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VIA ELECTRONIC SUBMISSION

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

Re: Docket No. FDA–2017–N–6107 (83 Fed. Reg. 12,901, Mar. 26, 2018) – Comments on Advance Notice of Proposed Rulemaking on the Regulation of "Premium" Cigars

Altria Client Services ("ALCS"), on behalf of John Middleton Co. ("JMC") and Sherman Group Holdings LLC and its subsidiaries ("Nat Sherman"),[1] submits these comments on the Food and Drug Administration's ("FDA" or the "Agency") Advance Notice of Proposed Rulemaking ("ANPRM") related to the regulation of "premium" cigars.

Altria, on behalf of its tobacco operating companies, supported the passage of the Family Smoking Prevention and Tobacco Control Act (the "Act" or "TCA") because it believes that a comprehensive regulatory framework can contribute to resolving many of the complex issues surrounding tobacco products. We support FDA regulation of all tobacco products, including "premium" cigars, because all cigars pose health risks. FDA regulation may nevertheless take into account the unique aspects and history of different tobacco product categories. Accordingly, FDA may regulate "premium" cigars differently from other cigars, so long as the differences are science- and evidence-based and FDA applies objective criteria to allow for predictable and fair application of its authority.

I. Background about JMC and Nat Sherman

The Altria family includes two companies in the cigar business. Founded in 1856 as a pipe tobacco retailer, JMC is a leading manufacturer of cigars and pipe tobacco, operating facilities in Pennsylvania and Virginia. JMC's cigar portfolio is led by the BLACK & MILD® brand family. The majority of JMC's cigars are tipped, with a plastic or wood mouthpiece. JMC's cigars are

[1] JMC and Nat Sherman are wholly-owned subsidiaries of Altria Group, Inc. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout these comments to refer to JMC and Nat Sherman collectively, except where the context requires otherwise.

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machine-made, with machines used for rod making, tip application and final packing. Building upon JMC's tradition as a retailer and manufacturer of pipe tobacco, the majority of JMC's cigars use pipe tobacco in filler.

Founded in 1930 in New York, Nat Sherman operated for decades as a small, family-owned business. The company's origins are in cigar retailing and distribution and the marketing and sale of premium handmade cigars remains a crucial component of its overall business. Nat Sherman's premium hand-made cigar brands include TIMELESS®, METROPOLITAN® and EPOCA®.

All of JMC's and Nat Sherman's cigars are classified as large cigars for federal excise tax purposes.[2]

II. FDA Should Regulate All Cigars, Including Premium Cigars

We agree with FDA that there is "no appropriate public health justification to exclude premium cigars from regulation."[3] As the ANPRM states: "[a]ll cigars pose serious negative health risks."[4] Excluding premium cigars from regulation could suggest to consumers that FDA has determined that some cigars are safer than other cigars, are safer than other types of tobacco products, or do not have the potential to cause disease. It could also motivate some manufacturers to evade regulation by changing the classification of their cigars.[5]

III. FDA Has the Authority, if Certain Standards Are Satisfied, to Develop Appropriate Differential Regulation that Reflects the Unique Characteristics of the Premium Cigar Category

While we believe that all tobacco products should be subject to FDA's regulatory oversight, we also accept that regulation need not be a one-size-fits-all approach. If supported by science and evidence, FDA may take into account particular attributes of a tobacco product category or particular products within a category in determining the appropriate level of regulation that should apply.

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[2] The Internal Revenue Code defines "cigar" for federal excise tax purposes. *See* 26 U.S.C. § 5702(a) ("'Cigar' means any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (b)(2).)") When specifying the tax rate applicable to cigars, the Internal Revenue Code distinguishes between "small cigars" and "large cigars," with the former defined as not weighing more than three pounds per thousand and the latter defined as weighing more than three pounds per thousand. *See* 26 U.S.C. § 5701(a).

[3] 83 Fed. Reg. 12,901, 12,902 (March 26, 2018).

[4] *Id*.

[5] For example, following amendments to federal excise tax rates implemented by the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009, Public Law No. 111-3 (Feb. 4 Tobacco Taxes, Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes, 2009), certain manufacturers obtained preferential tax treatment by making small changes to the amount of tobacco filler contained in various products, and thereby qualifying for the lower tax rates imposed on pipe tobacco or on large cigars. *See* Government Accountability Office, GAO 12-475 (April 2012) (hereafter "GAO report"). As FDA recognized in considering the regulation of cigars in connection with the deeming rule, "[w]ithout a common regulatory framework, tobacco firms can exploit differences in regulatory requirements to drive consumers to different product markets." 79 Fed. Reg. 23,141, 23,147 (Apr. 25, 2014).

In deciding how to regulate "premium" cigars, FDA should consider several factors. First, FDA should consider if the science and evidence justify differential regulation.[6] Second, if FDA pursues differential regulation, it should adopt a definition of "premium" cigars that is objective, allows for uniform application, and does not create loopholes that can be manipulated by manufacturers to avoid regulation. Third, if FDA pursues differential regulation, "premium" cigars should be subject to certain fundamental elements of FDA oversight.

A. FDA should consider the extent to which science and evidence supports distinguishing "premium" cigars from all other cigars

Currently, there is no scientifically based or accepted distinction between "premium" and non-premium cigars.[7] Government research has categorized various types of cigars differently. For example, the Centers for Disease Control and Prevention's National Adult Tobacco Survey asks respondents about their use of "cigars, cigarillos, or little filtered cigars."[8] The National Cancer Institute's Monograph 9 identifies four types of cigars: "little cigars, small cigars (also called cigarillos), regular cigars, and premium cigars."[9] The Federal Trade Commission ("FTC") Cigar Report divides cigars into three "weight categories": "little cigars, weighing not more than three pounds per thousand; medium cigars, weighing more than three but less than ten pounds per thousand; and large cigars, weighing more than ten pounds per thousand."[10] And the tax code only differentiates between small cigars, weighing not more than three pounds per thousand, and large cigars, weighing more than three pounds per thousand.[11]

Within existing literature, there is great inconsistency in how different products within the cigar category should be classified. For example, in one research study cited in the ANPRM, researchers differentiated smokers of "premium" and "non-premium" cigars based on their "usual brand and price."[12] Researchers used online searches about a "brand's tobacco blends, components (eg, long filler, whole leaf wrapper), and manufacturing process (eg, handmade)" to identify "premium" brands. Where brand information was unavailable, researchers identified

[6] FDA leaders have stressed that science and evidence are central to making decisions about regulatory policy: "We need evidence to support any policy that we might enact, because it carries the force of law. When we are exploring our regulatory policy options, we focus on those that have the strongest support in the science base." *Q&A: Mitch Zeller on the FDA and Tobacco*, Cancer Discovery (2014) 4:10-11.

[7] As the ANPRM recognizes, "tobacco research studies have not used a single, consistent definition of 'premium' cigars." 83 Fed. Reg. at 12,903.

[8] Centers for Disease Control and Prevention, National Adult Tobacco Survey, NATS 2013-2014 Codebook, *available at* https://www.cdc.gov/tobacco/data_statistics/surveys/nats/index.htm.

[9] National Cancer Institute, Smoking and Tobacco Control Monograph 9: Cigars: Health Effects and Trends, at 55 (1988) (Monograph 9) (emphasis added). The Monograph states that "[f]ew surveys have questioned cigar smokers about the quantity and type of cigars typically consumed." *Id.* at 27.

[10] FTC, Report to Congress: *Cigar Sales and Advertising and Promotional Expenditures for Calendar Years 1996 and 1997* (1999) at n.9.

[11] 26 U.S.C. § 5701(a).

[12] 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, 2013-2014*, Nicotine & Tobacco Research (Sep. 15, 2017) 1, 8, doi:10.1093/ntr/ntx209.

"premium" cigars based on a "usual price" of greater than $2 per stick.[13] In a different research study, the authors considered "premium" cigar smokers as those reporting that their "usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar, or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper."[14]

These different approaches for classifying "premium" cigars make it difficult to determine if there are distinctions between "premium" cigars and other cigars regarding topography, exposure, individual risk, or other potentially relevant factors.

B. If FDA pursues differential regulation, it should adopt a definition of "premium" cigars that is objective, allows for uniform application, and does not create loopholes that can be manipulated by manufacturers to avoid regulation

1. Any definition of "premium" cigars must be based on objective criteria that is not easily subject to manipulation

In considering the potential for differential regulation, FDA should use objective criteria to define "premium" cigars. Several of the topics for which FDA seeks comments in the ANPRM are either not objective in nature or do not apply uniformly to any type of cigar. For example, FDA should not base regulation on where a product is made, how a product is used, the frequency of price changes in the distribution chain, annual sales data, including market size and volume, or labeling, advertising, and marketing efforts.[15] Such criteria would be subject to manipulation and variability. Similarly, FDA should avoid a definition that could create disadvantages among competitors of similar products, and could encourage manufacturers to sell, manufacture, or market in ways that avoid regulation. Such a definition could encourage small changes in manufacturing or marketing practices to obtain preferential treatment.[16] Likewise, any definition that is based on how retailers or manufacturers identify or characterize their products can lead to an over-inclusive definition.

2. Any definition of "premium" cigars should be based on the construction and composition of the product

Any definition for "premium" cigars that FDA establishes should be based solely on the construction and composition of the product using a combination of verifiable criteria. The following would be appropriate elements of such a definition:

- Wrapped in 100 percent whole leaf;
- Contains 100 percent tobacco filler;

[13] *Id.*
[14] Catherine G. Corey et al., *Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults - United States, 2012–2013*, Morbidity and Mortality Weekly Report (Aug. 1, 2014), 63(30);650-654.
[15] 83 Fed. Reg. at 12,903.
[16] *See supra* n.5.

- Contains 100 percent tobacco binder;
- Made by hand, except to allow for the use of a manually operated machine to assist in bunching, rolling and binding;
- Contains no additives other than cigar glue and water;
- Does not contain a filter, tip or non-tobacco mouthpiece; and
- Weighs at least six pounds per 1,000 count.

These elements largely track those proposed by FDA in "option 2" of its proposed deeming rule.[17]

3. Any definition of "premium" cigars should not be based on price

Our prior comments cautioned FDA against regulating various types of cigars based on price.[18] FDA should not do so now.

First, defining "premium" cigars by price would be arbitrary. There is no evidentiary basis for distinguishing cigars sold for $10.01 and above as opposed to any other price, including $9.99. As noted, some may believe a cigar that costs as little as $2 to be "premium." Simply put, there is no consistent price point which is used to define a "premium" cigar.

Second, tax structures, which typically impact retail prices, also vary widely in jurisdictions across the country, at both the state and local levels. As such, a cigar meeting a threshold price in one jurisdiction may not cross that threshold in another jurisdiction, resulting in inconsistent and unpredictable regulation.[19] Moreover, other marketplace factors will vary by jurisdiction or locality that influence the final retail price of a cigar, including consumer demand, availability, and trade price competition among retailers.

Third, any price-based definition would be subject to manipulation. Manufacturers could seek to evade regulation simply by increasing the list price of their products. A similar type of manipulation occurred when the federal tax code gave preferential tax treatment to "large cigars," defined simply by weight; some manufacturers sought to avoid higher excise taxes by making minor increases to the weight of tobacco filler in their products.[20]

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[17] 79 Fed. Reg. at 23,203.

[18] ALCS Comments on Docket No. FDA-2014-N-0189 (RIN 0910-AG38) (79 Fed. Reg. 23,142), at 7 (submitted Aug. 8, 2014); Nat Sherman Comments on Docket No. FDA-2014-N-0189 (RIN 0910-AG38) (79 Fed. Reg. 23,142), at 7-8 (submitted Aug. 6, 2014).

[19] For example, cigars sold in New York are subject to an excise tax of 75% of wholesale price. N.Y. Tax Law § 471-b(1)(a). But the same cigars would be subject to an excise tax of only 12.8% in North Carolina. N.C. Gen. Stat. Ann. § 105-113.35(a).

[20] *See*, *e.g.*, GAO report at 1 (following enactment of CHIPRA, large cigar sales increased from 411 million to over 1 billion cigars, while small cigars dropped from about 430 million to 60 million cigars).

Fourth, there is no public health rationale to regulate cigars based on price. There is no evidence, for example, supporting or explaining why a cigar that costs $9.99 would affect public health differently from a cigar that costs $10.01.

C. If FDA pursues differential regulation, "premium" cigars still should be subject to certain fundamental elements of FDA oversight.

"Premium" cigars should continue to be subject to certain core elements of FDA oversight from the TCA:

1. **Registration of facilities and product listings.** Section 905 requires owners and operators of domestic manufacturing establishments engaged in manufacturing tobacco products to register with FDA and submit product listings.[21] FDA extended this requirement to all cigars in its deeming rule,[22] and including this requirement in a regulatory plan for "premium" cigars would allow FDA to continue to monitor the industry efficiently and to conduct inspections and facilitate recalls, if necessary.[23] These submissions would pose a minimal burden on "premium" cigar manufacturers.

2. **Ingredient reporting.** Section 904 requires manufacturers to report all ingredients, including tobacco, substances, compounds and additives, of each of their tobacco products.[24] FDA also extended this requirement to all cigars as part of its deeming rule.[25] Given the definition of "premium" cigars proposed above, these submissions pose a minimal burden on "premium" cigar manufacturers, as such products would be comprised of only tobacco, cigar glue and water.

3. **Simplified process for product modifications.**[26] In general, modified products are subject to a lengthy, burdensome and costly substantial equivalence ("SE") process.[27] FDA should tailor its review process for product modifications, if any, to address the unique attributes of "premium" cigars. To the extent it establishes premarket authorization pathways for "premium" cigars, FDA should consider expansion of the SE exemption pathway for these products. FDA could also consider pre-authorizing a list of tobacco types and/or approved cigar adhesives and maximum usage levels of such adhesives that "premium" cigar manufacturers may use without triggering the

[21] TCA §§ 905(b)–(i).
[22] 81 Fed. Reg. 28,973, 28,976 (May 10, 2016).
[23] Consistent with its current compliance policy, FDA should continue to enforce the registration and listing requirements of section 905 with respect to finished tobacco products only. *See FDA Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised)* at 6 (Dec. 2017).
[24] TCA §§ 904(a)(1), (c)(1).
[25] 81 Fed. Reg. at 28,976.
[26] We believe that a simplified process for product modifications should apply to all cigars. Requiring cigars, even those that do not qualify as "premium cigars," to submit to the lengthy and costly characterization-by-characterization review process that the Agency has adopted for establishing SE will significantly burden both manufacturers and the Agency with preparation and review of thousands of new applications and will divert limited resources away from a focus on harm reduction products.
[27] TCA § 905(j).

requirement to file an application.

4. **Premarket review requirements for modified risk claims.** Section 911 requires manufacturers to submit a Modified Risk Tobacco Product ("MRTP") application to FDA before making modified risk claims about a tobacco product.[28] "Premium" cigars seeking to assert a modified risk claim should be subject to MRTP requirements like all other tobacco products.

5. **Warning labels.** FDA has determined that all tobacco products, including those that FDA has deemed subject to the TCA, should bear appropriate health warning statements.[29] We agree that "premium" cigars should bear appropriate warnings that take into account unique attributes of their packaging and size.

6. **Marketing restrictions.** As part of the deeming rule, FDA imposed a requirement for a minimum age of purchase of covered tobacco products, and prohibited their sale with the assistance of an electronical or mechanical device, except in certain facilities where no person younger than 18 years of age is present or permitted to enter.[30] We agree that "premium" cigars should be subject to these requirements.

7. **Enforcement authority for misbranded or adulterated products.** FDA should continue to have enforcement authority against "premium" cigars that it determines to be misbranded or adulterated.[31] For example, any cigar marketed as a "premium" cigar must meet the definition set forth by FDA and contain only the ingredients identified in Section 904 ingredient reports.

8. **HPHC testing.** Section 904 requires tobacco product manufacturers to submit reports to FDA on constituents identified as harmful or potentially harmful ("HPHC") to health.[32] FDA has not yet determined how to communicate information from the HPHC testing of cigarettes and smokeless products to the public in a non-misleading manner, and accordingly FDA should not impose HPHC testing requirements on any cigars at this time either.[33] If FDA believes testing is necessary, then it should accept a so-called "market map" study[34] with small-volume representative testing, and

[28] TCA § 911.
[29] 21 CFR § 1143.5(a)(1).
[30] 21 CFR § 1140.14(b)(1)–(3).
[31] TCA §§ 902, 903.
[32] *Id.* § 904(a)(3).
[33] In addition, at present there are no standard testing methods for cigars. *See infra* p. 8-9. Such methods are a prerequisite for establishing HPHC reporting requirements for cigars.
[34] Market maps are surveys of physical and/or chemical properties of tobacco products, including smoke constituents for smokeable tobacco products. They typically include a large number of brands and, in many cases, a large number of analytes. Brand selection typically involves a representative subset of the marketplace at a point in time and, in some cases, includes products with unique features not common or newly introduced in the marketplace. Both FDA and industry scientists have published such market maps for cigarettes. *See, e.g.,* Agnew-Heard, K. A., Lancaster, V. A., Bravo, R., Watson, C., Walters, M. J., and Holman, M. R., *Multivariate Statistical Analysis of Cigarette Design Feature Influence on ISO TNCO Yields*, Chemical Research in Toxicology, *29*(6), 1051–1063 (2016); Edwards, S. H., Rossiter, L. M., Taylor, K. M., Holman, M. R., Zhang, L., Ding, Y. S., &

address the additional testing issues described in section IV below to allow for any meaningful application of testing results.

9. **Data submission requirements.** Section 904 authorizes FDA to require a manufacturer or importer to submit documents relating to research on the health, toxicological, behavioral, or physiological effects of tobacco products.[35] FDA should continue to be allowed to request such documents of "premium" cigar manufacturers or importers.

10. **TPMP requirements.** Section 906 authorizes FDA to establish tobacco product manufacturing practice ("TPMP") requirements.[36] Any such requirements should be extended to "premium" cigars, but tailored to their unique attributes. For example, any TPMP requirements should recognize differences between products manufactured by hand and those manufactured through automated processes.

IV. FDA Regulation of Cigars Must Be Predictable and Fair

Regardless of whether FDA regulates "premium" cigars differently, all FDA regulation of cigars must allow for predictable and fair application. To accomplish these goals, FDA will need to consider and address regulatory challenges facing the cigar category generally.[37]

First, cigars are a diverse product category, encompassing a wide range of lengths, gauges, and shapes. There are few standardized testing methods for cigars, unlike with other tobacco products such as cigarettes. Currently, there are no reference products for cigars.

Watson, C. H., *Tobacco-Specific Nitrosamines in the Tobacco and Mainstream Smoke of U.S. Commercial Cigarettes*, Chemical Research in Toxicology, *30*(2), 540–551 (2016); Pazo, D. Y., Moliere, F., Sampson, M. M., Reese, C. M., Agnew-Heard, K. A., Walters, Blount B., Watson, C., M. J., and Chambers, D. M., *Mainstream Smoke Levels of Volatile Organic Compounds in 50 US Domestic Cigarette Brands Smoked with the ISO and Canadian Intense Protocols*, Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco, *18*(9), 1886–1894 (2016); Bodnar, J. A., Morgan, W. T., Murphy, P. A., and Ogden, M. W., *Mainstream Smoke Chemistry Analysis of Samples from the 2009 US Cigarette Market*, Regul. Toxicol. Pharmacol. *64*, 35−42 (2012); Morton M.J., Laffoon S.W., *Cigarette smoke chemistry market maps under Massachusetts Department of Public Health smoking conditions,* Regul. Toxicol. Pharmacol. *51,* 1-30 (2008); Counts M.E., Hsu F.S., and Tewes F.J., *Development of a commercial cigarette "market map" comparison methodology for evaluating new or non-conventional cigarettes,* Regul. Toxicol. Pharmacol. *46,* 225–242 (2006); Swauger, J. E., Steichen, T. J., Murphy, P. A., and Kinsler, S., *An Analysis of the Mainstream Smoke Chemistry of Samples of the U.S. Cigarette Market Acquired between 1995 and 2000,* Regul. Toxicol. Pharmacol. *35,* 142−156 (2002).

[35] TCA § 904(b).

[36] *Id.* § 906(e).

[37] Consistent with the comments ALCS previously submitted on behalf of JMC on FDA's deeming rule, FDA should follow certain key principles when considering any potential regulation of tobacco products. *See* ALCS Comments on Docket No. FDA-2014-N-0189 (RIN 0910-AG38) (79 Fed. Reg. 23142), at 4-5 (submitted Aug. 8, 2014). FDA must base its regulations and decisions on science and evidence to protect the integrity of its decision-making process and provide a consistent and predictable regulatory environment. FDA should preserve and respect the choices of adult consumers while limiting access to minors, consistent with one of Congress's stated purposes. FDA also must ensure that its regulations do not violate constitutional principles. Tobacco product labeling, advertising and marketing are commercial speech protected by the First Amendment. In addition, overbroad regulation may constitute a "taking" in violation of the Fifth Amendment.

Second, there is significant analytical variability in the few testing methods that do exist for cigars. FDA has acknowledged the need to address the variability in methods for testing tobacco products, including the variability observed in measurements of tobacco reference products.[38] These concerns apply to the testing of cigars.

Third, there is variability inherent to the cigar manufacturing process. Cigars are manufactured with less sophisticated equipment and processes than other tobacco products. They are typically manufactured from a single year crop blend, which makes them particularly subject to natural agricultural variability. Cigars also are wrapped in tobacco, which makes the wrappers subject to the natural agricultural variability that does not exist in paper wrappers used on cigarettes.

FDA should address these issues to ensure it regulates all cigars predictably and fairly.

V. Conclusion

We appreciate the opportunity to submit these comments and hope FDA will consider them in developing any proposed rule for "premium" cigars, and in determining how to regulate cigars generally.

Sincerely,

[38] 77 Fed. Reg. 14,814, 14,814-15 (Mar. 13, 2012) (discussing a workshop that FDA convened 2012 to "solicit feedback on analysis of tobacco products," including "variability observed in measurements of tobacco reference products").