IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN MIDDLETON COMPANY LLC
6601 West Broad Street
Richmond, VA 23230

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201

SYLVIA M. BURWELL, in her official capacity as Secretary of Health and Human Services
Office of the Secretary
200 Independence Avenue SW
Washington, DC 20201

and

ROBERT CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993

Defendants.

Civil Action No. 1:16-cv-996

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. For nearly 40 years, Plaintiff John Middleton Company LLC ("Middleton" or "the Company") has sold cigars and pipe tobacco with the brand name BLACK & MILD®. Today, countless consumers associate the BLACK & MILD® trademark with the Company's cigars and pipe tobacco. Yet on May 10, 2016, the Food and Drug Administration ("FDA") published a Final Rule banning the BLACK & MILD® name. *See* 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140 and 1143).

2. The Final Rule terminates this iconic brand name on the bare supposition that the word "mild" impermissibly communicates to consumers that BLACK & MILD® products are safer than other cigars and pipe tobacco. FDA cited no evidence that the BLACK & MILD® name conveys any message about the health risks of the products. To the contrary, FDA ignored unrebutted evidence—including a study by a leading expert on consumer perception—that the name BLACK & MILD® does *not* communicate anything about health, risk, or safety. FDA also ignored unrebutted evidence that the word "mild," when used in the context of cigars and pipe tobacco, has for centuries described taste and body, not health risks.

3. The Agency further ignored Middleton's modest alternative request that, before categorically banning the word "mild," FDA at least should determine through an evidence-based process whether such a word in fact communicates a health claim in specific cigar and pipe tobacco labeling and advertising. Instead, without even that minimal safeguard, the Final Rule broadly bans the word "mild" regardless of its meaning in context, thereby extinguishing Middleton's longstanding and valuable trademark. In so doing, the Final Rule violates the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and

Tobacco Control Act ("TCA"), Pub. L. No. 111-31, the Administrative Procedure Act ("APA"), and the First and Fifth Amendments to the Constitution.

4. The TCA granted FDA initial authority to regulate only "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." TCA § 901(b). The statute, however, authorized FDA to expand its authority through a rulemaking that "deems" additional tobacco products subject to regulation. *Id*. FDA exercised this power in the Final Rule, extending its jurisdiction to cigars, pipe tobacco, and other tobacco products. Thus, Middleton's BLACK & MILD® products became subject to FDA regulation under the TCA.

5. Section 911 of the TCA is one of the provisions newly applicable to cigars and pipe tobacco. Originally aimed at cigarette labeling and advertising, this provision prohibits manufacturers from claiming that their products pose less health risk than others unless they prove the modified risk claim to FDA through an arduous application process. In furtherance of this general prohibition, Section 911 bars manufacturers from using the words "light," "mild," and "low" as "descriptors" of "modified risk" in the labeling and advertising of tobacco products. TCA § 911(b)(2)(A)(ii).

6. In the preamble to the Final Rule, FDA incorrectly asserted that Section 911 imposes a *per se* ban on the word "mild" in labeling and advertising for cigars and pipe tobacco. It does no such thing. The plain text of the statute bars the words "light," "mild," and "low" *only* when they are used as "*descriptors*" of "*modified risk*"—that is, when they communicate to consumers that a particular tobacco product poses reduced health risks. Context matters.

7. The TCA's legislative history and context also refute any notion that Congress intended to ban the words when used in other ways, as in famous trademarks like BLACK & MILD®. While the statutory "findings" in the TCA state that words such as "light" and "low"

connoted a modified risk in the unique context of cigarettes, Congress made no such determination for cigars and pipe tobacco. Nor could Congress have made such determinations, particularly with respect to the word "mild." It carries no safety-related connotation for cigars and pipe tobacco products, especially when it is integrated into a well-established brand name like BLACK & MILD®.

8. Categorically banning the word "mild" and extinguishing Middleton's BLACK & MILD® trademark violates not only the TCA and the APA, but also the Constitution. The First Amendment protects trademarks and brand names. A *per se* ban on certain words in a trademark or brand name, without regard to their meaning in context, does not advance any legitimate government interest, much less a compelling one. In addition, depriving Middleton of its trademark through such a *per se* ban violates the Fifth Amendment Takings Clause. The sensible, less restrictive alternative—which Middleton proposed but FDA ignored—is for the Agency to assess whether a word such as "mild" conveys a modified risk claim in cigar and pipe tobacco labeling and advertising, including in the BLACK & MILD® name. Particularly in light of the obligation to read statutes in a manner that avoids constitutional infirmities, the TCA requires such an inquiry before FDA can ban speech.

9. The Court accordingly should vacate and enjoin enforcement of the Final Rule to the extent that it bars Middleton from using its BLACK & MILD® trademark.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. § 1331. Middleton's causes of action arise under the laws and Constitution of the United States, including the APA, 5 U.S.C. § 702 *et seq.*, the TCA, and the First and Fifth Amendments.

11. Venue is proper in this district under 28 U.S.C. § 1391. Defendants FDA and the Department of Health and Human Services (HHS) reside in this district. Defendants Secretary Burwell and Commissioner Califf perform their official duties in this district. And a substantial part of the events giving rise to this action occurred in this district.

12. An actual controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant declaratory and injunctive relief, and to set aside the regulation. 28 U.S.C. §§ 2201, 2202; 5 U.S.C. §§ 705, 706.

PARTIES

13. Middleton is a Pennsylvania limited liability company headquartered in Richmond, Virginia. Middleton manufactures cigars and pipe tobacco products. It was not affiliated with Altria or Phillip Morris USA until Altria Group, Inc. acquired it in 2007, decades after BLACK & MILD® came on the market.

14. Defendant HHS is an executive department of the United States Government. HHS is headquartered in Washington, DC.

15. Defendant FDA is an administrative agency within HHS and is responsible for tobacco product regulation under the TCA.

16. Defendant Sylvia M. Burwell is Secretary of HHS and sued in her official capacity. The Secretary oversees FDA's activities with respect to the TCA.

17. Defendant Robert M. Califf, M.D. is Commissioner of Food and Drugs and sued in his official capacity. The Commissioner is directly responsible for FDA's administration of the TCA.

BACKGROUND

A. John Middleton Company's BLACK & MILD® Brand

18. Middleton has a long history in pipe tobacco and cigars. In 1856, John Middleton founded the company that bears his name as a small retail shop in Philadelphia, Pennsylvania, catering to pipe smokers. Over time, Middleton became renowned for its private blends of pipe tobacco. As a newspaper story from the 1940s explained, Middleton succeeded because its tobacco blend was "naturally aromatic, considered mild and mellow by experienced smokers." J. Harte, *The Middletons of Philadelphia*, Pipe Lovers Magazine, May 1946, at 164-65.

19. By the mid-1960s, after Middleton had shifted to manufacturing, the Company discovered that many consumers enjoyed the taste and aroma of pipe tobacco, but did not want to smoke a pipe. In 1968, the Company launched a new product: a "pipe-tobacco cigar" that used a popular blend of Middleton pipe tobacco.

20. In 1977, Middleton adopted the BLACK & MILD® trademark and introduced BLACK & MILD® pipe tobacco for sale. In 1980, Middleton launched BLACK & MILD® pipe-tobacco cigars.

21. When the Company chose the BLACK & MILD® mark in the 1970s, the word "black" was common in the names of pipe tobacco products. Middleton considered combining many other words with "black," such as Black & Mellow, Mellow Black, or Black & White. The Company chose BLACK & MILD® because Middleton executives thought it sounded good, and it was easy to remember. The Company never intended nor understood the name to convey anything about health risks.

22. By the mid-1990s, Middleton's BLACK & MILD® cigar five-pack had become the bestselling cigar package in the United States.

23. BLACK & MILD® today is a widely-recognized brand name and Middleton's flagship brand.

24. Based in part on the strength of the BLACK & MILD® trademark, Altria Group, Inc. purchased Middleton in 2007 for $2.9 billion dollars.

25. Today, Middleton markets dozens of cigar and pipe tobacco products under the BLACK & MILD® trademark.

B. The Tobacco Control Act

1. FDA's "Deeming" Authority

26. The TCA granted FDA initial authority to regulate "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," and at some future time, to extend its authority to "any other tobacco products that the Secretary by regulation deems to be subject to this chapter." TCA § 901(b). In any rulemaking to "deem" additional tobacco products subject to the TCA, FDA must comply with the APA. *Id.* § 901(d).

2. The TCA's Descriptor Ban for Cigarettes

27. Section 911 of the TCA provides that "[n]o person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product." TCA § 911(a). The TCA defines "modified risk tobacco product" as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." *Id.* § 911(b)(1). The TCA provides that a product is sold or distributed for this improper purpose if, among other things, its "label, labeling, or advertising . . . uses the descriptors 'light', 'mild', or 'low' or similar descriptors." *Id.* § 911(b)(2)(A)(ii).

28. As explained in the TCA's findings, Congress predicated the modified risk provisions, including the descriptor ban in Section 911(b)(2)(A)(ii), on conclusions of the

National Cancer Institute and other "[r]ecent studies" concerning "'low tar' and 'light' cigarettes," as well as the Federal Trade Commission's rescission of its 1966 guidance on the method to determine tar and nicotine yield in cigarettes. *Id.* § 2(38), (39), (41).

29. To obtain an order from FDA allowing a "modified risk tobacco product" on the market, the manufacturer must submit an extensive application demonstrating that the "product, as it is actually used by consumers, will—(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id.* § 911(g)(1).

30. For cigarettes and other tobacco products initially subject to the TCA, the descriptor ban took effect on June 22, 2010, 12 months after the TCA was enacted. *Id.* § 911(b)(3).

C. FDA's Final Rule Banning Use of the BLACK & MILD® Brand Name

1. FDA's Proposed Rule

31. On April 25, 2014, FDA issued a Proposed Rule to deem virtually all "tobacco products," including cigars and pipe tobacco, subject to regulation under the TCA. 79 Fed. Reg. 23,142, 23,143 (attached as **Exhibit A**).

32. The Proposed Rule stated that "products deemed under [the final] rule will be subject to the same FD&C Act provisions that cigarettes . . . are subject to . . . ." *Id.* In particular, FDA stated that deemed products would be subject in all respects to the "prohibition against use of modified risk descriptors (e.g., 'light,' 'low,' and 'mild' descriptors)." *Id.* FDA's unstated assumption was that these words conveyed a modified risk with regard to the newly deemed products. From this premise, the Agency reasoned that extending the TCA's descriptor ban to deemed products would "reduc[e] the use of misleading claims and descriptors about the

relative risk of tobacco products," *id.*, and would "help reduce consumer confusion and misconceptions about such products," *id.* at 23,149.

33. The Proposed Rule did not address whether FDA's premise was correct -- that is, whether the word "mild," when used in the context of cigars and pipe tobacco, is in fact a "descriptor" of "modified risk." FDA cited no evidence that the word "mild" conveys such a claim for those products. Nor did FDA acknowledge that categorically banning the word would destroy the BLACK & MILD® trademark.

2. Middleton's Comments on the Proposed Rule

34. Middleton submitted extensive comments (attached as **Exhibit B**) on the Proposed Rule in August 2014. The comments expressed concern that "FDA may reflexively apply the 'descriptor' prohibition in Section 911 of the [TCA] to cigars and pipe tobacco, with no assessment of whether words such as 'mild' convey a 'modified risk' claim for products other than cigarettes, and with no procedure to make such a determination." Ex. B, Middleton Comments at 1. A "categorical ban on the word 'mild'" was of particular concern, Middleton stated, because it is an intrinsic part of the brand name for BLACK & MILD® cigars and pipe tobacco that the Company has manufactured for decades, with BLACK & MILD® cigars today accounting for most of the Company's sales. *Id.* at 2.

35. As Middleton explained, "[t]here is no evidence that the BLACK & MILD® trademark communicates any claim about the risk of these products . . . ." *Id.* To the contrary, Middleton showed that the word "mild" for centuries has been used to describe the taste or body of cigars and pipe tobacco, not any attribute related to health. *Id.* at 9-10. In addition, Middleton explained, "[t]he prohibition on cigarette descriptors arose in the context of longstanding government tar and nicotine testing unique to the cigarette industry." *Id.* at 10. "By contrast,

manufacturers, government agencies, and retailers did not differentiate cigars or pipe tobacco based on relative average tar and nicotine yields." *Id.* at 11.

36. Middleton pointed out, in addition, that the United States Patent and Trademark Office's ("USPTO's") treatment of BLACK & MILD® reinforces the conclusion that it did not describe any modified risk. The USPTO will not grant registration on the Principal Register to a trademark that merely describes the product, absent a showing of acquired distinctiveness or secondary meaning in the marketplace. Generally, applicants must disclaim any exclusive right to descriptive elements within a trademark. The USPTO has treated BLACK & MILD® as a unitary brand name and acknowledged the acquired distinctiveness of that mark. *Id.* at 6 n.26.

37. Middleton further provided FDA with empirical evidence demonstrating that consumers do not understand the word "mild" in the BLACK & MILD® name to convey a modified-risk claim. Professor Itamar Simonson of Stanford University, one of the foremost experts on consumer behavior and perception, designed and conducted a rigorous survey at Middleton's request to determine consumers' understanding of the name BLACK & MILD® and other cigar brand names, and to assess what BLACK & MILD® communicates to cigar smokers about the type and characteristics of the cigars. Hundreds of cigar smokers, including many current and former cigarette smokers, participated in the study. *Id.*, Attachment A at 4. Participants were "blind" to the study's purpose and sponsor. *Id*. at 7.

38. The study found that smokers do not interpret the brand name BLACK & MILD® as referring to health. Further, the study showed "unambiguously" that the name BLACK & MILD® does not communicate to consumers a lower health risk or any characteristic potentially associated with a lower health risk. Instead, when asked whether the product name told them anything about the characteristics or features of the cigar compared to other cigars, the majority

said no, or they did not know. And of the minority of survey participants who thought the BLACK & MILD® name told them something about the cigar, most said that the name suggested a dark color or a mild taste or flavor. *Id.* at 2-3, 6-9. Not a single participant mentioned the words "health," "risk," or "safety" in response the survey's neutral, open-ended questions regarding the message conveyed by the name BLACK & MILD®. *Id.* at 8. Of the 312 participants, one person associated "mild" with "low nicotine." *Id.* Professor Simonson explained that such an isolated, aberrant response was statistically irrelevant "noise" or "guessing." *Id.*

39. Based on these results, Professor Simonson concluded that the survey "showed unambiguously that the brand name 'Black & Mild' does not communicate to consumers anything about health, risk, or safety of the cigars individually or compared to other cigars or tobacco products." *Id.*, Attachment A at 4. The results also "showed unambiguously that consumers do not perceive the brand name as conveying lower tar or nicotine." *Id.*

40. Middleton further explained that, of the 195 studies and references cited by FDA in its Proposed Rule, not one addressed the use of descriptors for cigars or pipe tobacco. And not one suggested that cigar or pipe tobacco manufacturers use, or that consumers perceive, the word "mild" to convey a modified risk claim for those products. *Id.* at 14-17.

41. Middleton accordingly advised FDA that a blanket extension of the descriptor ban to categorically prohibit use of the word "mild" for cigars and pipe tobacco would violate the TCA, the APA, the First Amendment, and the Fifth Amendment Takings Clause. *Id.* at 2-3.

42. Because the TCA prohibits the word "mild" only when it describes a modified risk, Middleton urged FDA to "adopt a procedure to assess whether terms such as 'mild' in

specific cigar or pipe tobacco labeling and advertising are used as 'descriptors' of 'modified risk,' or conversely, whether those terms convey no information related to health risk." *Id.* at 3.

3. FDA's Final Rule

43. On May 10, 2016, FDA published the Final Rule. 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140 and 1143) (attached as **Exhibit C**). The Final Rule extends FDA's regulatory authority under the TCA to cigars, pipe tobacco, and virtually all other "tobacco products." *Id.* at 29,102.

44. In issuing the Final Rule, FDA identified Section 911 of the TCA as "one of the *automatic* statutory provisions that will apply to newly deemed products on the effective date of this regulation." *Id.* at 29,053 (emphasis added). FDA thus took the erroneous position that deeming was all or nothing, that provisions designed to regulate existing products had to be extended *in haec verba* to distinctive new contexts, that FDA had no discretion to tailor deeming judiciously to the diversity of newly regulated products. Even so, the Final Rule went beyond merely extending Section 911 to additional products. It broadened the provision, misapplying the descriptor ban to categorically prohibit use of the word "mild" in labeling and advertising for cigars and pipe tobacco products, regardless of whether the word conveys a modified risk claim.

45. Without mentioning Middleton's comments or BLACK & MILD®, FDA generically noted some commenters' objections that "the brand names of newly deemed products that contain the descriptor 'low,' 'light,' or 'mild' should be prohibited only where the descriptors specifically convey a modified risk claim," and that categorically banning use of the words without regard to whether they convey a modified risk claim "would be unconstitutional, arbitrary, and capricious because the government does not advance any substantial interest by doing so." *Id.* FDA rejected these arguments in two short paragraphs.

46. First, regarding the First Amendment arguments, the Final Rule states:

> FDA disagrees with the suggestion that subjecting the newly deemed products to section 911 would be an unconstitutional restriction of free speech. The Sixth Circuit upheld the modified risk provisions against a First Amendment challenge to the facial validity of the statute in Discount Tobacco v. FDA, 674 F.3d 509, 531-37 (6th Cir. 2012). We discuss this issue in depth in section II.B.3.b. FDA has and will continue to apply section 911 of the FD&C Act consistent with the First Amendment and will take all relevant facts into account on a case-by-case basis.

Id. FDA's citation of *Discount Tobacco*, however, was not responsive to Middleton's points. Middleton's comments did not advance the claim at issue in *Discount Tobacco*—a facial challenge to the overall modified risk provision. And *Discount Tobacco* did not address the issue Middleton raised—whether the government can ban words like "mild" without regard to whether they are descriptors of modified risk.

47. Second, regarding the statutory and evidentiary arguments, the Final Rule states:

> FDA agrees with comments that supported the application of section 911 to all newly deemed products. Historically, certain users have initiated and continued using certain tobacco products based on unauthorized modified risk claims and consumers' unsubstantiated beliefs about the relative safety of these products. Section 911 will prevent the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or to continue using tobacco when they would otherwise quit. This will allow for better-informed consumers and help to prevent the use of misleading marketing targeted to youth populations.

Id. FDA cited no evidence or other support for any of these assertions. It failed to identify any consumer who would be or had been misled. It provided no insight on how the word "mild" in an established brand name like BLACK & MILD® could be misleading or convey a modified risk claim, or how a unitary name could be deconstructed into descriptors. And it offered no explanation how banning the word "mild" in contexts where the word does not convey a modified risk claim would lead to "better informed consumers."

48. Thus, in the 479 pages justifying the Final Rule, FDA provided not a scintilla of evidence that, in the context of cigars and pipe tobacco, the word "mild" is a descriptor of modified risk or relates in any way to health. No such evidence exists. Of the 279 studies and other references FDA cited in support of the Final Rule, *not one* addresses the use of descriptors for cigars or pipe tobacco. And *not one* suggests that cigar or pipe tobacco manufacturers use the word "mild," or that consumers understand it, to convey a modified risk claim.

49. Nor does FDA's defense of the Final Rule address, much less refute, Middleton's showing that (a) for centuries, the word "mild" has described the taste or body of cigars and pipe tobacco, not any attribute related to health; (b) in enacting the TCA's descriptor ban, Congress focused solely on the use of certain words as descriptors of modified risk for cigarettes; and (c) as reflected by Professor Simonson's survey and conclusions, the word "mild" in the BLACK & MILD® name does not communicate to consumers anything about health, risk, or safety.

50. In addition to disregarding this evidence, FDA failed to address Middleton's statutory argument that the language of Section 911 prohibits the word "mild" only if it is a descriptor of a modified risk. Critically, FDA also ignored Middleton's request that before banning the word "mild" and extinguishing Middleton's trademark, the Agency at least determine, through an evidence-based process, whether the word conveys a modified risk claim in labeling or advertising for cigars or pipe tobacco products. On FDA's indiscriminate approach, the ban applies no matter how the word "mild" is used.

51. Thus, under the Final Rule, Middleton cannot use its BLACK & MILD® trademark unless Middleton files, and FDA approves, a modified risk application. But Middleton cannot file a modified risk application for the BLACK & MILD® name because it does not communicate any modified risk. Middleton has never claimed, and is not claiming

now, that BLACK & MILD® products "significantly reduce harm and the risk of tobacco-related disease" and "benefit the health of the population as a whole," as compared with other cigar and pipe tobacco products. TCA § 911(g)(1).

SUBSTANTIVE, PROCEDURAL, AND CONSTITUTIONAL FLAWS IN THE FINAL RULE

A. FDA's *Per Se* Ban on the Word "Mild" in the BLACK & MILD® Trademark Conflicts With the Text, History, and Context of the TCA

1. The statutory text does not authorize a *per se* ban on the word "mild," particularly in brand names such as BLACK & MILD®

52. The plain language of Section 911 of the TCA does not authorize a categorical prohibition of the word "mild" in cigar and pipe tobacco labeling, advertising, or trademarks without regard to whether the term conveys a modified-risk claim. To the contrary, the descriptor ban in Section 911 applies only when a product's label, labeling, or advertising uses the "*descriptors* 'light', 'mild', or 'low' or similar *descriptors*" as "*descriptors*" of "modified risk," not when those words are used in other ways. TCA § 911(b)(2)(A)(ii) (emphases added).

53. The word "descriptors" preceding the words "'light', 'mild', and 'low'" limits the scope of Subsection 911(b)(2)(A)(ii). By inserting the modifier "descriptors," Congress necessarily conveyed that Subsection (b)(2)(A)(ii) covered something narrower than *all* uses of the listed words. The words are prohibited descriptors only if they communicate a "modified risk"—*i.e.*, that a product is sold "for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." TCA § 911(a), (b)(1). Otherwise, the word "descriptors" in Section 911 would be superfluous.

54. Likewise, the words "or similar descriptors" at the end of Subsection 911(b)(2)(A)(ii) raise the question as to what criterion a word would have to satisfy to qualify as a "similar descriptor[]" within the meaning of the statute. The answer necessarily is that the

word must *describe* a *modified risk* in the same manner as the listed words. FDA acknowledged as much when it requested comments to develop guidance regarding the meaning of "similar descriptors." The Agency asked for views "on ways in which descriptors that may be considered similar to 'light,' 'mild' and 'low' used on tobacco product packaging *could impact consumer perceptions of risk*." 75 Fed. Reg. 2879 (Jan. 19, 2010) (emphasis added). The very title of FDA's request—"Use of Tobacco Marketing Descriptors to Convey Modified Risk; Request for Comments"— also confirms this interpretation of Section 911. *Id.*

55. The structure of Section 911 likewise confirms this interpretation. Section 911(b)(2)(A) has three subsections identifying the ways a tobacco product may qualify as one "sold or distributed for use to reduce harm or the risk of tobacco-related disease." The first and third subsections deal explicitly with communication of lower risk, either in the label, labeling and advertising, § 911(b)(2)(A)(i), or by any other means. § 911(b)(2)(A)(iii). The second subsection, addressing use of the "descriptors 'light', 'mild', or 'low', or similar descriptors," § 911(b)(2)(A)(ii), must be interpreted in a manner that is consistent with the other two subsections and that exemplifies the phrase being defined. As a result, to qualify as a "descriptor" within the meaning of this subsection, the word must implicitly or explicitly describe a reduction in risk of, or harm from, tobacco-related disease. As discussed below, *see* ¶¶ 62-72, *infra*, Congress made statutory findings establishing that the words "light," "mild," and "low" met this test in the context of cigarettes, but the findings did not encompass other tobacco products.

56. This reading in addition tracks Congress's explanation of Section 911(b)(2)(A)(ii). Its purpose was to "prohibit[] the use of descriptors such as 'light,' 'mild' and 'low' *to characterize the level of a substance* in a product in labels or in advertising." H.R. Rep.

No. 111-58, pt. 1, at 3 (2009) (emphasis added). In other words, the provision prohibits the words only when used to "characterize"—that is, when they are descriptors of—modified risk.

57. Ignoring this statutory requirement, the Final Rule effectively imposes a *per se* ban on the word "mild" without regard to whether the word is used as a "descriptor" of "modified risk" for newly deemed products. By reading the word "descriptors" out of Section 911, FDA's interpretation violates the longstanding principle that a statute should be construed to "give effect, if possible, to every clause and word." *Roberts v. Sea-Land Servs., Inc.*, 132 S. Ct. 1350, 1362 (2012) (citation and internal quotation marks omitted).

58. FDA failed even to consider whether the word "mild" in fact makes an "unsubstantiated modified risk claim[]"—indeed, whether the word conveys anything about health risk—in the context of cigars and pipe tobacco, much less in the BLACK & MILD® name. While Congress based the descriptor ban on findings that the words "light," "low," and "mild" had been used to make unsubstantiated modified risk claims with respect to cigarettes, *see* TCA §§ 2(38)–(42), (47)–(49), Congress made no such determination for cigars and pipe tobacco. In promulgating the Final Rule, FDA does nothing to fill that gap, instead merely decreeing that the word "mild"—regardless of its meaning and context—is *per se* banned.

59. The Final Rule's *per se* ban on certain words is not only contrary to the plain text of the TCA, but also FDA's own prior practice of allowing manufacturers to use the words listed in Section 911(b)(2)(A)(ii) when they do not convey modified risk claims. Since the descriptor ban became effective for cigarettes in 2010, FDA has not objected to use of the word "low"—which Section 911(b)(2)(A)(ii) prohibits when used as a descriptor of modified risk—to describe price in cigarette labeling and advertising. For instance, in a warning letter challenging an advertisement for "LOW PRICE AND CHEMICAL FREE" cigarettes, FDA asserted that the

phrase "CHEMICAL FREE" was a prohibited descriptor of modified risk, but made no similar assertion with respect to the word "LOW." FDA, Warning Letter to Tobacco Source Three LLC (Feb. 1, 2012), www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm292873; *see also, e.g.*, FDA, Warning Letter to www.Low-Price-Cigarettes.com (May 11, 2012) (asserting that cigarettes sold on the website www.Low-Price-Cigarettes.com contained improper "characterizing flavors," but not objecting to the word "Low" in the vendor's name), www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm304655.

60. It is a fundamental precept of statutory interpretation that statutes should be read, if possible, in a manner that avoids constitutional concerns. *Clark v. Martinez*, 543 U.S. 371, 380-81 (2005). FDA's strained, sweeping, and fundamentally unsound interpretation of Section 911—barring certain words without regard to context—unnecessarily raises significant constitutional problems.

2. The context and history of the TCA refute a *per se* ban on the word "mild" in cigar or pipe tobacco brand names

61. The context in which Section 911 arose confirms that Congress did not authorize a ban on the word "mild" for cigars and pipe tobacco, including in the BLACK & MILD® trademark, without regard to whether the word communicates a modified risk.

62. The prohibition on cigarette descriptors arose in the context of longstanding government tar and nicotine testing unique to the cigarette industry. Beginning in the 1950s, scientific evidence suggested that reducing tar and nicotine yields in cigarettes would lower the risk cigarettes posed of diseases such as lung cancer. Based on this evidence, the public health community urged cigarette manufacturers to develop and market low tar cigarettes and advised smokers who would not quit to smoke such cigarettes. In the mid-1960s, the FTC decided to permit manufacturers to state the average tar and nicotine yields of their cigarettes based on the

"Cambridge method" that the FTC adopted as the standardized test methodology. Using the Cambridge method, manufacturers identified some cigarettes as "light" or "low tar" based on their lower tar and nicotine yield.

63. By contrast, manufacturers, government agencies, and retailers have never differentiated cigars or pipe tobacco products based on relative average tar and nicotine yields. Cigars and pipe tobacco were not subject to testing by the Cambridge method or any other method for purposes of federal average tar and nicotine reporting. There was no government health policy applicable to cigars or pipe tobacco that urged reductions in average tar and nicotine yields. And the FTC did not issue any guidance permitting manufacturers of cigars or pipe tobacco to disclose average tar and nicotine yields in advertisements for those products.

64. Cigar and pipe tobacco manufacturers thus did not describe tar and nicotine yields in labels or advertising. Nor did they use terms such as "light," "low tar," or "mild" to denote relative differences in tar or nicotine among cigar brands.

65. Further, while public health studies concluded that terms such as "light" suggested a reduced health risk to some cigarette consumers, no similar findings exist for cigars or pipe tobacco. In November 2001, the National Cancer Institute ("NCI") released Smoking and Tobacco Control Monograph No. 13, entitled "Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine" ("Monograph 13"). Monograph 13 concluded that "[m]any consumers use the terms 'Light' and 'Ultra Light' as a guide to the riskiness of particular brands of *cigarettes*." Monograph 13 at 198 (emphasis added).

66. Following Monograph 13, in 2008, the FTC rescinded its 1966 guidance regarding use of the Cambridge method, expressing concern that the method could mislead "consumers who rel[ied] on the ratings it produces as indicators of the amount of tar and nicotine

they actually will get from their *cigarettes*." *See* Rescission of FTC Guidance Concerning the Cambridge Filter Method, 73 Fed. Reg. 74,500, 74,501 (Dec. 8, 2008) (emphasis added).

67. Monograph 13 did not focus on cigars or pipe tobacco—only cigarettes.

68. The NCI monograph that did address cigars (Monograph 9, entitled "Cigars: Health Effects and Trends") never even alluded to descriptors as an issue. Monograph 9 was a 232-page publication by dozens of scientists and public health officials. Nowhere did this exhaustive analysis suggest that cigar smokers consider tar and nicotine measurements in determining the relative risks of smoking cigars or that consumers perceive words such as "mild" as a guide to the risks of particular brands of cigars.

69. Additionally, the litigation backdrop that prompted the descriptor ban for cigarettes did not apply to cigars or pipe tobacco. In 2006, the district court in the United States' lawsuit against cigarette manufacturers found that marketing cigarettes as "'low tar,' 'light,' 'mild,' 'medium' and 'ultra light' . . . create[s] the false impression that such *cigarettes* are less harmful to smokers." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 925 (D.D.C. 2006), *aff'd in part, vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009) ("the DOJ Case") (emphasis added).

70. The 1,682-page decision in the DOJ Case cited seven sources in support of its conclusion that consumers interpret certain descriptors as conveying reduced risk of harm. Each of those sources related to cigarettes, and not one concerned cigars or pipe tobacco. *Id.* at 448, 476, 509, 510, 925. The decision said nothing at all about cigars or pipe tobacco.

71. Although the FTC in 2000 challenged certain labeling, marketing, and advertising practices of cigar manufacturers, its suit advanced no objection to words such as "mild." Ultimately, the FTC and the manufacturers entered into a consent decree mandating new

warnings on cigar labeling and imposing other restrictions. Decision and Order, *In the Matter of John Middleton, Inc.*, No. C-3968 (F.T.C. Aug. 18, 2000). The FTC, however, neither sought nor obtained any prohibition on the then-widespread use of "mild" in cigar advertising and brand names, including BLACK & MILD®, which was a top-selling cigar brand. Nor did the FTC suggest that cigar labeling or advertising conveyed any modified risk claims.

72. Accordingly, none of Congress's "findings" in the TCA mentions cigars or pipe tobacco, much less modified risk claims about them, and no other provision of the TCA suggests Congress envisioned that the deeming process would automatically and categorically ban particular words with respect to these products. *See* TCA § 2.

B. FDA's *Per Se* Ban on the Word "Mild" for Cigars and Pipe Tobacco Is Arbitrary and Capricious, Especially for BLACK & MILD®

73. The Final Rule states that FDA "uses the best evidence available from peer reviewed journals and other reputable sources to support this rule and fulfill our public health mandate." 81 Fed. Reg. at 29,041. Nevertheless, the administrative record contains no evidence whatsoever supporting a *per se* ban on the word "mild" for cigars and pipe tobacco, particularly in the context of a well-established brand name like BLACK & MILD®.

1. No study or other evidence cited by FDA supports treating the word "mild" as a *per se* modified risk descriptor for cigars or pipe tobacco

74. Of the 195 scientific studies and other sources cited in the Proposed Rule, and the 279 sources cited in the Final Rule, not one analyzes, discusses, or mentions the use of modified risk descriptors in the context of cigars or pipe tobacco. 79 Fed. Reg. at 23,197-202; 81 Fed. Reg. at 29,094-102. Not one of the sources suggests that cigar or pipe tobacco manufacturers use, or that consumers perceive, the word "mild" to convey a modified risk claim.

75. To the contrary, many of FDA's cited sources show that "mild" traditionally characterizes the taste or body of cigars and invokes no association with any modified risk. For

instance, in Monograph 9, the only references to "mild" appear in a discussion of a 1996 article in *Cigar Aficionado* advising that, for a food, wine, and cigar event, planners should offer "a mix of full-bodied and mild cigars" to account for varying tastes. Defendant HHS likewise has noted that some cigars have a "mild taste." U.S. Dep't of Health and Human Services, Office of Inspector General, Youth Use of Cigars: Patterns of Use and Perceptions of Risk 7 (1999).

76. The study Middleton submitted to FDA "unambiguously" showed that the name BLACK & MILD® does not communicate to consumers a lower risk or any characteristic of the cigar potentially associated with a lower risk. Most respondents said that the product name did not tell them anything about the characteristics or features of BLACK & MILD® cigars compared to other brands.

2. FDA did not adequately explain the basis for categorically banning the word "mild" in the context of cigars and pipe tobacco, and did not respond to significant public comments

77. Neither the Proposed Rule nor the Final Rule offers an adequate basis for reflexively converting the cigarette descriptor ban into a wholesale ban of the word "mild" in connection with cigars and pipe tobacco. FDA's entire justification boils down to an assertion that "[h]istorically, certain users have initiated and continued using certain tobacco products based on unauthorized modified risk claims and consumers' unsubstantiated beliefs about the relative safety of these products." 81 Fed. Reg. at 29,053. This generalized assertion says nothing about cigars or pipe tobacco, nor does it shed light on whether "mild" is a descriptor of modified risk for these products. It simply assumes that conclusion.

78. Middleton submitted significant public comments on the Proposed Rule, identifying multiple reasons why FDA should not automatically extend the descriptor ban to cigar and pipe tobacco products. *See generally* Ex. B, Middleton Comments. These comments included evidence that consumers do not perceive the BLACK & MILD® name as

communicating any modified risk claim. *Id*. at 7-9. In promulgating the Final Rule, FDA did not substantively respond to the issues raised in Middleton's comment or even acknowledge—let alone address—the evidence Middleton presented.

79. Nor does the Final Rule explain FDA's refusal to adopt a procedure to evaluate whether specific product labeling or advertising uses words like "mild" as descriptors of modified risk. Nothing in the record indicates that FDA considered any alternative at all.

C. FDA's Ban on the BLACK & MILD® Name Violates the First Amendment

80. By banning the word "mild" as a *per se* descriptor of modified risk for cigars and pipe tobacco, FDA has impermissibly restricted protected speech in violation of the First Amendment. FDA's approach bans certain words regardless of how they are used, even where those words in fact communicate no modified risk to consumers, and even when they are truthful and not misleading. Without explanation, FDA rejected any effort to evaluate what, if anything, the words communicate to consumers, before censoring the words across the board.

81. The Final Rule bans speech only by companies that manufacture and market tobacco products, and does so based on content. Restrictions on speech based on the identity of the speaker and the content of the speech are subject to strict or heightened scrutiny. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2664-65 (2011). The Final Rule cannot satisfy such scrutiny, nor even an intermediate level of review.

82. FDA's categorical ban on the word "mild" for cigars and pipe tobacco does not advance a substantial government interest, much less a compelling one. There is no history of claimed misuse of modified risk descriptors with respect to cigars and pipe tobacco, and FDA has not identified any evidence establishing that extending the descriptor ban to these newly deemed products is reasonable. Further, with no procedure to evaluate the meaning of these words in context, FDA's *per se* ban on them restricts far more speech than necessary.

83. There are less restrictive alternatives to FDA's categorical ban, including a process allowing FDA to evaluate whether words used on specific cigar or pipe tobacco labeling or advertising communicate a modified risk claim to consumers. Alternatively, rather than an outright ban, FDA could consider disclaimers through an appropriate process. For instance, FDA could seek a disclosure that a particular cigar or pipe tobacco product with "mild" on its label is not safer than others. So far as the record shows, FDA never considered such alternatives.

D. FDA's Ban on the BLACK & MILD® Name Violates the Fifth Amendment

84. The Fifth Amendment prohibits the government from taking private property "for public use, without just compensation." U.S. Const. amend. V, cl. 4.

85. When determining whether a regulatory taking has occurred, courts assess the factors delineated in *Penn Central Transportation Co. v. City of New York*: (1) the character of the government action; (2) the economic impact of the regulation on the property owner; and (3) the regulation's interference with the property owner's reasonable investment-backed expectations. 438 U.S. 104, 124 (1978).

86. The character of the government action here is that of a Taking because FDA's categorical ban on the word "mild" for cigars and pipe tobacco prevents Middleton from using its established BLACK & MILD® trademark. Such a ban is unnecessary to prevent consumers from being misled, as the word does not communicate anything about, and has no historical association with, modified risk in the context of cigars or pipe tobacco.

87. Middleton faces an economic loss if FDA bars it from using the BLACK & MILD® trademark. The value of the name is reflected in the $2.9 billion purchase price that Altria paid in 2007 for Middleton, whose principal asset was its BLACK & MILD® product line.

88. FDA also interfered with Middleton's reasonable investment-backed expectations. Middleton has used the BLACK & MILD® trademark for decades without interference, and it reasonably expected to be able to continue doing so, particularly given the lack of evidence that "mild" communicates a modified risk claim for cigars or pipe tobacco. The USPTO has repeatedly granted protection to the BLACK & MILD® trademarks, establishing federal intellectual property rights for one of the country's iconic cigar and pipe tobacco brands. As the USPTO has granted protection to BLACK & MILD® on the Principal Register, without a disclaimer requirement, this confirms the conclusion that the word "mild," as used in the unitary BLACK & MILD® trademark, does not convey any modified risk claims to the relevant consumers.

CLAIMS FOR RELIEF

COUNT I
(Violation of the Administrative Procedure Act: the Final Rule Is Arbitrary, Capricious, and Not in Accordance With the TCA, and Exceeds FDA's Authority)

89. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

90. The Final Rule is "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704.

91. The APA proscribes agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A). The APA further proscribes agency action "in excess of statutory jurisdiction, authority, or limitations." *Id.* § 706(2)(C).

92. Section 911 of the TCA prohibits use of the word "mild" only when the word is used as a "descriptor" of "modified risk"—not when the word is used in other ways. In categorically barring the word "mild" for deemed products, regardless of whether it is used as a

descriptor of modified risk, the Final Rule is arbitrary, capricious, and contrary to the TCA, and exceeds FDA's authority because it conflicts with the TCA.

93. The Final Rule also is not in accordance with law because it violates the First and Fifth Amendments to the U.S. Constitution.

94. Plaintiff has no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

95. Plaintiff has no adequate remedy at law.

96. FDA's categorical ban on the word "mild" for cigars and pipe tobacco has imposed ongoing harm on Plaintiff.

97. This Court accordingly should set aside and declare unlawful FDA's categorical ban on the word "mild" for cigars and pipe tobacco. *See* 5 U.S.C. § 706(2).

COUNT II
(Violation of the Administrative Procedure Act: the Final Rule Is Unsupported By, and Lacks a Rational Connection to, the Evidence in the Administrative Record)

98. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

99. Under the APA, an agency rulemaking is arbitrary and capricious when the agency acts counter to the evidence in the record or when its action lacks a rational connection to the facts in the record. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-44 (1983).

100. Because the administrative record lacks evidence supporting a blanket extension of the descriptor ban to cigars and pipe tobacco, FDA did not make a reasoned decision based on reasonable extrapolations from reliable evidence. FDA in fact acted counter to the evidence in the record.

101. Plaintiff has no adequate remedy at law.

102. FDA's categorical ban on the word "mild" for cigars and pipe tobacco has imposed ongoing harm on Plaintiff.

103. This Court accordingly should set aside and declare unlawful FDA's categorical ban on the word "mild" for cigars and pipe tobacco. *See* 5 U.S.C. § 706(2).

COUNT III
(Violation of the Administrative Procedure Act:
FDA Failed Adequately To Explain the Basis for Extending the Descriptor Ban to Cigars

104. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

105. "The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result." *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993). Further, an agency must consider and explain its rejection of "reasonably obvious alternative[s]." *Natural Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1053 (D.C.Cir.1979).

106. FDA did not explain its basis for banning the word "mild" for cigars and pipe tobacco. Nor did FDA explain its rejection of reasonably obvious alternatives to treating the word "mild" as a *per se* descriptor of modified risk for cigars and pipe tobacco. FDA's actions are thus arbitrary and capricious.

107. Plaintiff has no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

108. Plaintiff has no adequate remedy at law.

109. FDA's categorical ban on the word "mild" for cigars and pipe tobacco has imposed ongoing harm on Plaintiff.

110. This Court accordingly should set aside declare unlawful FDA's categorical ban on the word "mild" for cigars and pipe tobacco. *See* 5 U.S.C. § 706(2).

COUNT IV
(Violation of the Administrative Procedure Act:
FDA Failed to Respond to Significant Comments on the Proposed Rule)

111. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

112. Agency action is arbitrary or capricious when the agency failed to "respond to 'relevant' and 'significant' public comments." *Pub. Citizen, Inc.*, 988 F.2d at 197.

113. Plaintiff submitted relevant and significant public comments on the Proposed Rule, addressing the application of Section 911 to cigar and pipe tobacco products and demonstrating that an indiscriminate extension of the TCA's descriptor ban to these products would conflict with the TCA and the evidence. In the Final Rule, FDA did not answer the issues raised in Plaintiff's comments.

114. Plaintiff has no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

115. Plaintiff has no adequate remedy at law.

116. FDA's categorical ban on the word "mild" for cigars and pipe tobacco has imposed ongoing harm on Plaintiff.

117. This Court accordingly should set aside and declare unlawful FDA's categorical ban on the word "mild" for cigars and pipe tobacco. *See* 5 U.S.C. § 706(2).

COUNT V
(Violation of the First Amendment to the U.S. Constitution:
the Final Rule Impermissibly Restricts Protected Speech)

118. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

119. Trademarks, product names, and advertising are speech protected by the First Amendment. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985).

120. The Final Rule prohibits Plaintiff from using its valuable and longstanding trademark by banning the word "mild" for cigar and pipe tobacco products without regard to whether it conveys a modified risk claim.

121. FDA banned the word "mild" with regard to cigar and pipe tobacco products without considering whether the word communicated a modified health risk to consumers.

122. FDA's ban on speech is speaker-based because it constrains only tobacco manufacturers and content-based because it bars only certain speech as to tobacco products.

123. The ban as implemented by FDA does not directly serve a substantial government interest (nor a compelling one), restricts far more speech than necessary to serve such interest, and is not narrowly tailored to accomplish FDA's regulatory goals.

124. Plaintiff has no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

125. Plaintiff has no adequate remedy at law.

126. FDA's categorical ban on the word "mild" for cigars and pipe tobacco has imposed ongoing harm on Plaintiff.

127. As a result, Plaintiff is entitled to a declaration that FDA's categorical ban on the word "mild" for cigars and pipe tobacco violates the First Amendment to the U.S. Constitution and should be set aside. *See* 28 U.S.C. § 2201(a).

COUNT VI
(Violation of the Fifth Amendment Due Process Clause: the Final Rule Constitutes an Impermissible Regulatory Taking of Plaintiff's Valuable BLACK & MILD® Trademark)

128. Plaintiff incorporates the preceding paragraphs as if fully set forth herein.

129. The Fifth Amendment prohibits the government from taking private property "for public use, without just compensation." U.S. Const. amend. V, cl. 4.

130. By categorically banning use of the word "mild" in labeling and advertising for cigars and pipe tobacco, FDA has prevented Plaintiff from continuing to use its longstanding and valuable trademark BLACK & MILD®.

131. Plaintiff has a property interest in its trademark, in which it has invested over many years.

132. Plaintiff has reasonable investment-backed expectations in its right to continue using that trademark and to continue earning revenue from its BLACK & MILD® products.

133. The United States, through FDA's action, has destroyed these reasonable investment-backed expectations and expropriated Plaintiff's property without just compensation.

134. Plaintiff is entitled to a declaration that FDA's categorical ban on Plaintiff's valuable trademark BLACK & MILD® constitutes a taking of Plaintiff's property. 28 U.S.C. § 2201(a).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that this Court enter judgment in its favor and:

a. Vacate and set aside the Final Rule under 5 U.S.C. § 706 as arbitrary and capricious, not in accordance with law, and in excess of FDA's authority, all in violation of the APA, because it expands and misapplies the descriptor ban in Section 911 of the TCA to categorically prohibit the word "mild" in labeling and advertising for cigars and pipe tobacco without regard to whether it conveys a modified risk claim;

b. Declare that the Final Rule is arbitrary and capricious, not in accordance with law, and in excess of FDA's authority, all in violation of the APA, because it expands and misapplies the descriptor ban in Section 911 of the TCA to categorically prohibit the word "mild" in

labeling and advertising for cigars and pipe tobacco without regard to whether it conveys a modified risk claim;

c. Declare that the Final Rule impermissibly restricts protected speech in violation of the First Amendment, by expanding and misapplying the descriptor ban in Section 911 of the TCA to categorically prohibit the word "mild" in labeling and advertising for cigars and pipe tobacco without regard to whether it conveys a modified risk claim;

d. Declare that the Final Rule constitutes a taking of Plaintiff's property by prohibiting Plaintiff from using its longstanding and valuable trademark BLACK & MILD®;

e. Enter a preliminary and a permanent injunction restraining Defendants from implementing or enforcing the descriptor ban to prohibit Plaintiff from using its trademark BLACK & MILD® in labeling and advertising for Plaintiff's cigars and pipe tobacco products;

f. In the alternative, enter a preliminary and a permanent injunction restraining Defendants from implementing or enforcing the descriptor ban to prohibit Plaintiff from using its trademark BLACK & MILD® in labeling and advertising for Plaintiff's cigars and pipe tobacco products unless and until Defendants determine, through an appropriate evidence-based process whether BLACK & MILD® conveys a modified risk;

g. Award Plaintiff its litigation costs and reasonable attorneys' fees; and

h. Order such other relief as the Court may deem just and proper.

Dated: May 26, 2016

Respectfully submitted,

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