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March 23, 2020

VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

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

The Honorable Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993
Stephen.Hahn@fda.hhs.gov

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 Premium 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:

This petition is filed on behalf of Alec Bradley Cigar Distributors, Inc.; Ashton Distributors, Inc.; Holt Cigar Company, Inc.; Crowned Heads, LLC; A. Fuente & Co.; Piloto Cigars, Inc.; Rocky Patel Premium Cigars; Oliva Cigar Co.; Cigar Rights of America; and the Premium Cigar Association. The above companies, on behalf of themselves, and associations, on behalf of their members, seek a stay of the pending May 12, 2020 deadline for substantial

equivalence reports 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). The petitioners request that the stay be strictly limited to "premium cigar" products, as that term is defined below, sold by the petitioner corporations and the members of the petitioner associations. Moreover, the stay would apply only to those premium cigars that entered the market between February 15, 2007 and August 8, 2016, the time frame of market entry to which the current May 12, 2020 deadline applies.

The petitioners request that the stay be put in place for *six months*, extending the deadline for the premium cigar products of the petitioner corporations and petitioner associations' members until November 12, 2020. The petitioners seek this stay pursuant to the Secretary's authority under the Public Health Service Act, 42 U.S.C. § 247d(d), and the Commissioner's authority under 21 C.F.R. § 10.35(b) to stay deadlines for regulatory programs, especially deadlines requiring "reports" from regulated industries, under appropriate circumstances. Proposed Order, Secretary of Health and Human Services (attached as Ex. 1); Proposed Order, Commissioner of Food and Drug Administration (attached as Ex. 2).

The justification for this stay is the COVID-19 pandemic. This pandemic has disrupted businesses around the globe. Government agencies have recognized that businesses that are struggling to survive through the pandemic cannot simultaneously comply with certain government regulatory information and payment deadlines. The United States Department of the Treasury, for example, has extended the routine April 15, 2020 deadline for tax filings and payments for 90 days. Internal Revenue Service, *Relief for Taxpayers Affected by Ongoing*

Coronavirus Disease 2019 Pandemic, Notice 2020-17 (Mar. 2020) (attached as Ex. 3); Internal Revenue Service, *Relief for Taxpayers Affected by Ongoing Coronavirus Disease 2019 Pandemic*, Notice 2020-18 (Mar. 2020) (attached as Ex. 4). The Securities Exchange Commission, the Federal Energy Regulatory Commission, and other regulatory agencies have extended regulatory deadlines. *See* U.S. Securities and Exchange Commission, *Order Under Section 36 of the Securities Exchange Act of 1934 Granting Exemptions from Specified Provisions of the Exchange Act and Certain Rules Thereunder* (Mar. 4, 2020) (attached as Ex. 5); *see also* Federal Energy Regulatory Commission, *Notice Granting Extension of Time*, Docket No. AD20-11-000 (May 19, 2020) (attached as Ex. 6). And the Supreme Court has issued a blanket 150-day extension for the filing of petitions for certiorari and ordered that reasonable extensions for responses and replies will be granted for COVID-related reasons as a "matter of course." U.S. Supreme Court, *Order* (Mar. 19, 2020) (attached as Ex. 7). Many lower courts similarly have extended deadlines for filings across the board and continued trials. *See, e.g.*, *In Re: Coronavirus Covid-19 Public Emergency*, Amended General Order 20-0012, N.D. Ill. 2020 (attached as Ex. 8).

Far from a routine regulatory deadline, the substantial equivalence process is the most burdensome and labor-intensive regulatory scheme ever imposed upon the premium cigar industry. The May 12, 2020 deadline—which dramatically reduced the time for compliance (until August 2021) put in place by the FDA in August 2017—in turn has stimulated the most significant regulatory compliance effort in the industry's history. Premium cigars are made by hand, from all-natural tobacco, and vary depending upon the best dark, air-cured tobacco available from different farms. This manufacturing process—which defines premium cigars—has resulted in tens of thousands of products of cigars, many of which entered the market after the Final Deeming Rule's 2007 "grandfather date," after which market entrants must seek FDA approval

At the most critical time for preparing to comply with the March 12, 2020 deadline, the pandemic is forcing premium cigar companies into an impossible choice: Ask their employees to come to the office and finish the substantial equivalence reports, in contravention of the President's plea to the country to work from home; or risk non-compliance with the deadline, with devastating consequences for their businesses. Importantly, preparing substantial equivalence reports is not an abstract process that can be performed from a home computer: Substantial equivalence reports require companies *physically* to compare applicant cigars to those on the market prior to 2007. This requires *in-person* access to each manufacturer's current and historical cigars. And, to a very significant extent, manufacturers have no choice at all. The President of Honduras just ordered the closure of all cigar factories in that country, one of three major manufacturing countries for premium cigars sold in the United States, to protect against the spread of the coronavirus. And manufacturers expect the government of the Dominican Republic to order similar measures in coming days. The COVID crisis makes compliance with the May 12, 2020 substantial equivalence deadline impossible.

At the same time, the requested stay is limited to premium cigars, as defined herein. For purposes of this requested stay, the petitioners define premium cigars as the FDA did in proposing the Proposed Deeming Rule in 2014, minus the requirement that a premium cigar be sold at a certain minimum price. 79 Fed. Reg. at 23,150. This definition ensures that the premium cigars subject to this stay will be handmade, from natural tobacco, and not used by youth. The FDA already has recognized that such premium cigars will be the "lowest priority" for enforcement, even after May 12, 2020, due to their "comparatively lower youth usage rates." FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Jan. 2020) at 31 ("January

2020 Guidance") (attached as Ex. 9). A stay of the substantial equivalence report deadline, limited to premium cigars, based on the coronavirus pandemic is consistent with the agency's existing judgments about the urgency and public health need for enforcement against premium cigars.

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

On May 10, 2016, FDA published a final rule entitled *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. The so-called "Final Deeming Rule" required cigar manufacturers to seek FDA approval for products that were commercial marketed for the first time after February 15, 2007. For premium cigar manufacturers, that mandate effectively required the submission of substantial equivalence reports, through which manufacturers would demonstrate that their post-2007 products presented no different issues of public health than a pre-2007 cigar. Family Smoking Prevention and Tobacco Control Act §§ 905(j) (21 U.S.C. § 387e(j)), 910(a) (21 U.S.C. § 387j(a)) (the "Act"). For cigars entering the market between February 15, 2007, and August 8, 2016, the Final Deeming Rule set an initial deadline for these submissions of February 8, 2018. 81 Fed. Reg. at 28,978, 29,003.

In August 2017, FDA extended the substantial equivalence deadline for premium cigars, and other combustible newly-deemed products, until August 8, 2021. *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) (attached as Ex. 10). On

January 2, 2020, the FDA observed that the deadline for submission of substantial equivalence reports for cigars is May 12, 2020, citing a decision in the U.S. District Court for the District of Maryland. January 2020, Ex. 9, at 27 (*citing 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.)).

B. <u>Action Requested: Stay Until November 12, 2020 the Deadline for the Corporate Petitioners and the Members of the Association Petitioners to Submit Substantial Equivalence Reports for their "Premium Cigar" Products that Entered the Market Between February 15, 2007 and August 8, 2016</u>

Petitioners request that the May 12, 2020, substantial equivalence report deadline be extended, for the premium cigar products of the corporate petitioners and the members of the association petitioners, for a six-month period until November 12, 2020. For purposes of the stay, petitioners request that "premium cigars" be defined as follows:

> a cigar that (1) is wrapped in whole tobacco leaf; (2) contains 100 percent tobacco leaf binder; (3) contains primarily long filler tobacco; (4) is made by manually combining the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) does not have a characterizing flavor other than tobacco; and (7) weighs more than 6 pounds per 1000 units.

This definition is the one crafted by the FDA in the Proposed Deeming Rule, minus its minimum retail price component, for reasons explained below. *Proposed Rule, Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act*, 79 Fed. Reg. at 23,150 (Apr. 25, 2014). The stay would be limited to those premium cigars introduced in the market prior to August 8, 2016. Proposed orders implementing the stay are attached to this petition.

The requested stay is sought under two, independent sources of authority. First, petitioners request that the FDA Commissioner act pursuant to his authority under 21 C.F.R. § 10.35(b) to stay the substantial equivalence report submission deadline for the premium cigars of the corporate

petitioners and the members of the association petitioners for six months, from May 12, 2020 to November 12, 2020. Section 10.35 of the Title 21 of the Code of Federal Regulations was in place before the Final Deeming Rule was adopted and is part of the backdrop of agency authority against which the agency adopted the Final Deeming Rule. As explained further below, granting the decision would be wholly consistent with the Final Deeming Rule.

Petitioners further request that the Secretary of the Department of Health and Human Services extend the substantial equivalence report deadline under identical terms as the stay requested of the Commissioner, pursuant to his authority under the Public Health Service Act. Under Section 319 of the Public Health Service Act, codified at 42 U.S.C. § 247d, the Secretary, when he has declared a public health emergency, may extend "deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary" and "may waive . . . any sanctions otherwise applicable to such failure to comply." *Id.* § 247d(d). To do so, he need only determine that "individuals or public or private entities are unable to comply with" the relevant deadline "wholly or partially as a result of a public health emergency" declared by the Secretary. *Id.* For the reasons explained below, the substantial equivalence report deadline concerns a "report[ ] required under [a] law administered by the Secretary," namely the Family Smoking Prevention and Tobacco Control Act. *Id.* On January 31, 2020, the Secretary declared a public health emergency due to the COVID-19 crisis. *See* U.S. Dep't of Health & Human Servs., *Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus* (2020) (attached as Ex. 11).

Petitioners request that both the Commissioner and the Secretary act, pursuant to their respective authorities, in order to reinforce the validity of any stay of the substantial equivalence

report deadline for the premium cigar products of the corporate petitioners and the members of the association petitioners.

C. Statement of Grounds for the Request that the Commissioner Grant a Stay under 21 C.F.R. § 10.35(b)

The COVID-19 pandemic is a global crisis, creating unprecedented and overwhelming challenges for all levels of government and businesses. On March 13, 2020, President Trump declared a national emergency due to the COVID-19 pandemic. *See Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak*, 85 Fed. Reg. 15,337 (Mar. 18, 2020) (attached as Ex. 12). The President and the Centers for Disease Control and Prevention have issued urgent guidance that employees work from home to the extent possible and Americans not gather in any setting in groups of greater than 10 people. *See* Ctrs. for Disease Control & Prevention, *Coronavirus Disease 2019 (COVID-19) Situation Summary* (attached as Ex. 13). The Government has insisted that avoiding workplaces is indispensable to stemming the spread of the virus. *See* President's Coronavirus Guidelines for America, *15 Days to Slow the Spread* (attached as Ex. 14). Businesses across the country have complied with federal Government guidance, shutting their offices and factories. In some jurisdictions, closing offices and factories is mandatory, as state and local governments have banned leaving homes except for essential purposes. *See, e.g.*, California Coronavirus Response, *Coronavirus (COVID-19) in California* (Mar. 19, 2020) (attached as Ex. 15). It is likely such state and local mandates will expand across the country. For example, petitioners Holt Cigar Company and Ashton Distributors' Pennsylvania office were forced to close after the Governor ordered that all "non-life sustaining businesses" must close immediately. *See* Declaration of Nadia Trowbridge ¶¶ 4-5 (attached as Ex. 28); Angela Couloumbis, *Gov. Tom Wolf orders all Pennsylvania businesses that aren't 'life-*

sustaining' to close, will enforce order, The Philadelphia Inquirer (Mar. 19, 2020) (attached as Ex. 16).

1. Because of the Public Health Emergency of the COVID-19 Crisis, Premium Cigar Manufacturer Compliance with the May 12, 2020 Substantial Equivalence Report Deadline Is Impossible

Under these unprecedented and severe circumstances, compliance with the May 12, 2020, substantial equivalence report deadline is virtually impossible.

First, preparing substantial equivalence submissions for premium cigars is extraordinarily labor intensive and, under the best of circumstances, was expected to burden all available premium cigar manufacturer staff resources, full time, right up until the May 12, 2020, deadline. As demonstrated in the attached declarations, each company has dedicated several personnel and advisors to preparing the submissions, with a carefully constructed work plan. Those work plans expected to consume every day between now and the deadline, under ideal working conditions. Most of the companies must make hundreds, if not thousands, of submissions, given the expansive number of different products of premium cigars. The vast number of products stems solely from the handmade character of premium cigars, harnessing the best tobacco from harvests in Nicaragua, the Dominican Republic, and Honduras.

Importantly, this is not work that can be accomplished from the homes of company employees. By definition, a substantial equivalence report requires the comparison of the physical qualities of a premium cigar that entered the market after February 15, 2007, to one that entered before. Accordingly, this work must be done in factories and corporate offices, with access to the inventory of cigars sold by the company, just when the federal Government is pleading with non-essential employees to stay in their homes.

The enclosed declaration from Robert T. Brady, Chief Financial Officer of A. Fuente & Co. and its affiliates, is emblematic of the challenges the industry is facing with the COVID-19 pandemic. As noted in the declaration, the pandemic has disrupted the company's substantial equivalence report workplan, making it "nearly impossible to meet the reporting deadline." Declaration of Robert Brady at ¶ 4 (attached as Ex. 29). At a time when many employees are unable to come into the office due to health or childcare needs, the work required to complete the substantial equivalence reports cannot be completed remotely. *Id.* at ¶¶ 4-5. An inability to get an extension on the May 12, 2020 deadline would be crushing for the company. *Id.* at ¶ 6. All other corporate petitioners are in a similar situation, and it is reasonable to assume that the manufacturer members of the association petitioners are similarly situated. *See* Declaration of Michael Conder at ¶¶ 3-6 (attached as Ex. 30); Declaration of Rafael Montero at ¶¶ 3-5 (attached as Ex. 27); Declaration of Rocky Patel at ¶¶ 4-6 (attached as Ex. 26); Declaration of Jorge L. Padrón at ¶¶ 4-6 (attached as Ex. 31); Declaration of Bernardo Rodriguez at ¶¶ 4-6 (attached as Ex. 32); Decl. of Nadia Trowbridge, Ex. 28, at ¶¶ 3-6.

This problem is underscored by foreign government mandates forcing premium cigar factories to shut down. Premium cigars, by definition, are made by hand, with one employee bringing the tobacco to another and to another. This system raises particular issues regarding the coronavirus, and governments have stepped in. Nearly all premium cigars sold in the United States are made in Honduras, Nicaragua, or the Dominican Republic. The Honduran government ordered all cigar factories to close their doors due to the coronavirus. *See* Charlie Minato, *All Cigar Factories in Honduras Closed this Week Due to Coronavirus*, Halfwheel (Mar. 16, 2020) (attached as Ex. 17). The Dominican Republic is expected to follow suit, and several premium cigar

factories have closed to protect their employees. *See* Decl. of Nadia Trowbridge, Ex. 28, at ¶ 4; *see also* Decl. of Rocky Patel, Ex. 26, at ¶¶ 4.

Many other agencies have recognized the difficulties of regulatory compliance deadlines, even regarding the submission of financial reports and information. Both the Securities and Exchange Commission and the Federal Energy Regulatory Commission have extended regulatory and report submission deadlines. U.S. Securities and Exchange Commission, *Order Under Section 36 of the Securities Exchange Act of 1934 Granting Exemptions from Specified Provisions of the Exchange Act and Certain Rules Thereunder* (Mar. 4, 2020) (attached as Ex. 5); *see also* Federal Energy Regulatory Commission, *Notice Granting Extension of Time*, Docket No. AD20-11-000 (May 19, 2020) (attached as Ex. 6). These relaxations apply to reports that do not necessarily require physical access to company inventory and could be performed remotely. The substantial equivalence reports are much more challenging than SEC and FERC regulatory submissions, as their preparation requires a physical presence at corporate offices and factories.

Second, the premium cigar industry is much less capable of responding to the substantial equivalence deadline under these circumstances than manufacturers of other tobacco products. Manufacturers of mass-produced cigars and cigarettes, for example, are massive conglomerates with thousands of corporate front-office employees. By contrast, the premium cigar industry is comprised of small, family-owned businesses, with at most dozens of corporate front-office employees. *See* Decl. of Rafael Montero ¶ 3 (attached as Ex. 27); Comment of Int'l Premium Cigar & Pipe Retailers Ass'n on Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, at 1, FDA-2014-N-0189 (Aug. 7, 2014) (attached as Ex. 18). This is an outgrowth of the handmade and artisanal nature of premium cigars, for which there is no economy of scale by

making huge machinery to facilitate production. The cigar companies individually seeking this relief here are among the examples of such small, family businesses. Alec Bradley Cigar Distributors, Inc., for example, has only 12 full time employees. *See* Decl. of Rafael Montero, Ex. 27, at ¶ 3.

Moreover, the regulatory burdens of substantial equivalence reports on premium cigar manufacturers are particularly grave compared to the volume of tobacco products they produce. Premium cigars constitute fewer than 3 percent of the cigars sold in the United States and fewer than 0.1 percent of all tobacco products sold in the United States. Comment of Cigar Rights of Am. on Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, at 3, FDA-2014-N-0189 (Aug. 8, 2014) (citing Alcohol and Tobacco Tax and Trade Bureau, 2013 – Tobacco Products Monthly Statistical Releases) (attached as Ex. 19). Notwithstanding these incredibly low volumes and miniscule impact on any public health issues presented by tobacco use in this country, premium cigars are expected to generate thousands, if not tens of thousands, of substantial equivalence reports because of the varieties of products stemming solely from their handmade construction. *See, e.g.*, *id.* at 16. Each of these varieties accounts for a very low volume of tobacco products. The multiplication of required reports, over this low volume, has presented a particularly severe burden for the premium cigar industry. While a mass-produced cigar company might be able to complete a handful of reports and spread the costs over millions of consumers, each premium cigar manufacturer must prepare hundreds over a much smaller volume and revenue base.

Third, the COVID-19 crisis compounds existing problems presented by the agency's apparent intention to enforce the substantial equivalence report deadline on May 12, 2020. When

the agency published its Final Deeming Rule, it recognized that implementing rules and guidance may very well be needed to instruct manufacturers about what substantial equivalence reports should contain. *See* 81 Fed. Reg. at 28,980, 28,996, 29,001, 29,004-05, 29,008, 29,012, 29,026, 29,046, 29,051-52, 29,078. The FDA set the substantial equivalence report deadline for 18 months later, understanding it would have flexibility further to delay it, to give the agency time to assess what rules and guidance would be needed and to issue it meaningfully in advance of when compliance would be required. 81 Fed. Reg. at 29,001, 29,012. Following through on the Final Rule, the agency determined in August 2017 that it needed to issue "foundational rules" for the premarket review process before requiring submissions and delayed the substantial equivalence report deadline until August 2021 to allow it to do so. *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death* (July 27, 2017) (attached as Ex. 20). The agency was wise to make this determination and to adjust the deadline, as the statute required the agency to issue a rule specifying the form and manner of substantial equivalence reports, before demanding compliance. Act § 905(j) (21 U.S.C. § 387e(j)). This is a statutory requirement particular to cigars and does not apply to e-cigarettes, which must pass through a separate process. Act § 910(a)(3) (21 U.S.C. § 387j(a)(3)). The agency has not yet finalized such rules and, as a result, even at this late stage, premium cigar manufacturers do not know what will be required in their substantial equivalence reports.

Premium cigar manufacturers had been faced, unfairly, with the burden of guessing what the agency would want in substantial equivalence reports, the May 12 deadline bearing down on them. Decl. of Rocky Patel, Ex. 26, at ¶ 7. That additional burden—entirely of the FDA's making—will be all the more difficult with corporate employees and outside advisors sequestered to their homes. One rule, which might have begun to address this deficiency, was expected in

April 2020. *Proposed Rule, Content and Format of Substantial Equivalence Reports*, FDA-2016-N-3818, 84 Fed. Reg. 12,740 (Apr. 2, 2019); Unified Regulatory Agenda, 0910-AH89 (accessed Mar. 22, 2020) (attached as Ex. 21). That was already too late to make a meaningful difference in this problem. The prospect of the Secretary of the Department of Health and Human Services issuing such a rule in April 2020, amidst his administration of the federal response to the COVID-19 crisis, is now even more far-fetched. This collision between the absence of agency implementing rules (uniquely statutorily required for cigars and other products going through the substantial equivalence process) and the May 12, 2020 deadline is additional justification for granting the stay.

2. The Requested Stay, Limited to Premium Cigars and to Address the Unforeseen COVID-19 Crisis, Is Not Inconsistent with the Public Health Objectives of the Agency

Granting the stay, in the light of these incredible burdens on premium cigar manufacturers compounded by the unprecedented coronavirus, will not interfere with the public health objectives of the Final Deeming Rule. The FDA has stated that premium cigars—handmade cigars that are expensive—are its "lowest priority" for enforcement. January 2020 Guidance, Ex. 9, at 31. Moreover, premium cigars constitute a sliver of tobacco products, as they are fewer than 3 percent of cigars sold in the United States and 0.1 percent of all tobacco products sold in the United States. *See* Comment of Cigar Rights of Am., Ex. __, at 3. And undisputed evidence before the agency—provided through studies conducted by the FDA's own staff—shows that premium cigar consumers are older, higher-income, and better-educated than consumers of other tobacco products. *See* Catherine G. Corey et al., *US 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, 2013-14*, Nicotine & Tobacco Res., at 1460 (2018) ("Corey

2018") (attached as Ex. 22). They use the product infrequently, the median consumer using premium cigars 1.4 days per month, in contrast to the 29.4 days per month cigarette consumers use their product. *Id.* at 1461. Fewer than 3 percent of premium cigar consumers use the product on a daily basis. *See* Catherine G. Corey et al., *Little Filtered Cigar, Cigarillo, And Premium Cigar Smoking Adults – United States, 2012-2013*, published in Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (Aug. 1, 2014) ("Corey 2014") (attached as Ex. 23); *see also* Comment of Int'l Premium Cigar & Pipe Retailers Ass'n and Cigar Rights of Am. on Regulation of Premium Cigars at 28-30 & Ex. 4, FDA-2017-N-6107 (July 25, 2018) (attached as Ex. 24). Importantly, a study in the *Journal of the American Medical Association* has concluded that less than daily use of cigars is not correlated with a statistically significant increase in premature mortality. *See* Carol H. Christensen et al., *Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population*, JAMA Internal Med., Feb. 19, 2018, at 1, 6 (attached as Ex. 25).

The agency is reconsidering whether it should regulate premium cigars at all. *Advanced Notice of Proposed Rulemaking*, *Regulation of Premium Cigars*, 83 Fed. Reg. 12,901 (Mar. 26, 2018). But, regardless of the agency's current position on whether premium cigars should be regulated, it is clear that a delay in the substantial equivalence deadline will not significantly affect the public health goals of regulation. Throughout litigation regarding when and how cigars should go through premarket review, no party—no public health group or government agency—has identified a feature of premium cigars for which premarket review is needed to detect and stop. This stands in contrast to other tobacco products, including other cigars, where parties have cited problems of youth usage, flavors that attract youth, or additives that make the product more addictive or dangerous. By definition, premium cigars do not present these problems. They are

made by hand, from all-natural tobacco, with no additives or artificial flavors. *See*, *e.g.*, Brief of Appellee Public Health Groups, ECF No. 114, *In re Cigar Ass'n of Am.*, No. 19-2130 (4th Cir. Feb. 20, 2020), at 11-13 (seeking to defend immediate enforcement of the premarket review deadlines against cigars only on the basis of mass-produced, flavored cigars).

In addition, premium cigars are nothing like e-cigarettes, for which many have advocated an urgent need for premarket review because they are novel products with unknown health effects. Premium cigars have been on the market—made the same way—for centuries. There is no urgent need to get a handle of what some innovative product is doing to consumers.

Even if there were some public health problem with premium cigar products and the May 12 deadline were enforced against premium cigars, there still would be many grandfathered premium cigars on the market and usage would not be affected. The only effect would be random economic dislocation among manufacturers. Premium cigar products will be forced off the market, based likely on company age, size, and their financial ability to push through the coronavirus crisis. Those factors have nothing to do with advancing the public health. Premium cigar companies would close and employees would lose their jobs, precisely when the American economy needs no more of that. The only responsible course of action is for the Commissioner to grant the stay and to prevent adding on to the disastrous economic consequences of the COVID-19 crisis. Failing to grant the stay would be an arbitrary and capricious action that federal law clearly forbids. *See* 5 U.S.C. § 706.

3. The FDA's 2014 Definition of Premium Cigars, Minus the Minimum Retail Price Component, Is the Appropriate Scope of the Stay

For purposes of providing the relief requested by this petition, the agency should use the definition of "premium cigars" that the FDA crafted in 2014 when proposing the Deeming Rule,

minus the requirement of a minimum retail price. 79 Fed. Reg. at 23,150. Therein, the agency proposed to define premium cigars as a cigar that "(1) [i]s wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar . . . ; (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units." *Id.* Commenters then widely accepted the agency's definition, with one adjustment: Eliminating the minimum price requirement, item number 6.

For purposes of the stay, the agency should use its 2014 definition of "premium cigars," minus the price requirement for several reasons. First, during this time of public health emergency, it will be impossible for manufacturers to know at what price retailers will sell their products. At the same time, the restrictions on the manner and materials of manufacturing—that the cigars be made entirely by hand, that they arise wholly from natural, whole leaf tobacco, and that they lack additives or flavors—will ensure that the resulting cigar is expensive and not attractive to youth.

Second, the definition will be used for a stay directed only at the substantial equivalence report requirement. That requirement focuses exclusively on whether the "physical" characteristics of the product, rather than the manner of sale, is different. *Philip Morris USA Inc. v. U.S. Food & Drug Admin.*, 202 F. Supp. 3d 31, 38, 42-43 (D.D.C. 2016) (Mehta, J.).

Third, it is now well recognized that the $10 minimum price threshold was too high. When the FDA's own scientists subsequently set out to study the usage patterns of premium cigars, they identified premium brands and then included any cigar selling for more than $2. *See* Corey 2018, Ex. 22, at 1469. That study produced the results described above—no measurable youth usage and very infrequent usage by adults—that the FDA already has determined is cause for

reconsidering whether premium cigars should be regulated. 83 Fed. Reg. at 12,902-03 (citing Corey 2018). The Commissioner should use the proposed definition for the limited purpose of putting the requested stay into place. Doing so would be without prejudice to the agency adjusting the definition for different contexts (including rules entirely exempting premium cigars from all regulation, *see, e.g.*, 83 Fed. Reg. 12,901).

4. Previous Agency Pronouncements Are Not Sufficient to Protect Premium Cigar Manufacturers from the May 12, 2020 Deadline

On January 2, 2020, the agency pronounced that premium cigars—what the agency referred to as handmade, expensive cigars—would be its "lowest priority" for enforcement, even if a premium cigar manufacturer had not submitted substantial equivalence reports by the May 12, 2020. January 2020 Guidance, Ex. 9, at 31. The agency said designating premium cigars as its lowest priority was warranted due to their "comparatively lower youth usage rates." *Id.* It has been suggested that the agency's statement is sufficient protection for premium cigar manufacturers who may not meet the deadline, as the agency does not itself appear poised to seize premium cigar products and penalize manufacturers and retailers on May 13, 2020.

That suggestion is wrong. The announcement that premium cigars will be the lowest enforcement priority, while perhaps providing comfort against agency action, provides no assurance that distributors and mail order companies will accept into their channels premium cigar products of manufacturers that have not managed to file substantial equivalence reports. The evidence thus far is actually to contrary. The major mail order distributors, and many retailers, are controlled by the Nation's largest tobacco companies, including Scandinavian Tobacco Group and Altadis. Those companies have many grandfathered products for which substantial equivalence reports are not needed and the vast corporate resources to push through the compressed compliance

schedule and the COVID crisis. They have issued letters to premium cigar manufacturers demanding evidence of timely substantial equivalence reports submissions and have stated that they will not otherwise accept products, notwithstanding the FDA's statements about premium cigar products being its "lowest priority" for enforcement. Decl. of Michael Conder, Ex. 30, at ¶ 6; Decl. of Rocky Patel, Ex. 26, at ¶ 6; Decl. of Bernardo Rodriguez, Ex. 32, at ¶ 7; Decl. of Jorge L. Padrón, Ex. 31, at ¶ 7. Presumably, they believe that cutting off technically non-compliant products from their channels will comparatively harm their competitors and permanently crush the smaller businesses unable to press on timely compliance during the COVID crisis. The agency should not be content that its January 2, 2020, announcement is enough. Absent a stay of the May 12, 2020, deadline, the largest companies will consolidate their position, other premium cigar manufacturers will close, and thousands will lose their jobs.

5. The Commissioner Has Ample Authority to Issue the Requested Stay

The Commissioner has ample authority under Section 10.35 of Title 21 of the Code of Federal Regulations to grant the requested stay. Section 10.35 authorizes the Commissioner to "stay or extend the effective date of an action pending or following a decision on any matter." 21 C.F.R. § 10.35(a). The Commissioner may do so of his own initiative or upon petition of a regulated party. *Id.* § 10.35(a)-(b). The Commissioner may grant the requested stay if he concludes that the stay "is in the public interest and in the interest of justice." *Id.* § 10.35(e). Moreover, Section 10.35(e) *requires* the Commissioner to grant a requested stay if: "(1) The petitioner will otherwise suffer irreparable injury[;] (2) The petitioner's case is not frivolous and is being pursued in good faith[;] (3) The petitioner has demonstrated sound public policy grounds supporting the stay[;] (4) The delay resulting from the stay is not outweighed by public health or other public interests." *Id.*

Petitioners respectfully submit that all of the requirements for mandating a grant of the stay have been satisfied.

First, the corporate petitioners and the members of the association petitioners clearly will suffer irreparable harm. As demonstrated in Section C.1 above, the COVID crisis renders compliance with the May 12, 2020 deadline impossible. Moreover, regardless of the agency's enforcement plans, the petitioners' premium cigar products will be dumped out of distribution channels in the absence of a stay. *See* Section C.4, *supra*. Combined with the demand and credit strains the COVID economic crisis will cause, premium cigar manufacturers will close, thousands will lose their jobs, and it will be difficult to recover any damages against the government agency that will be responsible for that. *See R.J. Reynolds Tobacco Co. v. FDA*, 823 F. Supp. 2d 36, 50 (D.D.C. 2011) (cost of compliance with FDA rule was irreparable because of unlikelihood of recovering from the agency); *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) ("[W]here . . . the plaintiff in question cannot recover damages from the defendant due to the defendant's sovereign immunity, any loss of income suffered by a plaintiff is irreparable *per se*."); *see also see also Texas v. EPA*, 829 F.3d 405, 433-34 (5th Cir. 2016) ("[C]omplying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs.").

Second, to the extent that pending litigation is a factor triggering a mandatory stay, the petitioner associations are maintaining lawsuits against the FDA challenging the substantial equivalence process, in which there is a pending motion for summary judgment. *Cigar Ass'n. of Am. v. U.S. Food & Drug Admin.*, No. 16-cv-1460 (D.D.C.), ECF Nos. 178, 180, 185-86, 188. The FDA did not move to dismiss those claims; they are hardly "frivolous," and they are being pursued "in good faith." 21 C.F.R. § 10.35(e)(2). Importantly, the FDA's regulatory standards requiring

granting a stay are different than those for a preliminary injunction in a court; the Commissioner need not determine that the association petitioners are likely to succeed in their litigation to conclude that a stay is required.

Third, "there are sound public policy grounds supporting [a] stay." 21 C.F.R. § 10.35(e)(3). In the absence of a stay, it will be nearly impossible for premium cigar manufacturers to comply with the May 12, 2020 deadline. *Id.* at Section C.1. *supra.* The result will be massive and entirely avoidable economic displacement, on top of that caused directly by the COVID crisis. *Id.* Other agencies have recognized this reality, relaxing and extending regulatory deadlines. *Id.*

Fourth, "the delay resulting from the stay is not outweighed by public health other public interests." 21 C.F.R. § 10.35(e)(4). The FDA already has determined that premium cigars will be their lowest priority for enforcement, even after May 12, 2020. *See* Section C.2, *supra.* Premium cigars are not used by youth and are used only infrequently by adults. *Id.* Moreover, they constitute only a sliver of the market for tobacco products, while bearing the brunt of the premarket review regulatory burdens given the wide range of their relatively harmless varieties. A stay—limited to premium cigar products—will not raise countervailing issues of public health that will outweigh the economic distress caused by the combination of the May 12 deadline and the COVID crisis.

This petition is timely. Under Section 10.35, a petition for a stay is timely, even if filed later than 30 days after "the date of the decision involved," if the "Commissioner permits the petition to be filed after 30 days" for "good cause." 21 C.F.R. § 10.35(b), (g). The Commissioner must exercise his discretion to accept a petition submitted later than 30 days after the decision involved in a manner that is not arbitrary or capricious. 5 U.S.C. § 706(2)(A).

The coronavirus national and public health emergency clearly constitutes "good cause," rendering the petition for stay timely. The coronavirus, plainly, was not extant within 30 days of the decision involved. This significant and intervening circumstance is plainly good cause and ample reason to accept the petition under Section 10.35(b), (g).

Nothing in decisions of the United States District Court of the District of Maryland is inconsistent with granting the requested stay. *Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019). That court held that the August 2017 guidance—extending premarket review deadlines for all so-called "newly deemed products," including mass-produced cigars and e-cigarettes—was outside the agency's authority and inconsistent with the Final Deeming Rule. But that guidance was not issued pursuant to a petition submitted under 21 C.F.R. § 10.35 or through an invocation of the Commissioner's Section 10.35 authority. The requested stay would occur under a different procedure than the August 2017 Guidance and under a different head of authority not invoked by the Guidance or in defense of the Guidance. Moreover, granting a stay pursuant to Section 10.35 is plainly consistent with the Final Deeming Rule. Section 10.35 was in place long before the Final Deeming Rule was adopted. The Final Deeming Rule, which amended Title 21 of the CFR, was adopted against the backdrop of the Commissioner's general authorities, including Section 10.35. Any deadlines set in the Final Deeming Rule, therefore, were set on the presumption that the Commissioner could receive a petition under Section 10.35 and then grant a stay, pursuant to the standards set forth in Section 10.35.

Moreover, the requested stay would be wholly consistent with the provision of the District Court's order providing that "[t]he FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis." *Acad. of Pediatrics*, 399 F. Supp. 3d at 487. The COVID-19 health crisis certainly qualifies as "good cause," as it prevents premium cigar

manufacturers from utilizing the necessary personnel to complete the substantial equivalence reports. And, because premium cigars comprise less than 3 percent of cigars and less than 0.1 percent of tobacco products sold in the United States, the FDA may stay the deadline as to all premium cigars and still be acting on a "case-by-case basis." The stay would leave the May 12, 2020, deadline in place for 97 percent of cigars, and well over 99 percent of the units of tobacco products, introduced into U.S. commerce between February 15, 2007 and August 8, 2016. Moreover, the stay would not apply even to premium cigars introduced into commerce after August 8, 2016.

Putting aside relief for the premium cigar products of the association's members, the agency at least should grant the requested stay for each of the corporation petitioners. Each corporation's request clearly would constitute a "case-by-case" extension. Should the Commissioner adopt this latter approach, the association petitioners respectfully request that the Commissioner announce a channel for individual companies selling premium cigars each to file such a request for stay and have it quickly granted.

D. Statement of Grounds for 42 U.S.C. § 247d(d) Request

The Public Health Service Act supplies an independent basis for granting the requested stay. Section 319 of the Act, codified at 42 U.S.C. § 247d, authorizes the Secretary of HHS to extend deadlines for regulatory schemes under his supervision when regulated 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" due to a public health emergency. 42 U.S.C. § 247d(d). The Secretary may grant such extensions "as the circumstances reasonably require." *Id.* The Secretary also "may waive . . . any sanctions otherwise applicable to such failure to comply." *Id.* § 247d(d). To extend any deadline or waive any sanction associated with missing a report deadline, the

Secretary need only determine that "individuals or public or private entities are unable to comply with" the relevant deadline "wholly or partially as a result of a public health emergency" declared by the Secretary. *Id.*

On January 31, 2020, the Secretary declared a public health emergency due to the COVID-19 pandemic. *See* U.S. Dep't of Health & Human Servs., *Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus*, Ex. 11. Moreover, deadlines related to the Final Deeming Rule are under the Secretary's supervision. The Family Smoking Prevention Act placed the deeming authority itself, as well as the authority for all implementing regulations, in the hands of the Secretary. 21 U.S.C. § 387a(a)-(b) ("Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 387k of this title, shall be regulated by the Secretary under this subchapter," and "[t]his subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.").

The required substantial equivalence reports are specifically placed under the supervision of the Secretary. Section 905(j)(1) of the Act expressly provides that a manufacturer shall "report to the Secretary" the basis for the determination that a tobacco product is "substantially equivalent" to tobacco product "commercially marketed in the United States . . . as of February 15, 2007." Act § 905(j)(1) (21 U.S.C. § 387e(j)(1)). The "report" must occur in "such form and manner as the Secretary shall prescribe." Act § 905(j)(1) (21 U.S.C. § 387e(j)(1)). In addition, the regulatory scheme depends on whether "the Secretary has issued an order that the tobacco product . . . is substantially equivalent to a product commercially marketed . . . in the United States as of February 15, 2007." Act § 910(a)(2)(A)(i) (21 U.S.C. § 387j(a)(2)(A)(i)). Even if the Secretary has

delegated some of these responsibilities to the Commissioner, *see* 21 U.S.C. § 393(d)(2) (noting that the Secretary may act through the Commissioner of Food and Drugs), the substantial equivalence report deadline clearly is a "deadline[ ] for the submission to the Secretary of data or reports required under any law administered by the Secretary." 42 U.S.C. § 247d(d). The Public Health Service Act authority to extend deadlines is not limited to reporting requirements imposed under Title 42; it applies to "data or reports required under any law administered by the Secretary." *Id.*

For the reasons stated in support of the Section 10.35 request, fully incorporated herein, the corporate petitioners and members of the association petitioners clearly are "unable to comply with" the May 12, 2020 substantial equivalence report deadline for their premium cigar products "wholly or partially as a result of a public health emergency" declared by the Secretary. *Id.* The COVID crisis renders petitioners' compliance with the May 12, 2020 deadline virtually impossible. *See* Section C.1 *supra*.

Declaring the requested extension under the Public Health Service Act is not contrary to decisions of the United States District Court of the District of Maryland. *See Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 487 (D. Md. 2019); *see also* Section C.5 *supra*. That court was addressing guidance issued in August 2017 extending certain premarket review deadlines for all newly deemed products. That guidance had not and could not have invoked the Secretary's authority under the Public Health Service Act, as there was not a public health emergency declared by the Secretary at the time. To the extent that the court expressed views about the appropriate interpretation of the Family Smoking Prevention and Tobacco Control Act, such holdings do not control the Secretary's authority under the Public Health Service Act. Importantly, the Secretary's authority to extend deadlines "for the submission to the Secretary of

data or reports required under any law administered by the Secretary" stands expressly "*notwithstanding any other provision of law*." 42 U.S.C. § 247d(d).

Accordingly, petitioners request that that the Secretary extend the May 12, 2020 substantial equivalence report requirement for the premium cigar products of the corporate petitioners and the members of the association petitioners for six months, to November 12, 2020. This extension shall apply to those premium cigar products, as that term is defined above (*see* Section C.3 *supra*) that were commercially marketed for the first time between February 15, 2007 and August 8, 2016. Petitioners further request that the Secretary "waive . . . any sanctions otherwise applicable" to the petitioners' "failure to comply" with requirements to submit substantial equivalence reports for their premium cigar products. Those sanctions would include any fines or penalties or provisions of law that would render products for which such reports have not been submitted eligible to be considered "adulterated" under Section 902, "misbranded" under Section 903, or for "recall" pursuant to Section 908(c). Act §§ 902 (21 U.S.C. § 387b), 903 (21 U.S.C. § 387c), 908(c) (21 U.S.C. § 387h(c)).

E. <u>Conclusion</u>

Due to the COVID-19 pandemic, petitioners request that the FDA Commissioner and the HHS Secretary stay the May 12, 2020, deadline for submitting substantial equivalence reports for the premium cigar products of the corporate petitioners and the members of the association petitioners for six months, to November 12, 2020. Proposed Order, Secretary of Health and Human Services, Ex. 1; Proposed Order, Commissioner of Food and Drug Administration, Ex. 2. The Commissioner and the Secretary may act pursuant to their respective authorities under 21 C.F.R. § 10.35(b) and 42 U.S.C. § 247d(d).

Petitioners request the stay and extension be granted within 7 days. This petition arises from a public health emergency, wherein many other federal agencies are extending regulatory deadlines. Should a favorable action not be taken in response to this petition within 7 days, Petitioners will move to amend their Complaint in *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 411 F. Supp. 3d 1, No. 16-cv-1460 (D.D.C. 2019), or otherwise bring claims to challenge what will, regrettably, have been the Commissioner's and Secretary's arbitrary and capricious failure to grant this petition. Petitioners will promptly move the Court for a preliminary injunction on such claims and will not consent to any extensions of time for the Department of Justice to respond to such motions.

Respectfully Submitted,

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