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VIA ELECTRONIC SUBMISSION AND FEDERAL EXPRESS

The Honorable Alex M. Azar II
Secretary Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Secretary@hhs.gov

The Honorable Stephen M. Hahn
Commissioner
Food and Drug Administration
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Filed at:
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Petition for Stay of Action of Substantial Equivalence Report Deadline for Cigars, Required as a Result of the *Final Deeming Rule, 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016)

To Be Filed in Docket Nos. FDA-2014-N-0189, FDA-2016-N-3818, FDA-2017-D-2834, FDA-2017-N-6107, and FDA-2019-D-0661; and with the Secretary of the Department of Health and Human Services pursuant to the Public Health Service Act

Dear Secretary Azar and Commissioner Hahn:

The Cigar Association of America, Inc. (CAA) is a leading national trade association representing the interests of cigar manufacturers, importers, distributors, retailers and major suppliers to the industry. CAA was founded in 1937 as a non-profit trade organization. Today, its member companies come from all sectors of the industry and include manufacturers of both hand-made premium cigars and machine-made cigars. CAA members manufacture a significant share of the premium, large, little and filtered cigars sold in the United States, and include internet retailers of cigars, as well as leaf and other suppliers to the cigar industry. CAA is a key

stakeholder in the implementation of any regulations of cigars as these regulations significantly affect its members' ability to conduct business.

A. Decision Involved: The Final Deeming Rule's Requirement That Cigars Entering the Market Since February 15, 2007 Seek FDA Approval, and Subsequent FDA Actions Setting the Deadline for the Process of Seeking Such Approval Through Substantial Equivalence Reports

In May 2016, the Center for Tobacco Products ("CTP") issued a Final Rule that deemed all cigars subject to regulation.[1] This Final Rule became effective on August 8, 2016. After that date, a manufacturer seeking to introduce a "new tobacco product" to the market would have to file a Substantial Equivalence Report ("SE Report") or Premarket Tobacco Product Application ("PMTA") to do so. As CTP has acknowledged previously, it expects all cigars to utilize the SE Report pathway.

The Final Rule stated that SE Reports for all newly deemed products (including all cigars) introduced to the market between February 15, 2007 and August 8, 2016 had to be filed by February 8, 2018 in order to remain on the market.[2] At that time, and still today, CTP had yet to issue a Final Rule on the Content and Format of Substantial Equivalence Reports. Given this, in August 2017, FDA extended the deadline for filing these initial SE Reports until August 2021.[3] FDA acknowledged that it needed to publish foundational regulations in order for manufacturers to produce quality SE Reports. As Former Commissioner Gottlieb stated, "CTP's task is to reconsider aspects of the implementation of the final deeming rule with an eye towards fostering innovation where innovation could truly make a public health difference, and making sure we have the *foundational regulations* we need in place to make the entire program transparent, predictable, and sustainable for the long run."[4]

After this public recognition of the work the Agency still needed to do, certain public health groups, solely focused on e-cigarettes, sued FDA over extending the deadlines for filing these initial reports. That lawsuit resulted in Judge Grimm of the District of Maryland ordering that **all** premarket review applications, be they SE Reports for products that have been on the market for

[1] 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) [hereinafter Final Deeming Rule].

[2] *Id.* at 28,978, 29,003.

[3] Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry, FDA-2017-D-2834, 82 Fed. Reg. 37,459 (Aug. 10, 2017)

[4] Scott Gottlieb, M.D., Former Comm'r, U.S. FOOD & DRUG ADMIN., Comprehensive Plan to Regulate Nicotine and Tobacco (July 28, 2017) (available at https://web.archive.org/web/20180125021652/https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (last accessed March 26, 2020).

decades or PMTAs for novel products, be filed by May 12, 2020.[5] On January 2, 2020, FDA stated the **only** reason it imposed this deadline for SE Reports was Judge Grimm's decision.[6] That decision had critical consequences in that it returned the cigar industry to the position it was in prior to July 2017 – rushing to prepare quality SE Reports, without the benefit of a Final Rule on the Content and Format of SE Reports, and now having a severely compressed timeline in which to complete the necessary work.

B. Action Requested: A Stay of the May 12, 2020 Deadline to Submit Substantial Equivalence Reports Due to The National COVID-19 Pandemic and an Extension for the Entire Cigar Industry For No Less than 90 Days[7]

CAA requests that the Secretary and Commissioner stay and extend the May 12, 2020 deadline for the submission of SE Reports for no less than 90 days.

C. Statement of Grounds for the Request that the Commissioner Grant a Stay Under 21 C.F.R. § 10.35 and the Secretary Grant a Stay under 42 U.S.C. § 247d(d)

On March 17, 2020, CAA made a formal request to CTP for an extension of the current May 12, 2020 deadline for the filing of SE Reports for all cigars introduced to the market by August 8, 2016.[8] The request was based on the current national COVID-19 emergency, which has closed offices and factories, restricted or prohibited travel, and (in many cases) confined people to their homes.[9] These circumstances make it literally impossible for companies to gather necessary information, and to prepare and file quality SE Reports. Importantly, these circumstances apply to all members of the cigar industry who intend to file SE Reports, and the extension request was, therefore, not limited to a small group of manufacturers or members of certain trade

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[5] *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019); *appeal pending, Am. Acad. of Pediatrics v. FDA*, No. 19-2130, No. 19-2132, No. 19-2198, and No. 19-2242 (4th Cir.).

[6] Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, Guidance for Industry, FDA–2019–D–0661, 85 Fed. Reg. 720-722 (January 7, 2020).

[7] A Proposed Order, Secretary of Health and Human Services, is attached as Exhibit 1; a Proposed Order, Commissioner of Food and Drug Administration, is attached as Exhibit 2.

[8] A copy of that Request is attached as Exhibit 3. Notably, CAA's request was made only for this segment of the market. CAA has not asked a suspension of the requirement to submit an SE Report prior to marketing new cigars introduced to the market after August 8, 2016.

[9] On January 31, 2020, the Secretary of Health and Human Services Alex M. Azar, issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS, Determination that a Public Health Emergency Exists. *See* Determination that a Public Health Emergency Exists (Jan. 31, 2020) (*available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx) (last accessed Mar. 26, 2020). The announcement is attached as Exhibit 4.

On March 13, 2020, the President declared a national emergency in response to COVID-19. *See* President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) (Mar. 13, 2020) (*available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerningnovel-coronavirus-disease-covid-19-outbreak/) (last accessed Mar. 26, 2020). The announcement is attached as Exhibit 5.

associations. For instance, simply among CAA member companies, offices are closed in Pennsylvania, Virginia, and many areas of Florida. Additionally factories are closed in Honduras, the Dominican Republic, and Nicaragua.[10] Further, many of our members not under government order to shut down have either done so on their own, or reduced staff in order to protect their employees from infection with the coronavirus.

The Secretary has declared that the United States is facing a public health emergency due to the COVID-19 pandemic and that he has the power, and the imperative, to extend deadlines as necessary to meet this national and global emergency. It is beyond dispute due to the public health emergency and resulting effects on businesses that the May 12, 2020 deadline for the filing of SE Reports needs to be extended. That extension, however, should apply to all those impacted by the current national emergency, not to only a subgroup. Indeed, there is no rational basis for extending the deadline for anything less than all parties subject to the regulation. CAA requests that the Secretary stay and extend the May 12, 2020 deadline for the submission of SE Reports for no less than 90 days.

CAA is aware that a petition has been filed to the above-referenced dockets, seeking an extension of the SE Report filing deadline, limited solely to "premium" cigars manufactured by seven companies, or to "premium" cigars manufactured or sold by members of two industry trade associations. The petition also proposes a definition of "premium" that, as CAA and others have noted in various comments filed with FDA, has no basis in science, law, or public health. While CAA fully supports an extension of the current May 12 filing deadline, it does not believe it can or should be restricted to a limited portion of the premium cigar category or bestowed only on a small group of companies seeking to gain a competitive advantage. Instead, the deadline should be extended to all companies impacted by the current national emergency.

Indeed, FDA has extended deadlines for tobacco regulation (regardless of product category) in the past due to unforeseen events, such as in the fall of 2018 when the ingredient reporting deadline for small-scale manufacturers was extended due to Hurricanes Florence and Michael and other natural disasters across the country.[11] In addition, as a result of the current national emergency, FDA has already extended compliance dates for other regulated products. For instance, on March 23, 2020, the Center for Devices and Radiological Health ("CDRH") issued a letter to industry outlining the steps it planned to take to "address the impact of the COVID-19 public health emergency on day-to-day operations in CDRH and in the medical device industry, while ensuring that government and private sector efforts to respond to this national emergency

[10] Further, CAA notes that the Pipe Tobacco Council also submitted an Extension Request to FDA, given that pipe tobacco manufacturers are facing the same closures as cigar manufacturers in light of the national emergency and global pandemic. That Extension Request is attached as Exhibit 6.

[11] *See* U.S. FOOD & DRUG ADMIN., Listing of Ingredients in Tobacco Products, Guidance for Industry (*available at* https://www.fda.gov/media/101162/download) (Nov. 2018) (last accessed Mar. 26, 2020)("Additionally, FDA is extending the compliance deadlines with respect to products on the 619 market as of August 8, 2016, by an additional six months for small-scale tobacco product manufacturers and importers in the areas impacted by recent natural disasters to May 8, 2019.").

receive the highest priority."[12] The letter outlines that CDRH has extended the deadlines of response due dates for marketing applications currently on hold automatically by 60 days, and that this applies to "Premarket Notifications (510(k)s), Premarket Approval (PMA) applications (original and supplements), Humanitarian Device Exemption (HDE) applications (original and supplements) and De Novo classification requests. CDRH intends to extend this due date automatically; no extension requests are necessary to be submitted."[13] As CDRH did, CTP needs to act in the best interests of the public health to extend the May 12, 2020 deadline for SE Reports for all products that are subject to the deadline.[14] CTP has already recognized this need with relation to routine domestic inspections, and "for the health and well-being of our staff, and those who conduct inspections for the agency under contract at the state level, that the Agency has temporarily postponed all routine domestic facility inspections."[15] As was noted in the prior petition, Secretary Azar has this authority under the Public Health Service Act based on his declaration of a Public Health Emergency. This Declaration allows him to:

> …determine[s] that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply.[16]

Further, Commissioner Hahn similarly has the authority to stay the deadline pursuant to his authority under 21 C.F.R.§10.35(b), and the global pandemic crisis and declaration

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[12] *See* U.S. FOOD & DRUG ADMIN., "Letter to Industry on COVID-19" (Mar. 23, 2020) (*available at* https://www.fda.gov/media/136383/download?utm_campaign=2020-03-24%20CDRH%20Issues%20Letter%20to%20Industry%20on%20COVID-19&utm_medium=email&utm_source=Eloqua) (last accessed Mar. 26, 2020),and attached hereto as Exhibit 7.

[13] *Id.*

[14] It is worth noting that the Centers for Disease Control and Prevention ("CDC") has already announced that it will suspend the March 31, 2020 deadline for ingredient reporting for cigarettes and smokeless tobacco products as required by the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, as "due to the current public health response to COVID-19 and related issues, OSH is not able to accept any ingredient submissions and will not be issuing Certificates of Compliance at this time. CDC will be communicating this information to state government entities. CDC will re-evaluate this approach as necessary." The Communication from CDC is attached as Exhibit 8.

[15]FDA Commissioner, Stephen M. Hahn, Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections (Mar. 18, 2020); Mitch Zeller, Director, Center for Tobacco Products, CTPNews: Domestic Inspections (Mar. 19, 2020) These updates are attached as Exhibit 9.

[16] Public Health Service Act, 42 U.S.C.A. § 247d(d) (West 2019).

of national emergency related to the COVID-19 virus give him the authority to issue a stay of the May 12, 2020 deadline.[17]

As noted in CAA's original Request for Extension, the Commissioner and Secretary should take all actions necessary to stay and extend the May 12, 2020 deadline for SE Report submission for all deemed products by at least 90 days.

D. The Definition of the "Premium Cigar" Category is a Separate Issue and Should Not Be a Consideration During a National Emergency

Given the current crisis, a petition seeking to extend a critical compliance deadline is not an appropriate means to address an issue of significant regulatory concern, unrelated to the crisis. Specifically, this emergency request is not the means for FDA to resolve questions about the appropriate definition of "premium cigar." The question of how to define a "premium" cigar is currently under consideration by FDA.[18] That rulemaking process should continue once the current situation abates, with FDA defining "premium" cigars and then excluding that category from further regulation. In comments to the Premium Cigar ANPRM and elsewhere, CAA has defined "premium" cigar as one that: i) is wrapped in whole leaf tobacco; (ii) contains a 100% leaf tobacco binder; (iii) is made by manually combining the wrapper, filler, and binder; (iv) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; and (v) weighs more than 6 pounds per 1000 units.[19] The only difference between this definition and the definition proposed in the previously filed petition is the absence of an unfounded restriction on the use of flavors in cigars that otherwise, in all respects, meet the criteria of a "premium" cigar. As set forth below, and as has been stated in numerous submissions to FDA dockets, the presence or absence of flavor should not be a determinative characteristic of premium cigars.[20]

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[17] 21 C.F.R. §10.35(b) ("An interested person may request the Commissioner to stay the effective date of any administrative action.")

[18] Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (proposed Mar. 26, 2018) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) [hereinafter Premium Cigar ANPRM].

[19] *See, e.g.*, Cigar Association of America, Inc.'s Comment on the Regulation of Premium Cigars, submitted to Docket FDA-2017-N-6107 (submitted July 25, 2018).

[20] *See, e.g.* Cigar Association of America, Inc.'s comments to the following dockets: Proposed Rule 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products submitted to docket FDA-2014-N-0189 (submitted August 7, 2014); Comment on the Regulation of Premium Cigars submitted to Docket FDA-2017-N-6107 (submitted July 25, 2018); Comment on Premarket Tobacco Product Applications: Public Meeting submitted to docket FDA-2018-N-3504 (submitted December 7, 2018); Comments on Modifications to Compliance Policy for Certain Deemed Tobacco Products submitted to docket FDA-2019-D-0661 (submitted April 30, 2019).

a. Scientific Evidence Proves "Flavored" Premium Cigars Are No Different from "Unflavored" Ones

Youth usage of premium cigars is virtually non-existent.[21] Table 1 below was prepared in connection with industry submissions to FDA that analyzed purchasing data from five of the largest online cigar retailers in the U.S for purchases for the year 2017. This table shows conclusively that there is no material difference in purchase patterns between flavored and unflavored premium cigars. Further, this table shows that the average age and median age of online purchasers of both flavored and unflavored premium cigars is over 50 years old. Additionally, over 86% of online flavored premium cigar purchasers are age 35 or older, and 97.5% are age 25 or over.

Table 1[22]

	Flavored Premium Cigars			Non-Flavored Premium Cigars		
Age Cohort	**Number**	**Percentage**	**Cumulative**	**Number**	**Percentage**	**Cumulative**
18 – 20	371	0.4%	0.4%	3,768	0.4%	0.4%
21 – 24	1,817	2.1%	2.5%	15,380	1.8%	2.2%
25 – 34	9,587	11.1%	13.6%	80,777	9.3%	11.5%
35 – 54	35,370	41.1%	54.7%	295,879	34.1%	45.6%
>55	38,916	45.3%	100.0%	471,481	54.4%	100.0%
Total	**86,061**	**100.0%**	**100.0%**	**867,285**	**100.0%**	**100.0%**
Avg Age	52.0			55.4		
Median Age	53.0			57.0		

No data was available in the Econsult report with respect to youth (under age 18) purchasing patterns since the online retailers, in compliance with applicable law, did not make sales to purchasers under age 18. However, youths aged 12-17 were studied in the PATH Study, a study conducted by FDA in partnership with the National Institutes of Health, which represents the most comprehensive study of tobacco usage in U.S. history. The published data (Waves 1 – 3) of the PATH Study was analyzed by NERA Economic Consulting in a report dated July 25, 2018

[21] Although recent federal legislation increased the minimum age to legally purchase cigars to 21, the minimum age for legal purchase in 2017 was 18 years of age. As set forth above, the Econsult data shows that for flavored (as well as unflavored) premium cigars only 0.4% of online purchasers were ages 18 – 20 in 2017.

[22] *See* Drew Estate Comment on Modifications to Compliance Policy for Certain Deemed Tobacco Products, Econsult Solutions, Inc. Letter Report, dated April 30, 2019 submitted to Docket FDA-2019-D-0661 (submitted April 30, 2019). The Econsult Report, as filed with CAA's comments on the Regulation of Premium Cigars, is attached as Exhibit 10. The Econsult Letter Report is attached as Exhibit 11.

(which has been submitted in industry Premium ANPRM Comments filed with FDA).[23] As set forth below, the published PATH Study data – which is representative of all premium cigars – including both flavored and unflavored premium cigars – demonstrates unequivocally that youth usage of premium cigars (including flavored premium cigars) is virtually non-existent.

Indeed, with respect to "flavored" premium cigars, the absence of reported youth usage in the PATH data was so complete that NERA reported "there were too few observations to produce reliable estimates" for youth usage of "flavored" premium cigars.[24]

Table 2[25]

PATH Wave	Overall Premium Cigars	Overall Unflavored
Wave 1 (13,651 youth respondents)		
Overall Youth		
Percentage	0.08%	0.08%
Confidence Interval	(0.02-0.14%)	(0.02-0.14%)
Number of Users	8	8
Wave 2 (12,172 youth respondents)		
Overall Youth		
Percentage	0.04%	0.04%
Confidence Interval	(0.00-0.08%)	(0.00-0.08%)
Number of Users	4	4
Wave 3 (11,814 youth respondents)		
Overall Youth		
Percentage	0.02%	0.02%
Confidence Interval	(0.00-0.05%)	(0.00-0.05%)
Number of Users	1	1

Other data also supports exempting all premium cigars from FDA regulation. For example, according to the published PATH Study data (i) the median usage for premium cigar smokers (including both flavored and unflavored) is 1.7 days per month and (ii) only 3.3% of premium cigar smokers (including both flavored and unflavored) do so on a daily basis.[26] This is of particular relevance where the available scientific literature (including research by FDA researches) shows that non-daily premium cigar smokers face no increased risk of mortality or

[23] *See, supra*, note 18.

[24] As can be seen in Table 2, the scant few reports of any youth usage of premium cigars in Waves 1 to 3 of the FDA's Path Study, were in each case reports of usage of unflavored premium cigars.

[25] The report of NERA Economic Consulting "Report Regarding Consumption Patterns of Premium Cigars" is attached hereto as Exhibit 12. Table 2 above adapts work from Table 1 of Exhibit 12.

[26] Corey C, et al., *U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and health (PATH) Study, 2013-2014*, Nicotine and Tob. Res. ntx209 (2017) (available at https://www.ncbi.nlm.nih.gov/pubmed/29059423) (last accessed Mar. 26, 2020).

disease rates as compared to non-smokers. Finally, the median retail price of a premium cigar in the US is $7.49.[27]

b. Manufacturers Arguing "Flavored" Premium Cigars are Not Truly "Premium" are Doing so to Gain a Competitive Advantage

All cigars – even those with some sort of flavoring – that fit every one of the criteria set forth in point III above should be considered premium. While some argue that a "premium" cigar cannot be flavored, they do so seeking to gain a competitive advantage in the marketplace by subjecting "flavored" premium cigars to regulatory requirements and costs that would not apply to unflavored premium cigars. The premium cigar category should be defined by the physical manufacturing characteristics outlined above. In addition, FDA is actively considering the appropriate treatment of all flavored tobacco products.[28] CAA and others have submitted extensive comments to that ANPRM, and that rulemaking process should continue, rather than prejudging a conclusion and applying it to a narrow segment of the cigar category. Moreover, a national emergency should not provide cover for a small group of manufacturers seeking to obtain a competitive advantage they have been unable to achieve in the marketplace.

c. The Compliance Obligations for Substantial Equivalence Are No Less Burdensome and No More Useful with Respect to Flavored Premium Cigars than Unflavored Premium Cigars

Like unflavored premium cigars, flavored premium cigars are an agricultural product comprised of 100% tobacco leaf filler, surrounded by a whole tobacco leaf binder and wrapped in a whole tobacco leaf wrapper. As such, flavored premium cigars are subject to the exact same vagaries of handmade, agriculture products as unflavored premium cigars. For example, all premium cigars share the fact that each cigar will vary due to different thicknesses, weights and natural constituents of tobacco leaves based on when and where such leaves were harvested (including from different parts of the same plant, let alone different locations on a single farm, different farms, or different times of year). Each cigar will also have different characteristics, resulting from a handmade, artisanal manufacturing process (where each and every cigar, even in the same box, will have a slightly different weights, shapes, and measures). Likewise, flavored premium cigars, just like unflavored premium cigars, are largely produced in small batches, special configurations and limited editions to meet the requirements of the premium cigar marketplace. The premium cigar marketplace is defined by consumers that smoke premium cigars infrequently and enjoy special, unique and varying experiences when they do smoke. Unlike mass produced, machine-made cigarettes where a handful of brands dominate the marketplace, the limited production element of the premium cigar category, coupled with the vast number of unique premium cigar products, makes the cost burden of regulatory compliance crushing on all

[27] *Id.*

[28] *See* Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018) (to be codified at 21 C.F.R. 1100, 1140, 1143).

premium cigar manufacturers – whether the cigars are flavored or not.[29] Further, the current pandemic does not discriminate – all cigar manufacturers whether they make flavored cigars or not – are equally affected and equally unable to operate their businesses as normal and prepare quality SE Reports.

E. Conclusion

The Secretary has declared that the United States is facing a public health emergency due to the COVID-19 pandemic and that he has the power, and the imperative, to extend deadlines as necessary to meet this national and global emergency. It is beyond dispute due to the public health emergency and resulting effects on businesses that the May 12, 2020 deadline for the filing of SE Reports needs to be extended. That extension, however, should apply to all those impacted by the current national emergency, not only to a subgroup. Indeed, there is no rational basis for extending the deadline for anything less than all parties subject to the regulation. CAA requests that the Secretary and Commissioner stay and extend the May 12, 2020 deadline for the submission of SE Reports for all newly deemed tobacco products for no less than 90 days.

Respectfully Submitted,

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[29] These fundamental characteristics of premium cigar manufacturing, which are exactly the same for both flavored and unflavored premium cigars, are the primary drivers that make substantial equivalence, constituent testing, and other FDA regulation irrational for this category of goods, particularly when balanced against the overwhelming scientific data proving the absence of youth usage or impact to the public health.