IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA
1100 G Street, N.W.
Washington, D.C. 20005-7505

INTERNATIONAL PREMIUM CIGAR AND PIPE RETAILERS ASSOCIATION
513 Capitol Court N.E.
Washington, D.C. 20002

CIGAR RIGHTS OF AMERICA
300 New Jersey Avenue N.W., Suite 900
Washington, D.C. 20001

Plaintiffs,

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
Washington, D.C. 20201

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

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-____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. This action seeks declaratory, injunctive, and other relief arising from an unlawful Final Rule published on May 10, 2016, by the Food and Drug Administration ("FDA") that threatens the sale of any cigars, pipe tobacco and associated products not on the market as of February 15, 2007. FDA's Final Rule is contrary to the language and purpose of the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"), Pub. L. 111-31, 123 Stat. 1776 *et seq.*, the basis of FDA's authority to regulate tobacco products. The Cigar Association of America, Inc. ("CAA"), the International Premium Cigar and Pipe Retailers Association ("IPCPR") and the Cigar Rights of America ("CRA") (together, the "Plaintiff Associations") bring this action to challenge the Final Rule and to enjoin its enforcement.

2. When Congress enacted the TCA in 2009, it established a carefully crafted regulatory scheme to immediately regulate four categories of tobacco products – cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco – (the "Originally Regulated Products"). It also granted FDA certain authority to "deem" other classes of tobacco products subject to regulation under the statute at some future date.

3. On May 10, 2016, FDA published its Final Rule "deeming" cigars, pipe tobacco and certain other products (*e.g.*, e-cigarettes) subject to regulation ("Newly Deemed Products"). *See* 81 Fed. Reg. 28974 (May 10, 2016) (to be codified at 21 C.F.R. Parts. 1100, 1140 and 1143) ("Final Rule").

4. The Final Rule is legally defective and contrary to the TCA and Congressional intent in several respects:

(a) It incorrectly and impermissibly subjects Newly Deemed Products to stricter regulatory restrictions than Originally Regulated Products.

(b) It effectively imposes a tax on cigars and pipe tobacco in the form of "user fees." Moreover, these "user fees" are imposed on only some of the Newly Deemed Products, contravening Congress's intention that all regulated entities will bear their fair share of the costs associated with regulating tobacco products.

(c) It fails to provide an adequate cost-benefit analysis determining that the benefits of the Final Rule outweigh its undeniably severe costs, particularly as to thousands of small businesses.

(d) It ignores Congressional intent that "appropriate" regulations permit the continued sale of cigars and pipe tobacco to adults.

(e) It imposes new and expanded warning label format requirements without analyzing whether the new requirements are necessary and least restrictive.

(f) It regulates as "manufacturers" small retail tobacconists who blend and/or repackage finished pipe tobacco and products received in bulk form into smaller quantities and cigar retailers who create "cigar samplers" from finished cigars.

(g) It purports to treat pipes as "components" or "parts" of tobacco products instead of as "accessories," contrary to the definitions in FDA's own regulations.

5. In these respects, the Final Rule violates the Federal Food, Drug and Cosmetic Act ("FD&C Act"), as amended by the TCA; the Administrative Procedure Act ("APA") (including but not limited to the Regulatory Flexibility Act ("RFA")); and the First and Fifth Amendments to the Constitution. Accordingly, and as set forth below, the Court should vacate, set aside, and enjoin enforcement of the Final Rule.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. § 1331. Plaintiffs' causes of action arise under the laws and Constitution of the United States, including the APA, 5 U.S.C. §§ 702 *et seq.*, the RFA, 5 U.S.C. §§ 601 *et seq.*, the FD&C Act, 21 U.S.C. §§ 301 *et seq.*, and the First and Fifth Amendments.

7. 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.

8. 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 Final Rule, as requested herein. 28 U.S.C. §§ 2201, 2202; 5 U.S.C. §§ 705, 706.

PARTIES

9. Plaintiff CAA, a non-profit trade association, is a national trade group representing cigar manufacturers, importers, distributors, and major suppliers to the industry. CAA has member companies from all sectors of the industry, from manufacturers of handmade premium cigars to producers of machine-made small cigars.

10. Plaintiff IPCPR is a non-profit trade association representing premium cigar and tobacco retail shops located throughout the United States and abroad. IPCPR has retail members that are small businesses, typically family-owned and operated. IPCPR members operate more than 2,000 retail stores, employ more than 35,000 people, and sell tobacco products, primarily premium cigars, in face-to-face sales, to adults. Plaintiff IPCPR is a "small organization" as that term is defined by the RFA, and IPCPR's members are "small businesses" for purposes of the RFA.

11. Plaintiff CRA is a non-profit association that serves as a voice of premium cigar manufacturers and consumers in the United States on matters of legislative and regulatory concern, with a membership that spans all 50 states. CRA members include over 60 diverse artisan producers of handmade premium cigars. Additionally, CRA includes members from the

entire spectrum of the supply chain, *i.e.*, distributors, growers, mail-order houses, logistics, and associated supporting enterprises as well as consumers of premium cigars.

12. As a result, the Plaintiff Associations have a vital interest in ensuring that any regulation of cigars and pipe tobacco imposed under the TCA is consistent with statutory and constitutional requirements.

13. Furthermore, the Plaintiff Associations have standing to bring this suit because (a) their members would otherwise have standing to sue in their own right; (b) the interests they seek to protect are germane to the organizations' purposes; and (c) neither the claims asserted nor the relief requested requires the participation of individual members in the lawsuit. *E.g., United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 552-57 (1996).

14. Defendant HHS is an executive department of the United States government. HHS is headquartered in Washington, D.C.

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. The Tobacco Control Act

18. In enacting the TCA in 2009, Congress determined that the Originally Regulated Products would be subject to immediate regulation. FD&C Act § 901(b) (21 U.S.C. § 387a(b)). That determination was expressed as a Congressional Finding in section 2(31) of the TCA that regulating cigarettes and smokeless tobacco was of crucial importance to preventing the life-threatening health consequences associated with their use. *See* 123 Stat. 1776, 1779 (stating that FDA's final regulation from 1996, after incorporation into current regulations, would "directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use.") There was no suggestion that any tobacco products other than these four categories posed a significant threat to public health.

19. Based on its findings, Congress set forth purposes, restrictions and limits of the TCA. Congress gave FDA regulatory authority for specific purposes and subject to various parameters such as: "(2) to ensure that the Food and Drug Administration has the ***authority to address issues of particular concern to public health officials***, ***especially the use of tobacco by young people*** . . . ; (4) to provide new and ***flexible*** enforcement authority to ensure that there is ***effective*** oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products . . . ; (7) ***to continue to permit the sale of tobacco products to adults*** in conjunction with ***measures to ensure that they are not sold or accessible to underage purchasers***; (8) to impose ***appropriate*** regulatory controls on the tobacco industry." 123 Stat. 1776, 1781-82 (emphasis added).

20. In contrast to the detailed and immediate regulation of the Originally Regulated Products, the TCA provides FDA with authority to "deem" other tobacco products subject to the TCA at a later date, but does not require it to do so. FD&C Act § 901(b) (21 U.S.C. § 387a(b)). Congress did not intend that, in "deeming" additional tobacco products subject to regulation, FDA would impose more intrusive regulatory burdens than those imposed on the Originally Regulated Products which were Congress's primary and immediate concern.

21. For all new tobacco products that were not on the market as of February 15, 2007, the date of the TCA's introduction in Congress, or for grandfathered products that were modified after that date, the FD&C Act requires a premarket application and an authorization order from FDA permitting the marketing of such products (referred to as a "marketing authorization order"). *See* FD&C Act § 910 (21 U.S.C. §§ 387j).

22. A marketing authorization order is not required if: (a) a manufacturer submits a "substantial equivalence" report to FDA under section 905(j) and obtains an order under section 910(a)(2) finding that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or a tobacco product that FDA determined was substantially equivalent to a tobacco product commercially marketed as of February 15, 2007 and in compliance with the requirements of the FD&C Act, or (b) a tobacco product is exempt from the substantial equivalence requirements. FD&C Act §§ 905(j), 910 (21 U.S.C. §§ 387e(j), 387j).

23. To determine substantial equivalence, the new tobacco product is compared to a predicate tobacco product. A predicate product is a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product

that was determined to be substantially equivalent to another predicate product and in compliance with the FD&C Act. FD&C Act § 905(j)(1)(A)(i) (21 U.S.C. §§ 387e(j)(1)(A)(i)).

24. The FD&C Act provides that manufacturers of the Originally Regulated Products are allowed to continue marketing products that were on the market on June 22, 2009, at the time they were first subject to regulation, and allows them to "look back" only two and a half years—to February 15, 2007—for predicate products. Under the Final Rule, by contrast, manufacturers of Newly Deemed Products, however, are forced to "look back" over nine years for predicate products. This puts Newly Deemed Products in a severely different regulatory scheme compared to Originally Regulated Products.

25. Under the TCA, manufacturers of Originally Regulated Products were permitted to change existing products and introduce new products until March 22, 2011, when marketing applications were first due.

26. Originally Regulated Products, for which applications were filed by March 22, 2011, could remain on the market (subject to compliance with the other provisions of the TCA) unless and until FDA rejected a product's application.

27. To fund regulatory programs under the TCA, Congress provided for payments from regulated entities in the form of "user fees." FD&C Act § 919 (21 U.S.C. § 387s). As Congress made clear in other contexts, "user fees" have three basic characteristics: (a) fees are predicated on a voluntary act by payers; (b) persons who pay the fees receive a specific service or benefit; and (c) payments are not meant for regulation of others or for general public benefit (i.e., a tax). *E.g.*, *User Fee Design Guide*, GAO-08-386SP; *National Cable Television Ass'n, Inc. v. United States.*, 415 U.S. 336, 340-41 (1974).

28. Consistent with its use of the term "user fees," Congress intended that user fees assessed under the TCA would be paid by manufacturers of classes of tobacco products subject to regulation under the TCA. Conversely, manufacturers of unregulated classes of products would not pay user fees. FD&C Act § 919(b)(2)(B)(iv) (21 U.S.C. § 387s(b)(2)(B)(iv)) (providing for reallocation so that manufacturers of regulated classes share the percentage of fees that would be otherwise applicable to unregulated classes of tobacco products).

29. Although Congress provided a formula to allocate "user fees" based on classes of tobacco products that existed on the market at the time of enactment, *id.* at § 919(b)(2)(B)(i) (21 U.S.C. § 387s(b)(2)(B)(i)), it did not in any manner suggest that additional classes of tobacco products, if "deemed" subject to regulation by FDA, would be exempt from paying user fees.

B. FDA's 2014 Proposed Rule

30. On April 25, 2014, FDA published a proposed rule for "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act," including "Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." 79 Fed. Reg. 23142 (Apr. 25, 2014) ("Proposed Rule").

31. The Proposed Rule applied to numerous categories of tobacco products that had not previously been subject to regulation, including cigars and pipe tobacco. It also proposed a phase-in period similar to that provided by statute for the Originally Regulated Products. Specifically, FDA proposed to extend the compliance period for submitting a substantial equivalence report to 24 months following the effective date of a final rule, and also proposed a 24-month compliance period for the submission of premarket tobacco applications. *Id.* at 23144.

32. Under the Proposed Rule, if a manufacturer submitted a substantial equivalence report or a premarket tobacco application within the applicable period, FDA would not initiate enforcement action against the product for failing to have an FDA marketing authorization pending FDA's review of the submission or unless or until FDA issued an order denying the substantial equivalence submission or the premarket tobacco application. *Id*. at 23175-76.

33. FDA's Proposed Rule included two regulatory options: "Option 1," under which all deemed tobacco products, including all types of cigars, would be subject to regulation; and "Option 2," under which premium cigars would not be included in the deeming regulation. *Id.* at 23143, 23150-52.[1]

34. FDA's Proposed Rule included comprehensive warning requirements for Newly Deemed Products that were essentially repeated in the Final Rule. The Proposed Rule did not consider or analyze the need for such format requirements in light of an existing framework for cigars contained in a consent decree entered into between the Federal Trade Commission ("FTC") and seven of the largest cigar manufacturers ("FTC Consent Decree"). The FTC Consent Decree required clear and conspicuous disclosure of four of the five FDA proposed warning statements for cigars.

35. In conjunction with the Proposed Rule, FDA submitted a legally required Preliminary Regulatory Impact Analysis ("PRIA") in which it admitted that it could not carry out a realistic prospective cost/benefit analysis, and instead suggested it would conduct a "retrospective review" after implementing the final rule. The PRIA wholly failed to justify the costs of

[1] For "Option 2," FDA defined premium cigars as any cigar that: "(1) [i]wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases to the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units." 79 Fed. Reg. 23150, 23203.

regulation against any benefits. Indeed, it failed to even attempt such a justification with respect to premium cigars and small businesses that would be covered by the Proposed Rule.

36. FDA's Proposed Rule defined "manufacturer" to include "any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product." 79 Fed. Reg. 23203. FDA's discussion in the Proposed Rule did not suggest that tobacconists who merely blend regulated, finished pipe tobacco products would be subject to regulation as "manufacturers."

37. FDA's Proposed Rule made clear that "accessories" of Newly Deemed Products would not be subject to regulation. Nothing in the proposed rule suggested that pipes would be considered as anything other than "accessories."

C. Comments on the Proposed Rule

38. CAA, IPCPR and CRA submitted detailed comments on the Proposed Rule.

39. CAA's comments challenged the Proposed Rule in numerous respects. For instance, CAA challenged the imposition of a February 15, 2007 "grandfather cut-off date for cigars" and noted that it would leave cigar manufacturers "significantly disadvantaged relative to cigarette manufacturers, without any rational justification" by effectively denying cigar manufacturers predicates upon which to compare their new cigar offerings, rendering substantial equivalence showings nearly impossible, unlike the manufacturers of the Originally Regulated Products. CAA opposed Option 1 (regulating all cigars, including premium cigars) and supported a modified version of Option 2 (the option excluding regulation of premium cigars). CAA's comments also expressed concerns about the proposed size of the warnings on both cigar labeling and advertising, noting that such requirements exceed those of the FTC Consent Decree, which satisfy the FTC's "clear and conspicuous" disclosure standard. CAA's comments stated

that user fees must be assessed on all newly-regulated products, not just a subset of them. Finally, CAA's comments challenged FDA's PRIA for failing to carry out a proper prospective review, failing to supply evidence of benefits for warning label requirements, failing to properly assess the costs and supposed benefits of premarket review for newly-regulated products, and inadequately considering less costly regulatory alternatives.

40. In its comments, IPCPR, among other things, strongly opposed Option 1 and stated its support for a slightly modified Option 2. IPCPR offered comments on the definition of "premium cigar," and the development of a "Safe Harbor" whereby the cigar manufacturer's characterization of a premium cigar would define the cigar's status for retailers. IPCPR also discussed the detrimental effects of a sampling ban on retailers. IPCPR commented that the financial burdens on premium cigar manufacturers and retailers under Option 1 would be devastating to the premium cigar industry, mostly comprised of small businesses, and cited FDA's PRIA that estimated that up to 50% of hand-rolled cigars would cease to be marketed in the U.S. if the Proposed Rule would become final with Option 1.

41. In its comments, CRA highlighted the differences between premium cigars and other tobacco products to support the position that these differences compel exempting premium cigars from FDA regulation under FDA's proposed Option 2. Additionally, CRA commented on specific aspects of the Proposed Rule, expressing particular concern with the proposed premarket approval requirement for cigars introduced, or modified, after February 15, 2007. CRA commented that the Proposed Rule would devastate the premium cigar industry, including forcing manufacturers to curtail their product offerings and forcing adult consumers to pay dramatically higher prices for premium cigars. Finally, CRA commented that the FDA failed to consider the downstream effects on small businesses, including distributors, retailers, suppliers,

trade show proprietors and workers foreign and domestic which depend on this industry as a way of life.

D. The Final Rule

42. FDA's Final Rule largely rejected the comments of CAA, IPCPR and CRA, and instead incorporated each of the defects that these organizations had identified in their comments, and added additional defects as well.

43. The Final Rule applied the TCA's general provisions, including its premarket review requirements and substantial equivalence provisions, to Newly Deemed Products. However, rather, than tailoring the timeline for implementation of these provisions to account for the passage of time since enactment of the TCA, FDA chose to apply some provisions as written by Congress, yet rewrite other provisions.

44. The Final Rule required that substantial equivalence showings demonstrate equivalence between Newly Deemed Products and tobacco products on the market as of February 15, 2007 – that is, nine years before the Final Rule was published.

45. FDA refused to consider alternatives to the February 2007 grandfather date that would regulate Newly Deemed Products in the same manner as Congress mandated Originally Regulated Products be regulated. FDA concluded that it "lack[ed] authority to change the grandfather date for the newly deemed products" based on what it considered "the clear language of the Tobacco Control Act." 81 Fed. Reg. 28993.

46. Further, FDA asserted that "manufacturers of the newly deemed products have been on notice for more than 4 years that these products could and likely would be regulated," *id.*, without identifying the basis for such notice and explaining how such "notice" would have assisted manufacturers in preparing for as yet promulgated regulations, let alone preparing

substantial equivalence reports ("SE Reports") for new products compared to products that were marketed nine years prior to the publication of the Final Rule.

47. The use of the February 2007 "grandfather date" is prejudicial to manufacturers of Newly Deemed Products. It is onerous, costly and time-consuming for them, nine years after the fact, to find "predicate" products for the substantial equivalence comparisons to new products required by FDA. Further, it will be impossible for cigar or pipe manufacturers who entered the market after February 15, 2007 to demonstrate the substantial equivalence of their products as they will not have a predicate product of their own by virtue of not being in business as of the grandfather date. This differs from the Originally Regulated Products, which were subject to only a two and a half year predicate look back.

48. The Final Rule also deviated from the TCA in prohibiting any modification of an existing cigar or pipe tobacco product, or introduction of a new product, immediately upon the effective date of the regulation. The TCA allowed manufacturers of Originally Regulated Products to make such adjustments until the due date for marketing authorization applications – 21 months after the TCA went into effect.

49. In the Final Rule FDA provides staggered compliance periods for Newly Deemed Products that were introduced after February 15, 2007, and on the market on the effective date of the Final Rule (August 8, 2016), based on the type of submission. The compliance periods for submissions are 12, 18 and 24 months following the effective date of the Final Rule based on the type of submission: Substantial Equivalence Exemption Requests ("SE Exemption") will have to be filed in 12 months; SE Reports in 18 months; and premarket tobacco applications in 24 months. 81 Fed. Reg. 28977-78.

50. Additionally, those products for which timely premarket submissions are made will be granted an additional continued compliance period of 12 months to accommodate the time anticipated by the agency for FDA's reviews. If at the conclusion of the continued compliance periods, an applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period. *Id.* at 28978.

51. FDA's compliance period approach for Newly Deemed Products in the Final Rule is starkly different from the approach required for Originally Regulated Products in the TCA, and from the approach FDA set forth in its Proposed Rule. FDA proposed a compliance period similar to the compliance period prescribed by statute for the Originally Regulated Products. In the Proposed Rule, FDA proposed that newly regulated products introduced or modified during the period from February 15, 2007, through a date 24 months after the effective date of the final rule, could continue to remain on the market without enforcement, as long as they submitted timely SE Reports or pre-market approval applications for such products during that period.

52. Unlike the Originally Regulated Products that can be marketed until FDA finishes its ongoing reviews and issues substantial equivalence determinations, the marketing of Newly Deemed Products is subject to a finite period of time and is entirely dependent on FDA to timely review new submissions, something it has been unable to do for the past five years, as described below.

53. Regarding warning labels, FDA imposed format requirements on cigars without any basis. In particular, FDA relied on international standards and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA)—a statute that set forth requirements for

products other than cigars—to justify imposing warning label requirements for cigars of 30% on a product's two principal display panels and 20% in advertising. 81 Fed. Reg. 29065-66. While five of the six FDA required warning statements are the same as those required by the FTC Consent Decree, and FDA expressly credited the FTC Consent Decree in adopting those warning messages, nonetheless, FDA offered no rationale for changing the format requirements of the FTC Consent Decree, which apply specifically to cigars; instead, FDA noted only that the formatting requirements in the Final Rule are "similar to the requirements for smokeless products and similar to those suggested by FCTC [*i.e.*, the World Health Organization's Framework Convention on Tobacco Control, and the CSTHEA]." *Id.*

54. Regarding user fees, FDA imposed user fees on manufacturers of cigars and pipe tobacco, but not on manufacturers of e-cigarettes and other electronic nicotine delivery systems ("ENDS"). 81 Fed. Reg. 28707.[2]

55. Without disputing that the end result of its user fee regulations would be a class of "free riders" who would be regulated under the Act but pay no user fees, FDA justified its differential treatment by averring that the formula referenced in section 919 of the TCA precluded the assessment of "user fees" on classes of Newly Deemed Products not specifically identified in that section. *Id.* at 28709-10.

56. FDA added that even if it believed that it had discretion to assess user fees on all classes of regulated products, it would nevertheless exercise that discretion in favor of assessing user fees only on the subset of the regulated entities identified in the TCA for purposes of administrative convenience. *Id.* at 28712 (citing an "easy-to-implement system").

[2] The Final Rule referred to another Rule, published that same day, supplying regulations for the assessment of "user fees" on some classed of Newly Deemed Products. Plaintiffs' challenges to the Final Rule include and incorporate, to the extent necessary, challenges to these separately published "user fee" regulations.

57. Another example of FDA's unlawful regulatory approach is reflected in its treatment of IPCPR's Citizen Petition to the agency requesting an exemption for premium cigars. IPCPR submitted its Petition in August 2011, nearly three years before FDA published its Proposed Rule. FDA did not respond to that Petition until the day the agency published the Final Rule. In that Citizen Petition Response, FDA stated that it interpreted the Citizen Petition "to either request that FDA initiate a rulemaking as to which cigars, if any, should be deemed subject to [the Tobacco Control Act] or to initiate a rulemaking that would deem all cigars subject to [the Tobacco Control Act] except for traditional large and premium cigars." *See* May 5, 2016, Letter from Beverly Chernaik, Director Office of Regulations, Center for Tobacco Products to David B. Clissold, Hyman, Phelps & McNamara in Response to IPCPR's Citizen Petition dated August 24, 2011.

58. In fact, FDA did neither of the above. In its draft notice of proposed rulemaking, sent by FDA to the Office of Management and Budget ("OMB") for regulatory clearance, FDA planned to regulate cigars, premium cigars and anything else that fell within the scope of the definition of "tobacco product." After OMB reviewed the draft rule, "Option 2," exempting premium cigars, was added to the Proposed Rule. The Final Rule, however, reveals that FDA never seriously considered that or any other option other than full regulation—regardless of the burden placed on the regulated industry, which by FDA's own estimate consisted largely of small businesses such as IPCPR's members.

59. Regarding blended pipe tobacco products, the Final Rule prohibits the action of thousands of small tobacconists nationwide that blend and/or apportion finished tobacco products in bulk form in response to customer requests or retailers' choice. In particular, the Final Rule provides that any retailer who blends finished pipe tobacco is subject to regulation as

a manufacturer. 81 Fed. Reg. 29004, 29049. The Final Rule also could turn retailers into manufacturers by virtue of placing the blended pipe tobacco into a generic container for consumers. The same problem will be true for certain cigar retailers who take finished cigars and create "cigar samplers" of these finished cigars.

60. In determining that local retailers that blend finished pipe tobacco would be subject to regulation as manufacturers, FDA rejected – without explanation – suggestions from industry commenters that retailers blending up to either 3,000 pounds or 5,000 pounds of finished pipe tobacco per year be exempt from the requirements of the law that apply to manufacturers. As a result, the Final Rule threatens to eliminate these sales which make up a minute portion of the industry, but are important to numerous small tobacco shops.

61. FDA's approach to the regulation of pipe tobacco ignores the fact that bulk pipe tobacco is a finished product. The "blending" of pipe tobacco that FDA refers to essentially consists of placing two different types of bulk tobacco into a single bag and then placing the blend in a small generic container. In particular, bulk tobacco that is "blended" is itself a finished tobacco product that was produced by a regulated tobacco product manufacturer and was subjected to premarket review. FDA's Final Rule creates an unjustified cost to the many small businesses that engage in pipe tobacco blending. The blending of finished pipe tobacco does not chemically or physically alter the tobacco in any way, and the bulk tobacco is not a component or part necessary for the construction of a finished tobacco product because the pipe tobacco is itself a finished product.

62. Likewise, the FDA's position on pipes is arbitrary and capricious. The preamble to the Final Rule inexplicably suggests that FDA intends to treat pipes as "components" or "parts" of

tobacco products, and therefore subject to regulation, rather than as "accessories" that are exempt from regulation. 81 Fed. Reg. 29042; *see id.* at 28975.

63. Under FDA's definitions of "component or part" and "accessory," pipes would not be considered as "components" or "parts." In particular, "accessory" is defined, in relevant part, to mean "any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and . . . (1) [i]s not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product." 81 Fed. Reg. 29102. A "component" or "part," by contrast, is "any software or assembly of materials intended or reasonably expected: (1) [t]o alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) [t]o be used with or for the human consumption of a tobacco product," except that "[c]omponent or part excludes anything that is an accessory of a tobacco product." *Id.* at 29103. Under these definitions, a pipe is clearly an accessory because it is not made or derived from tobacco and does not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. It is simply a container from which pipe tobacco is consumed; it is not a component or part of the tobacco. Further, a pipe is not a "tobacco product" itself, as a pipe sold without tobacco is not "made or derived from tobacco" and, therefore, pipes should not be subject to FDA regulation.

E. FDA's Final Regulatory Impact Analysis

64. FDA published its Final Regulatory Analysis ("FRIA") in May 2016.

65. FDA's FRIA did not properly assess the costs and benefits of the Final Rule, in violation of the requirements of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. §§ 1501 *et seq.*) and the RFA (5 U.S.C. §§ 601 *et seq.*). In addition, the RFA requires the agency to prepare a

"regulatory flexibility analysis" detailing the effects of regulations on small businesses. 5 U.S.C. § 604. The RFA is particularly salient here, given FDA's admission that "approximately 90 percent of domestic entities affected by this rule are estimated to be small." FRIA at 133. Although FDA purported to have followed these requirements, its FRIA is defective because it does not contain valid "factual, policy and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives . . . which affect small entities was rejected." 5 U.S.C. § 604 (a)(6).

66. Moreover, FDA did not follow Executive Order 12866 guidance that sets forth cost/benefit considerations applicable to the Unfunded Mandates Reform Act and the RFA and advises that "[e]ach agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." It also requires that "[e]ach agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations." Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993). The agency did not show that the benefits of the regulation justify its costs.

67. Notwithstanding Plaintiff Associations' comments on its PRIA, FDA did not correct the defects in that analysis when it published the FRIA in May 2016. In particular, FDA failed to address CAA's concern that FDA did not quantify the benefits of the intended regulation and admitted it was "unable to quantify any possible unintended offsetting effects." FRIA at 21. Further, FDA admitted that "[r]eliable evidence on the impacts of warning labels, premarket

review, and marketing restrictions on users of cigars . . . does not, to our knowledge, exist." FRIA at 62. Finally, FDA admitted that it had not quantified the benefits of "regulatory alternatives" or how they "would differ from those of the final rule." FRIA at 127.

68. FDA likewise did not adequately respond to IPCPR's comments to the Proposed Rule expressing concern, based on FDA's preliminary economic impact analysis, that as a result of the costs imposed on manufacturers of premium cigars under Option 1, up to 50% of handmade cigars would cease to be marketed in the United States, and that small businesses would be most affected by Option 1, potentially forcing some companies out of business. Instead, FDA glossed over the significant burdens that regulation would impose on premium cigar manufacturers and small businesses, and merely lumped premium cigars in with all other tobacco products in an undifferentiated way.

69. Indeed, FDA's consideration of Option 2 consisted of a single paragraph in which FDA recognized that adopting this option would provide regulatory relief to small businesses. Nonetheless, FDA stated: "Because we do not know the number of manufacturers and importers of premium and non-premium cigars, we do not analyze these effects quantitatively." FRIA at 134. Here FDA's regulatory flexibility analysis amounts to no analysis at all, but instead represents a complete abdication of FDA's duty to fairly consider alternatives that would achieve regulatory goals with less impact on small business.

70. FDA did not adequately address IPCPR's concerns that unnecessary overregulation of premium cigars would have a devastating effect on manufacturers and retailers, particularly small businesses, or CRA's comment that the agency failed to consider the downstream impacts of the proposed regulations, not just on tobacco product manufacturers and importers, but also

distributors, retailers, suppliers, trade show proprietors, and workers that depend on the tobacco industry, again many whom are small businesses.

71. While FDA acknowledged that numerous comments addressed the effects of the Proposed Rule on the retail sector, its response was that "any retailers who meet the definition of manufacturer due to other activities, such as mixing e-liquids or blending pipe tobacco, are likely to cease engaging in manufacturing activities and convert to a pure retail model." FRIA at 48. Moreover, FDA states, because it is "unable to estimate the extent to which this final rule would lead to a reduction in the use of tobacco products, [the agency is] unable to estimate the extent to which retailers of newly deemed tobacco products may lose sales." FRIA at 49. FDA asserts that "[e]conomy-wide, retailers would not be harmed as consumers would switch to purchasing other goods." *Id.*

72. Similarly, FDA did not provide any appropriate response to CRA's comment regarding the "dramatic" economic impact on the industry, including small businesses that would result from regulating premium cigars. With regard to cigar or pipe tobacco markets that are characterized by a large number of products with slight variations or frequent changes to products, FDA agreed "that product exit is likely to occur" but stated without explanation that "much of this may occur as a result of consolidation of similar products within product lines instead of through exit by manufacturers." FRIA at 39.

73. With regard to the significant adverse effect of regulation on employment in newly regulated industries FDA's response was only that "total tobacco industry employment accounts for only a small proportion of total employment in the US economy" and that "[n]ewly deemed segments of the tobacco industry would only account for a portion of total tobacco industry employment; therefore, the affected segments of the tobacco industry would be extremely small

in the context of the US economy." FRIA at 48. Finally, FDA concluded that "[w]hile increases in costs and potential reductions in revenue could lead to some reduction in jobs in certain segments of the tobacco industry, employment is not expected to drop to zero in any segment of the tobacco industry." *Id.*

F. The Backlog at the FDA and its Implications

74. Since the initiation of premarket review submissions in 2011, FDA's backlog of pending SE Reports has consistently been over 3,500, virtually ensuring that submissions by manufacturers of Newly Deemed Products will not be processed before the passage of time renders the marketing of their products illegal. In fact, in the context of Originally Regulated Products, FDA-Track indicates that there are over 4,000 SE Reports (both provisional and regular) pending before the agency.[3] In FY 2015, FDA received 967 SE Reports.[4]

75. Because the number of active stock keeping units ("SKUs") for cigars is much greater than the number of SKUs for cigarettes, there is a reasonable expectation that the number of SE Reports will increase significantly based on cigar submissions alone. CAA's comments to the Proposed Rule estimated that at that time, the three leading premium cigar manufacturers had over 8,000 SKUs and the three leading mass-market cigar manufacturers had over 2,000 SKUS.

76. Significantly, the cigar industry expects submission of approximately 10,000 SE Reports within eighteen months of the Final Rule's effective date if the February 15, 2007 grandfather

[3] *See* http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&status=public&id=CTP-OS-regular-SE-reports&fy=2015; *see* http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=CTP-OS-provisional-SE-reports (last visited July 8, 2016).

[4] *See* http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=CTP-OS-total-product-submissions-received. (last visited July 8, 2016).

date is used. Certainly, the pipe tobacco industry will have a significant number of submissions as well.

77. Further, FDA is not receiving any additional funds to review this larger influx of SE Reports. Based on the current backlog and the expected number of additional SE Reports, there is no reason to believe that FDA will be able to review the submissions for Newly Deemed Products within the allotted timeframe, with the result that such products will be deemed to be "adulterated" under section 902 of the TCA, and prohibited from commercial distribution.

78. The difficulty in completing review of many thousands of reports within 12 months will be compounded by the manner in which FDA has implemented the required filing of data regarding Harmful and Potentially Harmful Constituents ("HPHCs") for Newly Deemed Products. FDA requires the inclusion of comparative HPHC data as a part of any SE Report. *See, e.g.* 81 Fed. Reg. 28995 (noting that "FDA generally expects that cigars with blending changes . . . will be able to successfully use the SE pathway as long as the blending change does not significantly raise levels of HPHCs in the product . . . ."). HPHC requirements for cigars currently do not exist, yet FDA has stated that Guidance will be released in "enough time for manufacturers to report given the 3-year compliance period for HPHC reporting." *Id.* at 28996. However, SE filings will be required no later than 18 months after the effective date; which is 18 months prior to HPHC reporting, which will not be required until 36 months after the effective date. *Id.*

79. Moreover, FDA is arbitrarily regulating the Newly Deemed Products differently from the Originally Regulated Products, the products Congress chose to regulate. FDA is permitting those products to remain on the market until FDA completes its review of each product's SE

Report. Many such products continue in commercial distribution during the lengthy pendency of premarket submissions under FDA's review.

80. In sum, FDA's Final Rule threatens to regulate cigars and other Newly Deemed Products unnecessarily and impermissibly by: (a) denying manufacturers the ability to establish "predicate" products for substantial equivalence review through the operation of a February 2007 predicate date; (b) ensuring, by virtue of FDA's existing and anticipated backlog, that any SE Reports that manufacturers are able to submit will not be acted on in time to avoid the expiration of FDA's stipulated twelve-month review period; and (c) denying manufacturers the benefit of provisions that allow the continued marketing of products with a timely submitted and pending SE Report until such time as FDA determines that a new product is not substantially equivalent to a predicate.

81. In addition, the cost of compliance and regulatory uncertainty will be too great a burden for many manufacturers, particularly the many small manufacturers of specialty or seasonal premium cigar products. Finally, the increased regulatory burden on small business retailers will undeniably force many out of business. FDA's response to these small businesses is that they "would be able to shift shelf space and other activities to non-tobacco products." FRIA at 119. FDA offers no suggestions as to what non-tobacco products a small business tobacco and cigar shop should sell.

CLAIMS FOR RELIEF

COUNT I
(Violation of Administrative Procedure Act: FDA's Actions Regarding the Predicate Date and the Substantial Equivalence Process Are Arbitrary, Capricious, an Abuse of Discretion and Not in Accordance With Law, and Exceed FDA's Regulatory Authority)

82. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

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

84. The APA proscribes agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The APA further bars agency action that is "in excess of statutory jurisdiction, authority, or limitations." *Id.* at § 706(2)(C).

85. In establishing the regulatory framework for the Originally Regulated Products, Congress set out a precise timeline for implementation of the premarket review provisions. It also provided FDA with the authority to "deem" other products to be subject to the TCA.

86. The Final Rule, promulgated seven years after the enactment of the TCA, does not apply the timeline crafted by Congress. Instead, the Final Rule arbitrarily deviates from the statutory scheme mandated by the statute.

87. FDA applies a February 15, 2007 grandfather date to all Newly Deemed Products, including cigars and pipe tobacco. FDA claimed it that it had no authority to change the February 2007 grandfather date.

88. As a result, the Final Rule requires cigar and pipe tobacco manufacturers to use products at least nine years old as predicate products, making it nearly impossible to compare new tobacco products to grandfathered predicates for the purpose of establishing substantial equivalence.

89. Application of a February 15, 2007 grandfather date impermissibly favors the Originally Regulated Products. In particular, the Originally Regulated Products had only to look back two and a half years for predicate tobacco products for substantial equivalence comparisons, whereas Newly Deemed Products have to look back nine years for such predicate products.

90. The Originally Regulated Products were permitted by statute to remain on the market until FDA completed its review of the substantial equivalence application. However, FDA is not

affording Newly Deemed Products the same consideration. Instead, Newly Deemed Products that have filed substantial equivalence applications, even when those applications have not yet been reviewed by FDA, are subject to removal from the market after twelve months.

91. The Final Rule for Newly Deemed Products renders it onerous, costly and time-consuming to establish substantial equivalence given the passage of time and the lack of available predicate products, and also provides for limited compliance periods for deemed products to achieve substantial equivalence determinations or be withdrawn from the market. *See Motor Vehicle Mfs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (holding "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'") (internal citations omitted).

92. The result is a regulatory regime that is contrary to the structure and purpose of the TCA in that cigars and other Newly Deemed Products face different regulatory hurdles not faced by the Originally Regulated Products under the TCA to protect the public health.

93. Even assuming the presence of predicate products, application of the TCA's premarket review provisions, together with the FDA's inability to timely review SE Reports for Newly Deemed Products, will result in the removal from the market of these products, notwithstanding timely submission of SE Reports; this will occur because of FDA's inability to review such reports timely, not misconduct of tobacco product manufacturers or product deficiencies.

94. FDA's imposition of a February 2007 grandfather date also has the effect of penalizing cigar and pipe tobacco manufacturers from being able to identify predicate products for purposes of establishing substantial equivalence because the passage of time effectively eliminated them. FDA has entirely failed to justify the harmful "secondary retroactivity" of its Final Rule against

any benefit to be derived from applying that grandfather date. *See National Cable & Telecomms. Ass'n v. FCC*, 567 F.3d 659, 670 (D.C. Cir. 2009) (agency action is arbitrary and capricious when the agency fails to "balance the harmful 'secondary retroactivity' of upsetting prior expectations or existing investments against the benefits of applying their rules to those preexisting interests.") (internal citation omitted).

95. Here, application of a February 2007 grandfather cut-off date, resulting in immediate restrictions on modification or introduction of products, and the threat of removing products from the marketplace before FDA has even reviewed a product application, is contrary to the structure, object, and policy of the TCA and yields results that Congress could not have intended and did not intend.

96. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

97. Plaintiffs have no adequate remedy at law.

98. FDA's "substantial equivalence" process—specifically including the imposition of a February 2007 grandfather cut-off date—has imposed ongoing harm on Plaintiffs.

99. This Court should accordingly set aside and declare unlawful FDA's Final Rule establishing a February 15, 2007 grandfather cut-off date for Newly Deemed Products that denies manufacturers of Newly Deemed Products the same protections for continued marketing that the statute affords to manufacturers of Originally Regulated Products.

COUNT II
(Violation of Administrative Procedure Act:
The Final Rule's User Fee Provisions are Arbitrary, Capricious, and Not in Accordance With the TCA, and Exceed FDA's Regulatory Authority)

100. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

101. Section 919 of the TCA provides that amounts paid by regulated entities should be in the form of "user fees." In employing the term "user fees" to describe the payments to be made by regulated entities, Congress intended that these payments would bear the hallmarks of user fees as opposed to taxes—*i.e.*, fees are predicated on a voluntary act by payers; persons who pay the fees receive a specific service or benefit; and payments are not meant for regulation of others or for general public benefit.

102. FDA's construction of the TCA requires manufacturers of certain classes of tobacco products (*e.g.*, cigars and pipe tobacco) to pay for costs associated with regulating competing products (*e.g.*, e-cigarettes) that are not subject to "user fees"—in effect, taxing one group of product manufacturers for the benefit of another. Such a construction is contrary to the statutory language that makes clear that regulated entities are to pay "user fees," not taxes.

103. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

104. Plaintiffs have no adequate remedy at law.

105. FDA's "user fee" provisions, which require cigar and pipe tobacco manufacturers to bear the cost of regulation for other classes of tobacco products such as e-cigarettes, impose ongoing harm on Plaintiffs.

106. This Court accordingly should set aside and declare unlawful FDA's Final Rule establishing user fees for Newly Deemed Products.

COUNT III
(Violation of the Fifth Amendment to the U.S. Constitution: The Final Rule's User Fee Provisions Violate Plaintiffs' Members' Right to Due Process and Equal Protection)

107. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

108. The Equal Protection Clause, applicable to the federal government through the Due Process Clause of the Fifth Amendment (*Bolling v. Sharpe*, 347 U.S. 497 (1954)), requires "a rough equality in tax treatment" and demands that inequalities be supported by a rational basis. *Allegheny Pittsburgh Coal Co. v. Cty. Comm'n of Webster Cty.*, 488 U.S. 336, 343-44 (1989); *see Armour v. City of Indianapolis*, 132 S. Ct. 2073, 2083 (2012).

109. FDA's user fee regulations effectively impose a tax not a user fee on cigar and pipe tobacco manufacturers to pay for regulation of other "deemed" products such as e-cigarettes, for which FDA has elected to assess no user fees.

110. FDA has not even attempted to identify a rational basis or justification for excluding e-cigarettes from user fees while placing the entire burden of regulating such products on competitors such as cigars and pipe tobacco manufacturers, and no such basis exists.

111. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

112. Plaintiffs have no adequate remedy at law.

113. FDA's "user fee" provisions, which require cigar and pipe tobacco manufacturers to bear the cost of regulation for other classes of tobacco products such as e-cigarettes, impose ongoing harm on Plaintiffs.

114. As a result, Plaintiffs are entitled to a declaration that FDA's Final Rule establishing user fees for Newly Deemed Products violates the Fifth Amendment to the U.S. Constitution and should be set aside. *See* 28 U.S.C. § 2201(a).

COUNT IV
(Violation of the Administrative Procedure Act:
FDA's Failure to Carry Out a Proper Cost-Benefit Analysis Violates the Regulatory Flexibility Act and Unfunded Mandates Reform Act of 1995)

115. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

116. Agency action is arbitrary and capricious when the agency has failed to "respond to 'relevant' and 'significant' public comments." *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (internal citation omitted).

117. The Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104-4, 109 Stat. 48 *et seq.*) and the Regulatory Flexibility Act (5 U.S.C. §§ 601 *et seq.*) require agencies examine the potential economic consequences of rulemaking. Presidential Executive Order 12866, which elaborates on those requirements, provides that "[e]ach agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993).

118. In light of FDA's admission in its PRIA that it was unable to carry out a realistic prospective analysis, and its statement that it would conduct a "retrospective review" (PRIA at 52), Plaintiff Associations submitted comments challenging FDA to justify the costs of the proposed regulation through a proper Regulatory Impact Analysis before imposing those costs. Plaintiffs also submitted comments taking issue with aspects of FDA's Preliminary Regulatory Impact Analysis including, in particular, the costs and adverse economic impacts of regulation and the failure to properly consider regulatory alternatives.

119. In the FRIA, FDA either ignored or failed to adequately address Plaintiffs' comments and failed to supply a reasoned determination that the benefits of the regulation justify its costs. In particular, FDA failed to quantify the benefits of the intended regulation and admitted it was "unable to quantify any possible unintended offsetting effects" (FRIA at 21); admitted that "[r]eliable evidence on the impacts of warning labels, premarket review, and marketing

restrictions on users of cigars … does not, to our knowledge, exist" (FRIA at 62); and admitted that it had not analyzed the costs and benefits of available regulatory alternatives. FRIA at 127.

120. Indeed, because the Final Rule creates more onerous conditions than the Proposed Rule, in particular in relationship to the premarket submission review process, FDA's failure to carry out a proper Regulatory Impact Analysis is even more acute. The Final Rule provides no justification for imposing the costs of essentially wiping out entire classes of products through the application of premarket review and substantial equivalence procedures that present insurmountable obstacles to regulatory approval.

121. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

122. Plaintiffs have no adequate remedy at law.

123. FDA's adoption of a Final Rule without a proper cost-benefit analysis has imposed ongoing harm on Plaintiffs.

124. This Court accordingly should declare unlawful FDA's Final Rule insofar as it establishes a regulatory regime for Newly Deemed Products without a proper cost-benefit analysis determining that the benefits of the Final Rule outweigh its costs, and compel FDA to undertake a proper cost-benefit analysis and defer enforcement of the Final Rule against Plaintiffs' members until such analysis is completed.

COUNT V
(Violation of the Administrative Procedure Act:
FDA's Treatment of Premium Cigars and Failure to Consider Option Two is Arbitrary and Capricious)

125. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

126. FDA's justification for subjecting premium cigars to the same regulatory regime as other tobacco products is "that 'deeming all cigars, rather than a subset, more completely protects the

public health.'" 81 Fed. Reg. 29020. Even assuming that FDA's conclusion on that point is correct, Congress did not intend for that factor alone to be the basis for FDA's regulatory decision. Rather, Congress intended for FDA to consider the congressional findings and purposes in determining how to appropriately regulate premium cigars to continue to permit the sale of premium cigars to adults. FDA did not, and its failure to do so is arbitrary and capricious.

127. FDA recognized that ninety percent (90%) of the entities affected by the Final Rule were small businesses. FRIA at 133.

128. FDA further recognized that under the approach taken in the Final Rule, up to half of handmade cigar products on the market would disappear from the U.S. market. FRIA at 22.

129. FDA also recognized that subjecting premium cigars to some—but not all—of FDA's regulatory authority would both dramatically reduce costs on small businesses and further FDA's public health interests. Specifically, in its PRIA, FDA admitted that by exempting premium cigars from the labeling and premarket application requirements, the cost to small businesses "would be dramatically reduced." PRIA at 57. In light of FDA's own conclusions, FDA's conclusory statement that "deeming all cigars, rather than a subset, more completely protects the public health " entirely failed to consider an important aspect of the problem, namely the massive costs of regulation and whether FDA could achieve its public health goals with a less burdensome regulatory regime. 81 Fed. Reg. 29020.

130. In addition, FDA utterly failed to address Plaintiffs' comments addressing regulatory options for premium cigars other than the "Option 1" approach, under which FDA acknowledges that up to half of handmade cigar products on the market today would disappear. FRIA at 22. FDA could have analyzed a regulatory alternative that exempted premium cigars from labeling

change and new product submission requirements, which would have dramatically reduced the costs on small business without significantly affecting public benefits, but FDA did not do so. Instead, FDA entirely failed to address the potential costs and benefits of the regulatory alternative that would have exempted premium cigars from regulation, admitting that it "d[id] not analyze these effects quantitatively." FRIA at 134.

131. FDA's treatment of premium cigars in the Final Rule is arbitrary and capricious and has caused immediate and ongoing harm to Plaintiffs.

132. The cumulative effect of the Final Rule, including but not limited to user fees, premarket approval, and warning labels will threaten the very existence of many of the small businesses affected by the Final Rule.

133. This Court accordingly should declare unlawful FDA's Final Rule with respect to premium cigars and compel FDA to undertake a proper analysis of regulation of premium cigars. This Court should vacate and set aside enforcement of the Final Rule as to premium cigars until FDA does so.

COUNT VI
(Violation of the Administrative Procedure Act:
The Final Rule's Warning Label Requirements are Arbitrary and Capricious)

134. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

135. "The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result." *Public Citizen, Inc.*, 988 F.2d at 197. 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).

136. FDA's Final Rule imposes warning label format requirements of 20% disclosure space for advertising and 30% disclosure space for the two principal display areas for product

packaging without considering the adequacy of the existing FTC Consent Decree format requirements that apply specifically to cigars.

137. There is no evidence in the administrative record that the FTC "clear and conspicuous" disclosure requirements in the FTC Consent Decree are in any manner inadequate to protect the governmental interests advanced by the Final Rule.

138. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

139. Plaintiffs have no adequate remedy at law.

140. FDA's Final Rule containing warning label requirements in excess of the FTC Consent Decree has imposed ongoing harm on Plaintiffs.

141. This Court accordingly should set aside and declare unlawful the warning label requirements for cigars contained in FDA's Final Rule.

COUNT VII
(Violation of the First Amendment to the U.S. Constitution:
The Final Rule's Warning Label Requirements Impermissibly Restrict Free Speech)

142. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

143. Under the First Amendment, the burden is on FDA to show that its warning label and advertising disclosure requirements are supported by a "substantial governmental interest" and that the requirements achieve that interest "through the least restrictive available means." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985).

144. FDA has not met and cannot meet its burden of showing that its disclosure requirements are the "least restrictive available means" to achieve a legitimate governmental interest in disclosure.

145. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

146. Plaintiffs have no adequate remedy at law.

147. FDA's Final Rule containing warning label requirements has imposed ongoing harm on Plaintiffs.

148. As a result, Plaintiffs are entitled to a declaration that FDA's Final Rule establishing warning label requirements for cigars violates the First Amendment to the U.S. Constitution and should be set aside. *See* 28 U.S.C. § 2201(a).

COUNT VIII
(Violation of Administrative Procedure Act: Regulation of Tobacconists Who Blend or Apportion Finished Pipe Tobacco or Create "Cigar Samplers" as "Manufacturers" is Arbitrary, Capricious, and Not in Accordance With the TCA, and Exceeds FDA's Regulatory Authority)

149. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

150. The Final Rule deeming retailers who blend and/or apportion finished pipe tobacco in bulk form, or who create "cigar samplers" of finished cigars, to be "manufacturers," and subjecting them to the full range of regulations applicable to manufacturers of cigarettes and other tobacco products, has no basis in law, and threatens small businesses across the nation without adequate justification.

151. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

152. Plaintiffs have no adequate remedy at law.

153. FDA's Final Rule deeming retailers who blend and/or apportion finished pipe tobacco products, or who create "cigar samplers" of finished cigars, to be "manufacturers" subject to full regulation has imposed ongoing harm on Plaintiffs.

154. This Court accordingly should set aside and declare unlawful FDA's determination that retailers who blend and/or apportion finished pipe tobacco, or who create "cigar samplers" of finished cigars, are manufacturers subject to the requirements of the FD&C Act.

COUNT IX
(Violation of Administrative Procedure Act:
Regulation of Pipes as "Components" Rather Than as "Accessories" is Arbitrary, Capricious, and Not in Accordance With Law)

155. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

156. The Final Rule decreeing that pipes will be considered "components" or "parts" of tobacco products subject to regulation, as opposed to "accessories" not subject to regulation, contravenes FDA's own definitions as well as common sense and historical practice.

157. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

158. Plaintiffs have no adequate remedy at law.

159. FDA's Final Rule decreeing that pipes will be regulated as "components" or "parts" of tobacco products has imposed ongoing harm on Plaintiffs.

160. This Court accordingly should set aside and declare unlawful FDA's determination that pipes are "components" or "parts" of tobacco products.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court enter judgment in its favor and:

a. Vacate and set aside the Final Rule under 5 U.S.C. § 706 as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and in excess of FDA's authority, all in violation of the APA, because: (i) it applies a grandfather date of February 15, 2007 for substantial equivalence review to Newly Deemed Products that is inconsistent with the structure and purpose of the TCA, thus denying manufacturers of

such products a reasonable opportunity for the predicates necessary to make a substantial equivalence showing; and (ii) it denies Newly Deemed Products the benefit of statutory protection for continued marketing, unless and until the issuance of a not substantially equivalent order by FDA.

b. Vacate and set aside the Final Rule under 5 U.S.C. § 706 as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and in excess of FDA's authority, all in violation of the APA, because it imposes "user fees" on certain classes of Newly Deemed Products but not others.

c. Declare that the Final Rule imposing "user fees" on some classes of Newly Deemed Products but not others violates the Fifth Amendment to the U.S. Constitution.

d. Declare the Final Rule unlawful under 5 U.S.C. § 706 as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and in excess of FDA's authority, all in violation of the APA, insofar as it lacks the support of a proper cost-benefit analysis, and compel FDA to undertake a proper cost-benefit analysis and defer enforcement of the Final Rule against small entities until such analysis is completed.

e. Vacate and set aside the Final Rule under 5 U.S.C. § 706 as arbitrary and capricious, and not in accordance with law, and in excess of FDA's authority, all in violation of the APA, for imposing warning label format requirements on cigars in excess of the FTC Consent Decree's requirements without justification for the additional requirements.

f. Declare that the Final Rule imposing warning label format requirements on cigars in excess of those contained in FTC Consent Decree violates the First Amendment to the U.S. Constitution.

g. Vacate and set aside the Final Rule under 5 U.S.C. § 706 as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and in excess of FDA's authority, all in violation of the APA, because it treats retailers who blend and/or apportion finished tobacco products, or who create "cigar samplers" of finished cigars, as "manufacturers" subject to full regulation as such.

h. Vacate and set aside the Final Rule under 5 U.S.C. § 706 as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and in excess of FDA's authority, all in violation of the APA, because it decrees that pipes are to be regulated as "components" or "parts" of tobacco products instead of "accessories" which are not subject to regulation.

i. Enter a permanent injunction restraining Defendants from implementing or enforcing the Final Rule in violation of the APA and the Constitution, as set forth above.

j. Award Plaintiffs their litigation costs and reasonable attorneys' fees; and

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

Dated: July 15, 2016

Respectfully submitted,

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