



October 06, 2023

VIA ELECTRONIC SUBMISSION (www.regulations.gov)

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Requirements for Tobacco Manufacturing in Practice (Docket No. FDA-2013-N-0227)

The Boutique Cigar Association (“BCA”) submits these comments in response to the U.S. Food and Drug Administration’s (“FDA’s” or the “Agency’s”) March 10, 2023, proposed rule entitled “Requirements for Tobacco Product Manufacturing in Practice.” *See* 88 Fed. Reg. 15,174 (March 10, 2023) (the “Proposed Rule”).

The Boutique Cigar Association was founded in July of 2016 by Dr. Gaby Kafie, a retired physician with a great passion for premium cigars. He owns and operates Kafie 1901 Cigars and Kafie 1901 Coffee Co, out of Miami, Florida. The BCA is an organization which serves as a “collective voice” for many small family owned boutique cigar manufacturers in the United States. The BCA is rather unique because three of its members (2 of its Board of Directors) are physicians. We are very active within our industry and thrive on maintaining our members educated and compliant within the premium cigar industry.

The Boutique Cigar Association (BCA) currently comprises more than 35 member companies, all of which are distinguished as family-owned, independent boutique cigar manufacturers. It is our estimation that there exist approximately 150 additional companies fitting this category; however, given our status as a newly established association, the process of connecting with and recruiting these entities is an ongoing endeavor.

Our member companies specialize in the importation of premium cigars to the United States, subsequently distributing them to a network of over 3000 premium cigar retailers, a majority of which are family-owned brick-and-mortar establishments. The core commitment of our Association is to foster a fair and equitable marketplace for these premium cigar entities.

The BCA has diligently undertaken the task of reviewing and analyzing the comments submitted on behalf of the Premium Cigar Association. We wish to convey that our message harmonizes with all of the points articulated in their submissions. We wholeheartedly endorse their comments and share a common mission to safeguard the interests of all premium cigar manufacturers. This endorsement is particularly pronounced in relation to their comments delineated in footnote 1, which we have provided below for your reference.

¹ Following FDA's publication of the Proposed Rule, the U.S. District Court for the District of Columbia vacated the Deeming Rule as applied to premium cigars based on the court's earlier finding that the Agency acted arbitrarily and capriciously in including premium cigars within the scope of the Deeming Rule. *See Cigar Ass'n of Am. et al. v. U.S. Food & Drug Admin.*, Case No. 16-CV-01460, Doc. 276 (D.D.C., Aug. 9, 2023). Accordingly, as premium cigars no longer qualify as FDA-regulated tobacco products, PCA's comments pertain to pipe tobacco and to other handmade cigars (i.e., those handmade cigar products that do not meet the definition of "premium cigar" established by the U.S. District Court for the District of Columbia defined in its August 19, 2020, order in *Cigar Ass'n of Am.*) (referred to as "non-premium handmade cigars" for purposes of these comments). However, in the event any change in the regulatory status of premium cigars under Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 387 et seq.) occurs following the close of this comment period (for example, due to any successful appeal by FDA of the U.S. District Court for the District of Columbia's August 9, 2023, order), PCA would request that FDA re-open the comment period for the Proposed Rule to receive comments regarding the applicability of tobacco product manufacturing practice requirements to premium cigars.

While we appreciate the FDA's efforts to protect public health, we believe that these regulations may have unintended consequences that could negatively impact small business owners in the premium cigar industry.

Please allow us the opportunity to present the Board of Directors of the BCA. The Board is made up of seven members. They are listed below.

President	Armen Caprielian (<i>Owner of D.A.V. Cigars</i>)
Vice President	Dr. Garo (<i>Owner of Garo Cigars</i>)
Secretary	John J. Jordan (<i>Owner of Mountain Smoke Premium Cigars</i>)
Treasurer	Dr. Gaby Kafie (<i>Owner of Kafie 1901 Cigars & Coffee Co.</i>)
Board Member	Alan Rouleau (<i>Owner of Alan Rouleau Couture</i>)
Board Member	Jamie DeViese (<i>Law Student / Owner of MSPC</i>)
Board Member	Chet King (<i>General Manager OTR Premium Cigars</i>)

Our Board is comprised exclusively of dedicated volunteers who harbor a profound enthusiasm for family-owned boutique premium cigar enterprises. Within the purview of the BCA, the term "boutique" is precisely delineated as pertaining to companies with an annual production of fewer than 500,000 premium cigars. As stakeholders in the premium cigar industry, we possess firsthand awareness of the susceptibilities of our segment to external influences, particularly in the realm of FDA regulations. It is with this cognizance that we maintain an unwavering commitment to labor diligently in order to mitigate the challenges confronting our industry.

Our objective is to advocate for equitable and judicious FDA regulations, thereby aiming to secure a prosperous future for small businesses and family-owned ventures within the premium cigar marketplace. We ardently aspire to foster an environment where these entities can flourish unhindered.

The premium cigar industry stands apart, characterized primarily by family-owned enterprises, many of which have been cherished through successive generations. This realm is deeply rooted in tradition and the values of kinship, warranting steadfast protection and preservation for posterity. In our Association, we take immense pride in contributing to these preservation efforts.

We take pleasure in introducing "Protecting the Legacy," our distinguished podcast available on all major podcast platforms. Each episode is a reverent tribute to the families entrenched in the premium cigar industry, a commemoration of their past, a celebration of their present, and a nod to their enduring legacy. Through this podcast, our intent is to illuminate the tapestry of history and tradition woven into this industry and to inspire others to join us in safeguarding it for the generations yet to come.

At the Boutique Cigar Association (BCA), our foremost objective is to safeguard the enduring vitality of all boutique family-owned cigar enterprises. Our sector within the industry is notably delicate and, in our assessment, confronts the most formidable challenges posed by FDA regulations. Over the past seven years, the FDA has exerted substantial pressure on our industry, precipitating the closure of numerous firms or their acquisition by larger entities. A palpable sense of apprehension permeates our community, and many proprietors find themselves fatigued by the relentless demands imposed upon them.

Nevertheless, our commitment to our mission remains unwavering. We firmly believe that the small, family-owned cigar companies constitute the heart and soul of our industry. In light of this conviction, we are resolute in our determination to employ every resource at our disposal to ensure their continued existence.

In spite of the formidable pressures our industry contends with from the FDA, the Boutique Cigar Association (BCA) remains focused in its unwavering dedication to championing the interests of small, family-owned cigar enterprises. We are of the firm conviction that the FDA's comprehension of our industry is lacking, notably in its grasp of the intricate workings of premium cigar businesses. This deficiency is particularly conspicuous when considering the unique trials faced by small family-owned boutique cigar manufacturers striving to thrive in this sector.

Our resolve, however, is unyielding. Through an amalgamation of educational initiatives, tireless advocacy efforts, and extensive outreach endeavors, we are diligently working to rectify this disparity in understanding. Our aim is to ensure that regulatory bodies, including the FDA, develop a more comprehensive appreciation of our member companies and the distinctive

challenges they encounter. With your support, we are confident that we can safeguard the legacy of small, family-owned cigar enterprises for generations yet to come.

At the Boutique Cigar Association (BCA), we take immense pride in our identity as artisanal companies. For us, "craft" is not merely a fashionable term; it is a fundamental ethos that underpins our essence. Our member companies epitomize small-scale operations, typically staffed by no more than 50 individuals within their factories. Even our distribution entities, by industry standards, are notably smaller, often overseen by a single family and staffed with only a handful of dedicated employees. In our approach, we maintain a streamlined sales force, leaning on independent representatives for the promotion and sale of our products. Rather than constraining us, our modest size stands as a testament to our resilience, granting us the agility, adaptability, and a dedicated commitment to our craft.

The Boutique Cigar Association (BCA) has established a definitive criterion for delineating the size and character of our member companies. In strict accordance with this definition, our annual production does not exceed 500,000 large premium cigars, rendering us the most vulnerable segment within the premium cigar industry. While we take immense pride in our artisanal approach and commitment to quality, our constrained budgets and resources bestow upon us a set of distinctive challenges when navigating the intricate regulatory landscape.

Notably, the FDA's regulations stand as a risk to our operations, given our limited manpower and financial means to meet the extensive requirements they impose. Nevertheless, our commitment remains steadfast. We persist in our support for the industry, safeguarding the livelihoods of our members, all of whom share an indomitable passion for the craft of producing the finest premium cigars in the world.

Within the Boutique Cigar Association (BCA), we take immense pride in embodying the American dream. A significant portion of our member companies arrived on these shores in pursuit of a brighter future, channeling their resources and boundless passion into the establishment and growth of their businesses. We firmly believe that the United States stands as an exceptional crucible for nurturing creativity, fostering innovation, and enabling the unfettered expression of one's self. Our hearts are filled with gratitude for the myriad opportunities this great nation has bestowed upon us.

Nonetheless, a challenge looms in the form of the "Requirements for Tobacco Product Manufacturing Practices" regulations. While we wholeheartedly appreciate the imperative of upholding the safety and quality standards for tobacco products, we maintain a firm conviction that these regulations are both ill-suited for and should be exempted from application within our artisanal industry.

In the ensuing paragraphs, we aim to articulate the fundamental distinctions between our industry and the large-scale tobacco manufacturers, elucidating why the regulations tailored to the latter are ill-suited for our unique craft. Despite our modest scale and limited resources, our

commitment to championing our rights and advocating on this pivotal matter remains priority number one.

Drawing from our experience, we have observed that small factories with compact workforces consistently uphold higher operational standards when juxtaposed with their larger, mass-production counterparts. The rationale behind this phenomenon is straightforward: in settings with fewer personnel, the oversight and supervision of all processes become notably more manageable.

Our member companies are deeply engrossed in the art of crafting premium cigars through meticulous small-batch production methods. We firmly contend that our small size and artisanal approach afford us a distinctive fusion of passion, innovation, and tradition that we add to the industry. This sets us apart from larger factories that may prioritize quantity over the meticulous craftsmanship required to produce exceptional quality.

Rather than subjecting small businesses like ours to rigorous regulatory mandates, we advocate for the preservation and protection of our factories and enterprises. We serve as a living testament to the origins of every cigar factory, which began as modest establishments at some point in their history. By nurturing and endorsing small-scale production, we fortify the artistic essence and craftsmanship that constitute the very essence of the cigar-making industry.

In summary, we take great pride in our role as a close-knit, dedicated team of cigar artisans who infuse a personal touch into every facet of our craft. We firmly hold that our approach warrants safeguarding and nurturing for the betterment of all who savor the finest cigars.

Within the realm of the Boutique Cigar Association (BCA), we wish to emphasize a clear perspective: premium cigars should not be equated with the challenges posed by combustible tobacco products. Unlike cigarettes, premium cigars do not align with patterns of nicotine addiction. Indeed, many cigar enthusiasts indulge in premium cigars as a leisurely pursuit, often in moderation, savoring the nuances of taste and aroma.

We have undertaken an extensive quest for scientific evidence substantiating the FDA's proposed regulations on premium cigars, yet our search has yielded no conclusive findings. There exists no substantial basis to contend that premium cigars carry the same health risks as cigarettes or other tobacco products.

We firmly advocate for a nuanced distinction between premium cigars and other tobacco products when formulating regulatory measures. Treating premium cigars identically to other tobacco products would be an erroneous course of action, unjustly burdening small, artisanal enterprises already grappling with the complexities of the regulatory landscape. We earnestly implore the FDA to reconsider its approach and collaborate with us in devising regulations that aptly suit the unique characteristics of our industry.

The Board of Directors of the BCA deeply value the FDA's role in overseeing manufacturing facilities abroad, particularly when it pertains to companies involved in the production of drugs or medical devices destined for the United States. In cases involving pharmaceutical or biomedical enterprises, the rationale for FDA supervision is readily apparent, given the critical nature of public health and safety.

In stark contrast, the artisanal character inherent to premium cigar production renders it impervious to the same type of objective measurements and scientific scrutiny applied to other industries. The craft of making a premium cigar has persevered virtually unchanged for well over two and a half centuries, relying predominantly on subjective judgments and sensory discernment rather than quantifiable, objective metrics.

One specific example of concern is the FDA's expressed interest in regulating the pH testing of tobacco utilized in premium cigars. However, due to the artisanal essence of premium cigar crafting, such testing may be deemed inappropriate or unnecessary. In the subsequent paragraphs, we will delve into this matter further, elucidating why the FDA's proposed regulations are ill-suited for our industry.

Premium cigar production is a refined art form that hinges on a careful and time-honored blending process, where the blending of different tobacco varieties is conducted based on a master blender's intuition and experience. This expertise is built on a nuanced understanding of the flavors, aromas, and characteristics of different tobacco leaves. Unlike other industries that rely heavily on precise measurements and scientific data, premium cigar blending primarily relies on the subjective mastery of skilled artisans.

The pH testing of tobacco, while valuable in other contexts, may not be relevant in the context of premium cigars. It is an objective metric that does not necessarily correlate with the complex and multifaceted sensory experience that premium cigar enthusiasts seek. The character and quality of a premium cigar are defined by intricate flavor profiles, aging processes, and the blending artistry of the cigar maker. Therefore, imposing standardized pH testing could disrupt the traditional craftsmanship and intricate blending techniques that are at the heart of premium cigar production.

In conclusion, the FDA's proposed regulations, such as pH testing requirements, must be evaluated within the context of the unique artisanal nature of premium cigar manufacturing. While scientific measurements have their place in various industries, the essence of premium cigars lies in the expertise, creativity, and sensory mastery of the artisans who have honed their craft over generations. Imposing regulations that do not align with the artisanal tradition could inadvertently stifle creativity and compromise the quality of these cherished products.

1) pH Testing of Tobacco

The pH testing of tobacco provides insights into its acidity or alkalinity levels. pH, a measure of hydrogen ion concentration in a solution, ranges from 0 (highly acidic) to 14 (highly alkaline or basic).

In the context of tobacco, pH plays a vital role as it influences the absorption of nicotine in the human body. Nicotine is a weak base; in an acidic environment (low pH), it predominantly exists in a charged form, hindering its absorption through the mouth or lungs. Conversely, in a more alkaline (higher pH) environment, nicotine remains mostly uncharged, facilitating easy absorption. Within the premium cigar industry, a noteworthy practice is the months- or years-long fermentation of tobacco, specifically aimed at reducing its alkalinity by removing ammonia. This process lowers the tobacco's pH, thereby diminishing the absorption of nicotine in the body. It's worth noting that no other tobacco sector undertakes such extensive ammonia removal from the tobacco.

Consequently, the pH level of tobacco significantly impacts nicotine delivery to the body, warranting measurement and monitoring by tobacco manufacturers, particularly those in the cigarette industry. Cigarette companies are known to increase the pH of their tobacco by ammonia application, thereby enhancing nicotine absorption. Different tobacco types may exhibit varying pH levels, influencing the flavor, aroma, and overall quality of the tobacco product.

The premium cigar industry uniquely distinguishes itself by dedicating substantial time to tobacco fermentation, a process geared towards minimizing ammonia content. By removing ammonia, the tobacco leaf attains a neutral pH, ensuring that the finest cigars deliver natural flavors. This transformation also renders the nicotine molecule less volatile, essentially converting it into a nicotine salt, which is inert and not easily absorbed through the oral mucosa and mouth.

In the past, Dr. Gaby Kafie authored a thesis paper on this subject to elucidate to the FDA why premium cigars are not an efficient nicotine delivery mechanism. We have included this paper and references at the end of this letter for your review. We hope you find it resourceful.

In summary, pH testing of tobacco used in premium cigars is superfluous because it is a standard protocol in our industry to subject tobacco to extensive fermentation, eliminating ammonia from the tobacco leaf. Every cigar factory worldwide adheres to this practice. It is the sole method of producing high-quality premium cigars with natural and appealing flavors, devoid of the risk associated with volatile nicotine molecules that contribute to addiction in other tobacco products.

Now, we will delve into explaining tobacco fermentation for premium cigars in a comprehensible manner and expound on why supervising such processes within the premium cigar industry lacks rationale. Also, we will explain why it makes no sense to supervise such processes in the premium cigar industry.

2) Tobacco Fermentation Supervision

Cigar tobacco fermentation stands as an indispensable phase in the production of top-tier premium cigars. This meticulous process is pivotal in metamorphosing raw tobacco leaves into matured, flavorful components suitable for crafting premium cigars.

The essence of cigar tobacco fermentation lies in orchestrating temperature and humidity with precision, coaxing the natural degradation of organic compounds within the tobacco leaves. This transformation releases volatile compounds, instrumental in shaping the distinct aroma and flavor characterizing the finished cigar. By eradicating elements such as ammonia commonly found in green leaves, we effectively render the nicotine molecule inert, underscoring that the nicotine in premium cigars is non-addictive.

Initiating the fermentation process involves the initial drying of harvested tobacco leaves, either in natural sunlight or specialized curing barns. Following this, the dried leaves undergo sorting based on size, color, and quality. These sorted leaves are then bundled into large groups known as *;*, which are arranged in controlled environments termed fermentation rooms. These rooms are meticulously maintained at temperatures ranging from 75 to 90 degrees Fahrenheit, accompanied by humidity levels between 60 and 75 percent.

Over the course of several months and/or years, the tobacco leaves are vigilantly monitored and rotated at intervals to ensure uniform fermentation. The combined effects of heat and moisture encourage the breakdown of natural sugars and oils within the tobacco, fostering the emergence of new flavors and aromas.

Once the tobacco attains the desired level of fermentation, it is extracted from the pilons and subjected to another round of sorting, this time based on color and texture. The fermented tobacco then embarks on an additional aging process, spanning several months to several years, allowing flavors and aromas to mature further. Notably, premium cigar manufacturers employ tobacco that has undergone a minimum of two to four years of fermentation and aging, contingent upon the varietal of the tobacco leaf. The thickness of the leaf dictates the duration of this process, ensuring the development of superior flavors and aromas, hallmarking a quality premium cigar.

In summary, cigar tobacco fermentation is a pivotal step in the crafting of exceptional cigars. It entails precise control of temperature and humidity, which triggers the natural decomposition of organic compounds within the tobacco leaves, ultimately yielding a product rich in flavor and aroma.

The Boutique Cigar Association (BCA) grapples with comprehending the FDA's intent to supervise a process that is inherently subjective and unfolds over a timeframe of two to four years. Such additional oversight appears to be an unproductive undertaking, unlikely to yield

justifiable findings that protect consumers from a product that, as of now, has not demonstrated any harm.

Statistically, the typical premium cigar aficionado indulges in one to two cigars each month, with the average age of initial use being 27 years. These facts underscore that premium cigars are not marketed to minors, and usage patterns corroborate this assertion.

Furthermore, the FDA's proposal to monitor cigar weights to regulate tobacco exposure per cigar size lacks practicality within the domain of artisanal, handcrafted premium cigars. Each premium cigar is meticulously fashioned entirely by hand, resulting in weight variations, even within a single box of 20 cigars. These weight measurements can fluctuate by 10 to 20% from one cigar to another. The intricacies of handcrafted products defy the standardization associated with machine-made counterparts, rendering such an approach unworkable.

In essence, the BCA does not understand how the FDA plans to oversee a process that is inherently subjective and stretches over a duration of two to four years. This added layer of regulation appears as an exercise in futility and is unlikely to yield findings that can be substantiated in safeguarding consumers from a product that, to date, has shown no evidence of harm. Premium cigars, as reflected in consumption patterns, do not cater to minors, and the proposal to standardize cigar weights is untenable given the nature of artisanal, handcrafted production.

3) Cigar Weights are not consistent.

Allow us to elucidate the reasons behind the significant variations in premium cigars, even within the confines of a single cigar box. These variations can be attributed to the types of molds employed in the cigar-making process and the inherently handmade nature of these products.

Cigar artisans craft premium cigars entirely by hand, devoid of specific measurements or ratios for the tobacco blend's weight. This artisanal approach inherently introduces natural variances in the weight of each individual cigar.

Handcrafted cigar molds, frequently made from wood, serve as integral tools in shaping cigars. These molds possess a propensity to warp over time due to various influences, such as exposure to moisture and fluctuations in temperature. Although wood molds are designed for durability and longevity, they remain susceptible to warping and damage if not diligently maintained.

Over time, cigar molds inevitably undergo changes, including slight alterations in the shape of the cigars they produce. The replacement of these molds is a costly endeavor, which leads many factories, particularly small family-owned establishments, to extend the lifespan of their molds as much as possible.

Interestingly, some factories even prefer using older wood molds due to the natural oils inherent in tobacco leaves that have permeated the mold's inner lining. These oils impart enhanced flavors to the finished product, offering connoisseurs an entirely natural and non-harmful experience.

Given these factors, it becomes evident that measuring the weights of cigars to attain consistency is an impractical endeavor within an industry governed by artisanal methods and meticulously crafted, hand-rolled labor. The inherent variations stemming from these factors are an integral part of the charm and uniqueness of premium cigars.

4) On site inspections of Central America cigar factories.

The prospect of on-site factory inspections to enforce manufacturing standards by the FDA presents a complex and challenging scenario. Such visits by U.S. regulators could potentially provoke political tensions and diplomatic strains.

Indeed, Central American nations, like any sovereign countries, are typically reluctant to welcome visits from foreign regulatory agencies, including the FDA. The idea of foreign oversight and regulatory audits can be met with skepticism and resistance, especially when the reasons for such inspections have yet to be fully justified.

At present, the scientific basis for imposing stringent regulations and factory-level oversight in the premium cigar industry remains questionable. The unique artisanal nature of premium cigar production, coupled with the lack of compelling evidence demonstrating harm, underscores the need for a careful and considered approach to regulation.

Therefore, it is imperative for regulatory agencies to engage in open dialogue and collaboration with industry stakeholders to reach a balanced and informed decision regarding factory inspections. Such efforts should prioritize mutual understanding and cooperation rather than unilateral actions that may strain diplomatic relations.

In the paragraphs below, you can read about one example of such tensions that arose in 2016 when U.S. State Department officials visited Nicaragua unannounced.

In 2016, tensions in this regard came to the fore when U.S. State Department officials conducted unannounced visits to Nicaragua. These visits, undertaken without prior notice or communication with Nicaraguan authorities, exacerbated diplomatic sensitivities. It underscores the delicate nature of international regulatory oversight, particularly in regions with complex political dynamics and historical contexts.

In 2016, the country of Nicaragua expelled three U.S. government officials on temporary duty in Nicaragua, an action the U.S. State Department said on Thursday was "unwarranted and inconsistent with the positive and constructive agenda" it seeks with Managua. State Department spokesman John Kirby told a news briefing the three officials had only recently arrived in

Nicaragua when they were expelled on Tuesday. He did not elaborate on what they were doing in the Central American country. "Such treatment has the potential to negatively impact U.S. and Nicaraguan bilateral relations, particularly trade," Kirby told reporters when asked about the incident. "We've conveyed our strong displeasure," Kirby said, referring specifically to Francisco Campbell, Nicaragua's ambassador to the United States. The Nicaraguan Embassy could not immediately be reached for comment. Kirby did not say whether the ambassador had been summoned to the State Department or the U.S. sentiments had been conveyed in some other manner. "We've made clear our concerns about this expulsion," he told reporters. "We believe it was unwarranted and inconsistent with the positive and constructive agenda that we seek with the government of Nicaragua," Kirby added. (Reporting by David Alexander; Editing by Tom Brown)

(Link: <https://finance.yahoo.com/news/three-u-officials-expelled-nicaragua-state-department-194752351.html>)

5) Countries in Central America and elsewhere are indeed evolving their standards of operation and protocols, and many are adopting more defensive positions in their interactions with foreign governments. This shift has led to a growing reluctance to exchange information with United States Federal Agencies.

While the ideal scenario for the FDA would involve oversight of manufacturing protocols in cigar factories, the reality is that we are dealing with countries that operate under different standards and have unique political dynamics. As an illustration of these complexities, just last month on March 23, 2023, the Ortega-Murillo Regime took the drastic step of dissolving Nicaragua's Private Bank Association. For more information on this development, please refer to the links provided below.

<https://dialogo-americas.com/articles/ortega-murillo-regime-dissolves-nicaraguas-private-banks-association/#.ZDx7GS-B1hE>

<https://havanatimes.org/news/ortega-shutters-nicaraguas-private-bank-association/>

The regulation and oversight of the premium cigar industry, especially its factories, indeed presents a formidable challenge. It is likely to encounter substantial resistance from foreign governments, which could exert significant pressure on small companies. Compliance with stringent factory regulatory measures is anticipated to be a complex and demanding process, one that may ultimately force many small cigar makers out of the market. This raises concerns about the potential economic impact on these businesses and the broader industry. Balancing regulatory objectives with the preservation of artisanal cigar craftsmanship will be a delicate endeavor that requires careful consideration of the industry's unique characteristics and challenges.

6) The Boutique Cigar Association (BCA) holds a strong conviction that the FDA's regulations on premium cigars are fostering an environment in which only large, well-established companies

will thrive, potentially contributing to the creation of a monopoly within the premium cigar industry. This concern highlights the need for regulatory measures that consider and accommodate the diverse range of businesses in the industry, from small boutique manufacturers to larger enterprises, to ensure fair competition and preserve the industry's unique character.

The Sherman Antitrust Act is a significant federal law that dates back to 1890. Its primary purpose is to address and counteract anti-competitive practices while fostering fair competition within the marketplace. The act derives its name from Senator John Sherman of Ohio, who played a pivotal role in advocating for the enactment of antitrust legislation.

The Sherman Act serves as a vital piece of legislation by prohibiting various anti-competitive practices, including price fixing, bid rigging, market allocation schemes, and collusion among businesses. Moreover, it also outlaws monopolization or attempts to monopolize any aspect of commerce, encompassing the production, distribution, and sale of goods and services.

Critics argue that the FDA's imposition and enforcement of what they consider unwarranted regulations in the premium cigar industry may inadvertently foster an environment where only large multinational corporations can thrive, potentially leading to a total monopoly in the marketplace.

Section D of the Sherman Act, which emphasizes the protection of competition rather than individual competitors, holds particular significance. It underscores that competition can yield both positive and negative outcomes—it may harm rivals' profits or even force them out of business, but it can also benefit consumers by driving down prices, enhancing quality, and promoting innovation.

The Boutique Cigar Association is committed to advocating for an equitable business platform, particularly for small boutique cigar manufacturers. These passionate and dedicated companies contribute to the art of crafting high-quality premium cigars, and the BCA's focus remains on preserving their place within the industry.

The current FDA regulations, as they stand today, have raised concerns that they may severely impact the family-owned boutique cigar segment and other medium-sized companies that may struggle to comply due to limited budgets and a smaller labor force.

Throughout its history, the Sherman Act has been a powerful tool in addressing monopolistic practices and anti-competitive behavior across various industries, including railroads, oil, steel, and telecommunications. The law has also been used to scrutinize mergers and acquisitions that could potentially harm competition and consumer well-being.

In the contemporary context, the Sherman Act continues to play a pivotal role in promoting competition and safeguarding consumers from anti-competitive practices. While ongoing debates

revolve around the extent and enforcement of antitrust laws, there is a consensus among experts that fair competition is fundamental for maintaining a healthy and dynamic marketplace.

The Boutique Cigar Association asserts that the FDA's intentions to protect consumers by ensuring the quality of products are commendable. However, it raises concerns that the regulations, if implemented without consideration for the unique characteristics of the premium cigar industry, may inadvertently eliminate an entire segment of family-owned and operated companies. This outcome could consolidate the industry into the hands of a few large conglomerates primarily focused on market share and profits, potentially diminishing the diversity and artisanal craftsmanship that defines the premium cigar industry.

The Boutique Cigar Association (BCA) can confidently affirm, representing all of its member companies, that the commitment to the art of boutique cigars is rooted in a profound passion for quality, rather than purely profit-driven motives. Consequently, our sector of the industry consistently prioritizes the creation of meticulously crafted, high-quality, handmade products.

We uphold a steadfast dedication to upholding exacting standards and do not waver when it comes to the readiness of our cigars for connoisseur enjoyment. Quality is never compromised for the sake of profit in our segment of the industry. Our commitment is to deliver premium cigars that are crafted with precision and designed to be savored by discerning enthusiasts.

Allow us to end this letter, which has been a pleasure for us to present to FDA officials by stating the following. To date, no scientific evidence has been presented on behalf of the FDA in a court of law, or outside a court of law which warrants such rigorous regulations on our industry. Furthermore, the National Academies of Science, Engineering, and Medicine (NASEM) has not been able to present any concrete evidence which can designate premium cigars as :

- 1) An ideal delivery tool for nicotine
- 2) A tobacco product which causes nicotine addiction
- 3) A tobacco product which targets minors
- 4) A tobacco product that is marketed to minors
- 5) A tobacco product that is readily available to minors.

On behalf of the Boutique Cigar Association, its 35 member companies, and our Board of Directors, we respectfully urge the FDA to consider leaving premium cigars untouched by regulations. Premium cigars have never been the source of the problem under scrutiny.

For the reasons set forth above, the BCA urges FDA to take into serious consideration the consequences of its actions in implementing new regulations that will harm our entire industry. We request the FDA to exempt manufacturing facilities that produce premium cigars to be exempt from the tobacco manufacturing practices requirements to the extent that the Agency moves forward to finalizing the Proposed Rule.

The BCA stands united with our fellow industry associations such as the Premium Cigar Association and Cigar Rights of America, as we share a collective belief that we are one industry. We emphasize that every cigar company, regardless of its current size or stature, embarked on its journey as a small, family-owned operation.

Our artisanal industry carries a rich historical legacy in the United States, one that we are deeply committed to preserving for future generations. We respectfully request the FDA's consideration of these concerns and the preservation of our unique industry.

The BCA appreciates the opportunity to comment on the Proposed Rule. If you have any questions or require additional information about these comments or the BCA, please contact us via telephone at 305-255-6368 or via email at info@boutquecigarassociation.com

Sincerely,

President	Armen Caprielian (<i>Owner of D.A.V. Cigars</i>)
Vice President	Dr. Garo Bouldoukian (<i>Owner of Garo Cigars</i>)
Founder/Treasurer	Dr. Gaby Kafie (<i>Owner of Kafie 1901 Cigars / Kafie 1901 Coffee Co.</i>)
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