first place without fully understanding every difference between the predicate product and the new product.

C. FDA is Not Required to Issue a Final Rule Defining the Requirements for Substantial Equivalence in Order to Implement Substantial Equivalence Review.

Plaintiffs contend that requiring Substantial Equivalence Reports ("SE reports") to be filed by May 12, 2020 in order to permit manufacturers to keep new tobacco products on the market after that date is a violation of the TCA and is arbitrary and capricious in violation of the APA because FDA has not yet issued a Final Rule establishing all requirements for Substantial Equivalence Reports. Pl. Br. at 19-24. However, as explained by the Government, the statutory obligation for manufacturers to submit applications for premarket review in order to market new tobacco products is unconditional and does not require the issuance of a formal rule as a precondition for premarket review. Gov't Br. at 19-23. In short, there is no "right" to market any deemed tobacco product, including cigars, without a marketing order, and Congress did not require FDA to issue any additional rules or guidances elucidating the agency's requirements for

[20] See, note 19 *supra*. FDA reiterated this intention in 2011. Letter to Stakeholders from Lawrence Deyton, Dir., FDA Ctr. for Tobacco Prods. & Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, Regulation of E-Cigarettes and Other Tobacco Products (Apr. 25, 2011), https://tinyurl.com/yx6xdsak.

a showing of "substantial equivalence." Nor does the statutory provision directing manufacturers to file SE reports "in such form and manner as the Secretary shall require" mean that promulgation of a final rule is a prerequisite to implement SE review. This language merely requires applicants to conform to whatever form and manner of SE report FDA may establish. Where Congress required issuance of a regulation for FDA action to be effective it specifically so stated. *See*, e.g., 21 U.S.C. §387a(b) (regulation required for deeming); 21 U.S.C. § 387f(d) (regulation required for restrictions on advertising); 21 U.S.C. §387g (regulation required to issue a product standard).

Furthermore, the statements in the Deeming Rule cited by Plaintiffs wherein FDA alludes to future guidance (e.g., Pl. Br. at 20) related almost exclusively to product testing and reporting requirements not yet established, not to premarket review requirements. Yet FDA repeatedly states that "until these testing and reporting requirements have been established newly deemed tobacco products are not subject to the testing and reporting provisions." (e.g., 81 Fed. Reg. at 28,980). Plaintiffs' complaints that they cannot comply with these requirements are both speculative and unripe.

In fact, Plaintiffs have had, for some time, ample information to permit them to file SE report. In addition to being defined in the TCA itself, the term "substantial equivalence" has been further explained by this Court and in numerous guidance documents by FDA. Since 2010, FDA has received more than 5,000 SE reports and has granted 1,070 of them, including several cigar reports.[21] This fact alone should demonstrate that manufacturers can indeed file successful SE reports—and have been able to do so for years. But the information available to manufacturers

[21] *See* Decl. of Mitchell Zeller, ¶ 5, 5a, 5b. *AAP v. FDA*, No. 18-cv-883 (D. Md. June, 12, 2019) ECF120-1.

is even greater. FDA has issued guidance documents, conducted webinars, invited questions from manufacturers, and met with manufacturers regarding the content of potential SE reports. For each of the more than 1000 products it has found substantially equivalent to a grandfathered product, FDA has posted on its website the detailed administrative, compliance and substantive scientific reviews performed, as well as summaries of the reports it has rejected.[22] A sample set of documents from FDA's website is attached as Exhibit 3. FDA follows the well-established practice of developing regulatory standard through case-by-case review. *See Qwest Serv. Corp. v. FCC*, 509 F.3d 531, 536 (D.C. Cir. 2007) ("Most norms that emerge from a rulemaking are equally capable of emerging (legitimately) from an adjudication, and accordingly agencies have very broad discretion whether to proceed by way of adjudication or rulemaking." (quotations and citations omitted.)) Moreover, on April 2, 2019 FDA issued a detailed Proposed Regulation on the preparation of SE reports for new products, thus further informing manufacturers of what is required in an SE report.[23]

If more information were required to process an SE report, FDA has demonstrated its willingness to permit applicants to provide it. FDA has encouraged applicants to engage in a dialogue with the agency concerning product applications and has consistently urged them to file applications long before the deadline. The *AAP v. FDA* Court characterized industry claims that manufacturers could not complete their applications without further formal guidance as "disingenuous" and noted that "it is commonplace for companies and individuals to call the FDA for guidance and the FDA has made clear that it is willing to work with manufacturers in the

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[22] *See* FDA, *Marketing Orders for SE, available at* https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se.

[23] Content and Format of Substantial Equivalence Reports; FDA Actions on Substantial Equivalence Reports, April 2, 2019, 84 Fed. Reg. 12,740.

interim to provide informal guidance." 399 F. Supp. 3d at 485. Moreover, under the FDA guidance as well as under the order in *AAP v. FDA*, a company that files its application by the deadline can continue marketing its product for a full additional year without being subject to enforcement and will be eligible for an additional period of non-enforcement if FDA finds, on a case-by-case basis, that good cause exists for an extension.

Rather than engaging with the actual substantial equivalence process, Plaintiffs present an absurd caricature that bears no resemblance to reality. As the district court found in issuing its remedial order in *AAP v. FDA*, "the record shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so." 399 F. Supp. 3d at 485. Many products may ultimately be found ineligible for marketing orders but the claim that an applicant will not have an adequate opportunity to establish Substantial Equivalence if it is required to file its SE report by May 12, 2020 is wholly unwarranted.

D. Invalidating the Deeming Rule Would Impair Public Health

Plaintiffs' proposed remedy for a problem that does not exist—scrapping the Deeming Rule four years after it was issued and telling the agency to start over—would undermine the fundamental public health purpose of the TCA. The holiday from regulation that cigar manufacturers have already been accorded has been disastrous for the public health. During that holiday—from the August 8, 2016 effective date of the Deeming Rule to the present, two million young people under the age of 18 have initiated cigar smoking.[24] Protection of the public health—the fundamental purpose of the statute—requires that at long last the manufacturers of those products demonstrate that their products meet the standard established by Congress a

[24] Substance Abuse and Mental Health Services Administration, HHS, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health," Aug. 2019, tbl. A.3A, https://tinyurl.com/t5qkbc7.

decade ago. It seems apparent that no matter how much guidance FDA provides, and how much information is available to Plaintiffs, they will still complain that they need more. Plaintiffs do not seek a way to satisfy the statutory requirements but seek merely to delay application of those requirements for as long as possible while they continue to sell their products.

Plaintiffs make the curious argument that FDA would not have set an August 8, 2016 effective date for the Deeming Rule if it had understood that "all the provisions had to be enforced immediately upon the effective date of the Rule and could not be subject to later compliance dates..." Pl. Br. at 26. First, it is utter speculation that FDA's adoption of the August 2016 effective date was premised on the agency's assumptions about allowable compliance periods. Indeed, it is reasonable to assume that the effective date was established because FDA thought it important to subject addictive and hazardous products like cigars to the various public health protections of the TCA without further delay.

Second, neither the court nor the plaintiffs in *AAP v. FDA* took the position that FDA had no discretion under the deeming rule to establish a compliance period that would allow products to remain on the market for a limited time period while preparing premarket review applications. As the district court stated, "certainly the parties agree that FDA has some discretion to allow for a compliance period for new tobacco products and FDA did just that in the Deeming Rule." 379 F. Supp. 3d at 484. The public health organizations did not challenge—and the district court did not invalidate—the compliance periods originally established by the Deeming Rule, which for cigars would have ended on February 8, 2018. The district court invalidated the August, 2017 extension of the Deeming Rule because, in contrast to the compliance period created by the Deeming Rule, the extension—coming on top of the compliance period FDA had earlier established—was so long that it constituted "an abandonment of [FDA's] statutory duty to

review new tobacco products in the prompt fashion mandated by Congress." *Id.* at 492. Moreover, when FDA established the original compliance periods in the Deeming Rule it explained its reasoning for doing so in detail. 81 Fed. Reg. at 28,978, 29,009-15. By contrast, as the district court noted in *AAP v. FDA*, the August 2017 extension contained no explanation of the reasons for the extension. Furthermore, when the district court established a remedy it ordered a further 10-month compliance period consistent with FDA's representation that manufacturers could prepare and FDA could prepare to process applications in that time period. 399 F. Supp. 3d at 484-85

Plaintiffs' argument that FDA would not have established the August 8, 2016 effective date if it had believed that it would have to resort to notice-and-comment rulemaking to change the compliance period (Pl. Br. at 26) is mere speculation unsupported by any evidence whatsoever. Additionally, when FDA proposed to change the terms of the compliance period in March, 2019—months before the district court's decision—it published a Draft Guidance for public comment.[25] FDA's January 2, 2020 order establishing the May 12, 2020 deadline was the outcome of that very notice-and-comment process. Thus, the allegation that FDA viewed avoidance of notice-and-comment as essential to the Deeming Rule is wholly lacking in support and contradicted by FDA's actual practice.

Finally, the effective date of the Deeming Rule is irrelevant to this case. What is at issue is the multi-year postponement of premarket review of new tobacco products, a problem that would exist regardless of what effective date FDA might have established.

IV. The Existence of an Advanced Notice of Proposed Rulemaking for a Tiny Percentage of the Cigar Market Does Not Justify Indefinite Delay in Requiring Premarket Review for All Cigars.

[25] Modifications to Compliance Policy for Certain Deemed Tobacco Products, 84 Fed. Reg. 9345, Mar. 14, 2019.

A. FDA Validly Deemed Premium Cigars Subject to the TCA.

Plaintiffs' argue that requiring premarket review is arbitrary and capricious as applied to "premium" cigars. In the Deeming Rule, FDA sought comments on an option to exempt premium cigars. 79 Fed. Reg. at 23,151-52. Ultimately, "after a thorough review of the comments and the scientific evidence" FDA concluded that premium cigars should not be exempted and explained its reasoning at length 81 Fed. Reg. at 29,020-27, basing its decision on findings that "(1) all cigars pose serious negative health risks; (2) the available evidence does not provide a basis for FDA to conclude that the patterns of cigar use sufficiently reduce the health risk to warrant exclusion; and (3) premium cigars are used by youth and young adults." 81 Fed. Reg. at 29,020. In deciding not to exempt premium cigars, FDA cited the importance of subjecting all cigars to premarket review, remarking that "implementation of...premarket review...will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market." *Id.* Thus, even if it could be shown that grandfathered premium cigars posed a lesser danger to public health than other cigars, premarket review would be important to ensure that new premium cigars were not becoming more harmful or addictive than the grandfathered products. A contrary result would have undermined the Congressional objective of "[taking] the then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health." *Nicopure*, 944 F.3d 267 at 271.

Moreover, FDA concluded that "there were no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks." 81 Fed. Reg. at 29,020. FDA addressed the studies regarding premium cigar use cited in comments and explained why they did not permit a conclusion that premium cigars "do not present a public health threat significant enough to warrant regulation" *Id.* at 29021. (evaluating

data from at least 14 studies (*Id.*, notes 35, 69-72, 74-82) and concluding that regulation of premium cigars—including premarket review—would "substantially improve public health.") FDA found that "all cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders." *Id.* at 29022-23. Moreover, FDA found that exempting premium cigars could mislead consumers into believing that premium cigars are safe and lead youth and young adults to initiate use of these products. *Id.* at 29020-21 FDA also concluded, after discussing numerous studies, that although youth have a higher use of cigarillos and other mass market cigars, they are also using premium cigars. *Id.*

The relevant inquiry is not whether premium cigars carry the same risk to public health as cheap, flavored cigars, but whether premium cigars present enough of a public health issue to warrant regulation at all. FDA could not regulate premium cigars at all without deeming them subject to the TCA 21 U.S.C. § 387a(b) and once it did so the statute required premarket review. 944 F.3d 267 at 281. As the D.C. Circuit held, "it was Congress, not the FDA, that imposed the premarket approval requirement" on all products subject to the TCA and once FDA deems tobacco products subject to the TCA "FDA is not authorized to deviate from the statutory standard." *Id.* Thus, unlike requiring warning labels, a discretionary choice even after FDA deemed cigars subject to the TCA, FDA could not provide premium cigars an "easier path" (Pl. Br. at 38-43) without leaving them entirely unregulated. FDA's examination of the evidence regarding premium cigars provides no basis for finding its decision arbitrary and capricious.

B. The Advanced Notice of Proposed Rulemaking Should Not Prevent Enforcement of Premarket Review as to Premium Cigars.

Plaintiffs argue that FDA's subsequent issuance of an ANPRM requesting new information about premium cigars, 83 Fed. Reg. 12,901 (Mar. 26, 2018), precludes requiring premarket review for premium cigars. Pl. Br. at 34-36. But the ANPRM reiterated that FDA's

decision to subject premium cigars to the Deeming Rule had been made "after carefully considering the public comments on the rule" and that FDA had concluded that "there was no appropriate public health justification to exclude premium cigars from regulation." 83 Fed. Reg. at 12,902. FDA characterized comments against regulation as providing "little data to support the opinions expressed." *Id.* Thus, FDA limited its request for information in the ANPRM to new and different information, data and analysis not submitted in the administrative record of the deeming rule.

The existence of the ANPRM does not justify ignoring the decision FDA reached after careful consideration in the Deeming Rule. *See, e.g., Robles v. Domino's Pizza, LLC*, 913 F.3d 898, 909-910 (9th Cir. 2019) (reversing dismissal based on argument that pending ANPRM precluded statute from being applied). Almost two years after FDA issued the ANPRM, nothing indicates that FDA intends to alter its prior decision. Information submitted in the ANPRM is not a part of the administrative record of the Deeming Rule and provides no basis for judicial invalidation of the Deeming Rule. Speculation about changes FDA might or might not make in the future cannot justify the damage to the public health that would result from continuing to defer the statutory requirement that all new cigars be subjected to premarket review.

This Court's decision to enjoin the application of the warning label requirement for new cigars pending resolution of their appeal to the D.C. Circuit, 317 Fed. Supp. 355 (D.D.C. 2018), provides no precedent for invalidating FDA's order requiring manufacturers to file premarket applications by May 12. The injunctive factors applicable to warning labels were far different from those at issue now. In evaluating likelihood of success on the merits in the warning label context, this Court cited "the complexity of the [First Amendment] issues raised on appeal and the Supreme Court's [intervening] decision in *NIFLA v. Becerra,*" 138 S. Ct. 2361 (2018), that

created uncertainty as to the ultimate outcome. 317 F. Supp. 3d at 561. By contrast, the main injury that warranted relief, the irreparable loss of First Amendment rights, *Id.* at 562, is absent in this case and Plaintiffs' likelihood of success on the merits is minimal.

Moreover, this Court found that the public interest would not be seriously harmed by deferring the warning label requirement until Plaintiffs' appeal had been resolved. *Id.* at 563. As Plaintiffs had argued, most cigars already carried warning labels with text very similar to those FDA proposed to require, albeit somewhat smaller, and the Court found that deferring the statutory warnings would not cause substantial harm to the public interest. *Id.* By contrast, in this case the damage to the public health that would result from extending the industry's holiday from premarket review is clear: cigars that would never be found substantially equivalent to a grandfathered product—including addictive, kid-friendly cigars—will continue to be marketed for many more years without premarket review. As a coordinate district court has already found,

> Instead of addressing public health concerns associated with tobacco use by minors and others, the August 2017 Guidance exacerbates the situation by stating, in essence, that manufacturers can continue to advertise and sell products that are addictive and that target a youth market. . . Arguably, the five-year compliance safe-harbor has allowed the manufacturers enough time to attract new, young users and get them addicted before any of their products, labels, or flavors are pulled from the market, at which time the youth are likely to switch to one of the other thousands of tobacco products that already are approved—results entirely contrary to the express purpose of the [TCA].

AAP v. FDA, 379 F. Supp. 3d at 492 (D. Md. 2019).

Whatever considerations may apply to premium cigars, by Plaintiffs' estimate they constitute only about three percent of the cigar market. Pl. Br. at 14. None of the arguments supporting an exemption from premarket review for premium cigars justify an exemption for the 97 percent that are not premium cigars. In light of the damage done to the public health by the holiday from premarket review FDA has already granted to all cigars, it would be unconscionable under any circumstances to prolong that holiday for the other 97 percent.

V. This Court's Order of February 3 Finding That the Requirement for Warning Labels for Premium Cigars is Inconsistent with the APA Has No Bearing on the Validity of Requiring Premarket Review.

This Court's February 3 order finding the requirement of warning labels on premium cigars inconsistent with the APA, ECF-181, has no bearing on the validity of requiring premarket review for all cigars. As shown above, the TCA itself requires premarket review for all new tobacco products deemed subject to the TCA. By contrast, warning labels for cigars were not required by the TCA but rather by a rule promulgated at FDA's discretion under 21 U.S.C. §387f. The Court found that FDA had not complied with the APA solely because it had not found that users of premium cigars were unaware of their health risks and therefore in need of warnings. See ECF-181 at 28. ("[FDA] fail[ed] to analyze whether consumers are in fact misinformed or underinformed as to premium cigar health effects.") By contrast, premarket review "allow[s] FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market," a purpose that exists regardless of consumer awareness of the risks of cigars. 81 Fed. Reg. at 29,020. FDA's findings— supported by scientific authority—established that *all* cigars, including premium cigars, are addictive and expose both users and non-users to substances that cause fatal disease 81 Fed. Reg. 29,020-27, and support FDA's deeming all cigars subject to the TCA and thus require premarket review.

CONCLUSION

The Court should deny the Plaintiffs' Motions for Preliminary Injunction and Partial Summary Judgments and grant the Defendants' Motion for Partial Summary Judgment and Entry of Judgment for Defendants on All Remaining Claims.

Respectfully Submitted,

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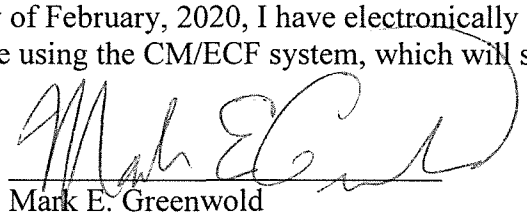
February 10, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this tenth day of February, 2020, I have electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF system, which will send a notice of filing to all counsel of record.



Mark E. Greenwold
Counsel for Amici Curiae

APPENDIX
Description of *Amici Curiae*

1. The American Academy of Pediatrics

The American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of the AAP has grown to 67,000 pediatricians. The AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to protect the well-being of America's children. The AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

2. The American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is making cancer a top priority for public officials. Created in 2001 as the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, ACS CAN empowers advocates across the country to make their voices heard. ACS CAN has volunteers nationwide, many of whom advocate for effective tobacco control at the federal, state, and local levels. In 2020, an estimated 228,820 new cases of lung cancer will be diagnosed in the US, and 135,720 people will die from the disease; the vast majority of these cases are attributable to tobacco use. This devastating impact makes regulation of tobacco products critical to our mission.

3. The American Heart Association

The American Heart Association ("AHA") is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Founded in 1924, AHA now includes more than 33 million volunteers and supporters, with local chapters in all 50 states, as well as in Washington D.C., and Puerto Rico. The association invests in research, professional and public education, and advocacy so people across American can live stronger, longer lives. AHA has long been active before Congress and regulatory agencies on tobacco and other health-related matters and has petitioned the Food and Drug Administration on several occasions seeking regulation of cigarette and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

4. The American Lung Association

The American Lung Association is the nation's oldest voluntary health organization. Because smoking is a major cause of lung cancer and chronic obstructive pulmonary disease (COPD), the American Lung Association has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, as well as efforts to regulate the marketing, manufacture and sale of tobacco products.

5. The Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke.

6. Truth Initiative

The Truth Initiative envisions an America where tobacco is a thing of the past and where all youth and young adults reject tobacco use. Truth Initiative's proven -effective and nationally recognized public education programs include truth®, the national youth smoking prevention campaign that has been cited as contributing to significant declines in youth smoking; EX®, an innovative smoking cessation program; and research initiatives exploring the causes, consequences, and approaches to reducing tobacco use. Truth Initiative also develops programs to address the health effects of tobacco use–with a focus on priority populations disproportionately affected by the toll of tobacco–through alliances, youth activism, training, and technical assistance. Located in Washington, D.C., Truth Initiative was created as a result of the November 1998 Master Settlement Agreement between attorneys general from 46 states, five U.S. territories, and the tobacco industry.

EXHIBIT 1


Cheyenne
PREMIUM
FULL FLAVOR
100's
LITTLE 20 CIGARS
Cheyenne
FULL FLAVOR
100's
MADE IN U.S.A.
CIGARS 20
Cheyenne
WILD CHERRY
FLAVOR
100's
MADE IN U.S.A.
CIGARS 20
Cheyenne
WILD CHERRY
100's
MADE IN U.S.A.


Cheyenne
WILD CHERRY
100's
MADE IN U.S.A.

EXHIBIT 2

View Rule

View EO 12866 Meetings | Printer-Friendly Version | Download RIN Data in XML

HHS/FDA **RIN:** 0910-AG38 **Publication ID:** Spring 2010

Title: ●Cigars Subject to the Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Section 901 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the Tobacco Control Act. This proposed rule would deem cigars to be subject to the Tobacco Control Act and include provisions to address public health concerns raised by cigars.

Agency: Department of Health and Human Services(HHS)
Priority: Economically Significant
RIN Status: First time published in the Unified Agenda
Agenda Stage of Rulemaking: Proposed Rule Stage
Major: Yes
Unfunded Mandates: Undetermined
EO 13771 Designation: uncollected
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations.)
Legal Authority: 21 USC 301 et seq, The Federal Food, Drug, and Cosmetic Act PL 111-31, The Family Smoking Prevention and Tobacco Control Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Yes
Government Levels Affected: Undetermined
Small Entities Affected: Businesses
Federalism: Undetermined
Included in the Regulatory Plan: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
RIN Data Printed in the FR: Yes

Agency Contact:
Gerie Voss
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Silver Spring, MD 20993
Phone:877 287-1373
Email: ctpregulations@fda.hhs.gov

EXHIBIT 3

FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014857

SE0014857: Black & Mild®	
Package Type	Cellophane (polypropylene plastic wrap)
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic
Characterizing Flavor	None
Attributes of SE Report	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigars
Product Sub-Category	Unfiltered, Sheet-Wrapped Cigar
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Melissa Mcculloch -S

Digitally signed by Melissa Mcculloch -S
Date: 2019.04.05 11:02:10 -04'00'

Melissa McCulloch, Ph.D.
Senior Regulatory Scientist
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.04.08 06:45:09 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0014857: Black & Mild	
Product Name	Black & Mild
Package Type	Cellophane (Polypropylene plastic wrap)
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	None

The predicate tobacco product is a sheet wrapped, unfiltered cigar manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 22, 2018, FDA received one SE Report from John Middleton Co. FDA issued an Acknowledgement letter to the applicant on August 27, 2018. FDA issued an Advice and Information (A/I) Request letter on October 30, 2018. On January 15, 2019, FDA received the response to the A/I Request letter (SE0015060).

Product Name	SE Report	Amendment
Black & Mild	SE0014857	SE0015060

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

A Regulatory review was completed by Keyur Patel on August 27, 2018.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated September 17, 2018, concludes that the evidence

submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated April 3, 2019 concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Selvin Edwards on October 9, 2018, and Jiu Ai on March 1, 2019.

The final chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Decrease in target tobacco filler weight of (b) (4) mg/cigar (6.4%)
  - Decrease in ingredient (b) (4) weight of (b) (4) mg/cigar (4.3%)
  - Decrease in (b) (4) of (b) (4) /cigar (8.7%)
- Several non-tobacco ingredients have been removed
- (b) (4) is added to the wrapper and binder to replace (b) (4)
- (b) (4) increased 33% to replace (b) (4) in the wrapper and binder
- Decrease of the weight of the wrapper (9.8%)
- Decrease of the weight of the binder (11.2%)
- Decrease in binder moisture (22.6%)[1]
- Decrease in wrapper moisture (17.2%)[1]

The tobacco blend of the cigar filler for the new tobacco product contains lower quantities of (b) (4) and identical quantities of (b) (4) compared to the predicate tobacco product, which is expected to reduce HPHC smoke yields. Therefore, the tobacco blend differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. Since several non-tobacco ingredients have been removed from the new tobacco product, the non-tobacco ingredients added to the cigar filler of the new tobacco product are lower than those in the predicate tobacco product. The non-tobacco ingredient differences in the cigar fillers between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. The wrapper and binder of the new tobacco product are reformulated with (b) (4) replacing (b) (4) in the wrapper and binder of the predicate tobacco product and additional (b) (4) to replace (b) (4) in the

[1] This difference is noted in the engineering reviews and discussed in the 1st chemistry review, dated October 9, 2018.

binder of the predicate tobacco product. However, the total quantity of (b) (4) in all the combusted components (wrapper, binder and seam adhesive) in the new tobacco product is approximately (b) (4) mg/cigar, which is less than (b) (4) of the tobacco rod weight of the cigar and it is not expected to influence the smoke chemistry. Although the (b) (4) quantity in the binder of the new tobacco product is 33% higher than that of the predicate product, the total quantity of the (b) (4) in the tobacco rod of the new tobacco product is (b) (4) mg/cigar lower than of the predicate tobacco product. Additionally, the decreased weight and moisture for the binder and wrapper between the new and corresponding predicate tobacco products are both expected to generate lower amounts of HPHC smoke yields. Therefore, the differences in ingredients, decreased weight and decreased moisture between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Raymond Williamson on October 18, 2018, and Jim Melchiors on March 5, 2019.

The final engineering review concludes that the new tobacco product has different characteristics related to product engineering compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Decrease in tobacco filler mass (6.4%)
- Decrease in cigar mass (5.5%)
- Decrease in binder moisture (22.6%)
- Decrease in wrapper moisture (17.2%)
- Decrease in (b) (4) tobacco processed at (b) (4) (5.4%)
- Increase in (b) (4) tobacco processed at (b) (4) (6.8%)

The new tobacco product has 5.5% less mass than the predicate tobacco product. This decreased mass is due to the new tobacco product containing 6.4% less tobacco filler and the removal of several non-tobacco ingredients. A decrease in tobacco mass is expected to reduce HPHC smoke yields. Therefore, the differences in tobacco filler and overall cigar mass do not cause the new tobacco product to raise different questions of public health. The new tobacco product uses a different wrapper and binder than the predicate tobacco product. For both the wrapper and binder used on the new tobacco product, the moisture decreased compared to the wrapper and binder used on the predicate tobacco product. A decrease in the binder moisture and wrapper moisture may reduce puff count and is expected to reduce HPHC smoke yields. Therefore, the decrease in binder and wrapper moisture does not cause the new tobacco product to raise different questions of public health. For tobacco cut size, the new tobacco product used 5.4% less (b) (4) tobacco at (b) (4) and 6.8% more (b) (4) tobacco (b) (4) when compared to the predicate tobacco product.

The applicant was asked to provide additional information on the tobacco cut size including upper and lower range limits, test data, test protocols, and acceptance criteria for the new and predicate tobacco products. The applicant amended their report to verify that the same machine settings were used for the new and predicate tobacco products and submitted that they do not measure tobacco cut size for the production of their cigar products and, therefore, do not have test data, test protocols, or acceptance criteria for the new or predicate tobacco products. Since the applicant established that there are no differences between the new and predicate tobacco products with respect to tobacco cut size, the differences in tobacco cut size discussed above do not cause the new tobacco product to raise different questions of public health.

Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Ana Depina on October 19, 2018, and February 26, 2019.

The final toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- (b) (4) is added to the wrapper and binder to replace (b) (4)
- (b) (4) increased 33% to replace (b) (4) in the wrapper and binder

(b) (4) was added to the new tobacco product as a substitute for (b) (4) at less than 0.1% of the total product mass. The (b) (4) increase in the new product is not expected to result in increased HPHC smoke yields, and thus does not cause the new tobacco product to raise different questions of public health. (b) (4) was used as a substitute for (b) (4) and is increased in the binder of the new product, but the overall amount of (b) (4) in the burned region of the cigar is lower in the new tobacco product compared to the predicate tobacco product. Therefore, increased (b) (4) in the binder does not cause the new tobacco product to raise different questions of public health.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Dilip Venugopal on October 3, 2018, and February 20, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 6, 2019. The FONSI was supported by an environmental assessment prepared by FDA on March 6, 2019.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco products:

- Decrease in target tobacco filler weight of (b) (4) mg/cigar (6.4%)
  - Decrease in ingredient free tobacco weight of (b) (4) mg/cigar (4.3%)
  - Decrease in (b) (4) of (b) (4) mg/cigar (8.7%)
- Several non-tobacco ingredients have been removed
- (b) (4) is added to the wrapper and binder to replace (b) (4)
- (b) (4) increased 33% to replace (b) (4) in the wrapper and binder
- Decrease of the weight of the wrapper (9.8%)
- Decrease of the weight of the binder (11.2%)
- Decrease in binder moisture (22.6%)
- Decrease in wrapper moisture (17.2%)
- Decrease in (b) (4) tobacco processed at (b) (4) inch (5.4%)
- Increase in (b) (4) tobacco processed at (b) (4) inch (6.8%)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The total mass, as well as the mass of several components of the new tobacco product, decrease compared to the predicate tobacco product. The decrease in mass is due to the new tobacco product containing 6.4% less tobacco filler and the removal of several non-tobacco ingredients. A decrease in tobacco mass is expected to reduce HPHC smoke yields. Therefore, the decreased mass does not cause the new tobacco product to raise different questions of public health. The new tobacco product uses a different wrapper and binder than the predicate tobacco product. For both the wrapper and binder used on the new tobacco product, the moisture decreased compared to the wrapper and binder used on the predicate tobacco product. A decrease in the binder moisture and wrapper moisture may reduce puff count and is expected to reduce HPHC smoke yields. Therefore, the decrease in binder and wrapper moisture does not cause the new tobacco product to raise different questions of public health. For tobacco cut size, the new tobacco product used 5.4% less (b) (4) tobacco at (b) (4) and 6.8% more (b) (4) tobacco (b) (4) when compared to the predicate tobacco product. The applicant established that there are no differences between the new and predicate tobacco products with respect to tobacco cut size; therefore, the differences in tobacco cut size do not cause the new tobacco product to raise different questions of public health. (b) (4) was added to the new tobacco product as a substitute for (b) (4) at less than 0.1% of the total product mass. The (b) (4) increase in the new tobacco product is not expected to result in increased HPHC smoke yields. (b) (4) was used as a substitute for (b) (4) and is increased in the binder of the new tobacco product, but the overall amount of (b) (4)

in the burned region of the cigar are lower in the new tobacco product compared to the predicate tobacco product. Therefore, the addition of (b) (4) and the increased (b) (4) in the binder does not cause the new tobacco product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it was determined that it is a grandfathered tobacco product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco product are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0014857, as identified on the cover page of this review.