UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

SWISHER INTERNATIONAL, INC.,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

JANET WOODCOCK, in her official capacity as Acting Commissioner of Food and Drugs,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,

Defendants.

Civil Action No. _____

Preliminary Injunctive Relief Requested

COMPLAINT

Plaintiff Swisher International, Inc. alleges as follows:

I. Introduction

1. The Food and Drug Administration ("FDA") is on the brink of destroying a historic American company headquartered in Jacksonville. On September 9, unless this Court intervenes, Plaintiff Swisher International, Inc. will be forced to remove all of its cigar products from retail shelves across the country, indefinitely, or risk massive civil and criminal penalties. The harm will be swift and irreparable, with

devastating consequences for Swisher and its nearly 3,000 workers in the United States and the Dominican Republic.

2. The cause of this imminent disaster originates in 2016, when the FDA adopted the "Deeming Rule" that purportedly subjected all of Swisher's cigars to the requirements of the Tobacco Control Act ("TCA" or "the Act"). When that law was enacted in 2009, Congress excluded cigars from its ambit, providing that it applied only to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). But in the "Deeming Provision," Congress purported to delegate to the FDA the unlimited discretion to "deem[]" other tobacco products to be subject to the Act. *See id.*

3. The Deeming Rule created a predictable crisis: thousands of cigars, and millions of other tobacco products that were *already* on the market became subject to the illogically named "premarket review" requirements in the TCA. Unless cigar companies obtained FDA orders authorizing them to sell their products, the products would be illegal overnight. To address this problem, the FDA repeatedly promised that it would *not* force newly deemed products off the shelf, representing that it would defer enforcement until manufacturers had a meaningful opportunity to make it through the FDA's labyrinth of "substantial equivalence reports" and "premarket review tobacco applications."

4. Over the next several years, Swisher relied on the FDA's repeated promises that it would have a meaningful opportunity for its cigars to make it through premarket review before they could become subject to any enforcement action. Swisher

dutifully complied with the FDA's instructions, met the FDA's deadlines, and spent millions of dollars on its own initiative filling in the gaps of the FDA's opaque application process.

5. Despite Swisher's best efforts, the FDA is unable (or unwilling) to do its job under the TCA and take final action on Swisher's requests for premarket review of 171 of its cigar products—virtually the company's entire cigar portfolio, representing the vast majority of its revenue. Despite Swisher's efforts to seek action, the FDA continues to sit on Swisher's requests, and is now explicitly threatening to bring enforcement actions against Swisher and other companies for selling products that are stuck in this regulatory quagmire of the FDA's own creation.

6. As alleged in greater detail below and set forth in Swisher's contemporaneously filed motion for an emergency preliminary injunction, the FDA's conduct is unlawful for a number of independent reasons.

7. *First*, the TCA's Deeming Provision—the FDA's sole basis for the Deeming Rule—is an unconstitutional delegation of legislative power to the Executive Branch. Because the Deeming Rule is the product of an unconstitutional delegation, the Deeming Rule is also invalid. And the Rule, promulgated by a lone FDA employee, was issued in violation of the Appointments Clause.

8. *Second*, even if the Deeming Provision is constitutional, the Deeming Rule exceeds the FDA's statutory authority by purporting to overrule Congress's express decision *not* to regulate all tobacco products. The Deeming Rule also violates the substantive and procedural requirements of the Administrative Procedure Act

("APA") in multiple ways, including the FDA's failure to recognize and grapple with the crisis that it was about to create by subjecting millions of existing tobacco products to the Act's requirements for "premarket" review, which is an oxymoron as applied to newly deemed products. Since the Deeming Rule itself is unlawful, the FDA should be enjoined from enforcing the TCA against Swisher's cigars.

9. *Third*, the FDA is unlawfully and unreasonably withholding final agency action that it is required to take. Specifically, the FDA has failed to act in a timely manner on Swisher's pending substantial-equivalence reports, contrary to due process, the APA, and the TCA itself. Moreover, the FDA's failure to act coupled with its explicit threat of enforcement operates in practical effect as a de facto ban on Swisher's cigars. The Act does not allow the FDA to ban entire categories of tobacco products such as cigars, and the FDA may not avoid that statutory limitation by simply refusing to act on requests for premarket review.

10. *Fourth*, even setting all that aside, the FDA's threatened enforcement would still be unlawful under the Due Process Clause and the fundamental requirement of fair notice. Swisher lacked fair notice that its cigars would be forced off the market even if Swisher complied with the FDA's deadlines and instructions. The FDA expressly promised that cigar companies such as Swisher would have a chance to successfully complete the approval process *before* any enforcement action would occur, and then did a 180. The FDA may not now punish Swisher for taking the government at its word.

11. For these reasons and more, this Court should vacate the Deeming Rule and/or enter declaratory and injunctive relief barring the FDA and the other Defendants from enforcing the TCA against Swisher's cigars.

12. In the meantime, the Court should preserve the status quo, save Swisher and its employees from imminent and irreparable disaster, and preliminarily enjoin the FDA and other Defendants from enforcing the TCA against Swisher's cigars for the duration of this lawsuit.

II. Parties

13. Plaintiff Swisher International, Inc. is a Delaware corporation headquartered in Jacksonville, Florida. As of the date of this filing, Swisher employs nearly 1,000 people inside the United States. Swisher's manufacturing affiliate, Swisher Dominicana, Inc., employs more than 2,000 people in the Dominican Republic.

14. Defendant U.S. Department of Health and Human Services ("HHS") is an executive department of the United States.

15. Defendant Xavier Becerra is the Secretary of HHS and the official charged by statute with administering the TCA, including the Act's premarket-review provisions. *See* 21 U.S.C. §§ 387a, 387j. Secretary Becerra is named in his official capacity only.

16. Defendant FDA is an agency within HHS.

17. Defendant Janet Woodcock is the Acting Commissioner of Food and Drugs. She has been delegated authority to administer the TCA by the Secretary of HHS. *See* 2016 FDA Staff Manual Guide § 1410.10(1)(A)(1) (Aug. 26, 2016),

https://bit.ly/2KGT7Ts. Acting Commissioner Woodcock is named in her official capacity only.

III. Jurisdiction and Venue

18. This action arises under the U.S. Constitution, the APA, 5 U.S.C. §§ 500 *et seq.*, the TCA, 21 U.S.C. §§ 387 *et seq.*, and FDA rules and regulations.

19. This Court therefore has jurisdiction under 28 U.S.C. § 1331.

20. Swisher has standing to bring this suit.

21. Venue is proper in this district under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States, Swisher resides in this judicial district, and no real property is involved in this action.

IV. Background

A. The TCA

22. In 2009, the TCA amended the Food, Drug, and Cosmetic Act, granting the FDA authority to regulate tobacco products that fall within the statute's ambit. 21 U.S.C. § 387a(a).

23. Initially, the Act applied only to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). Congress did not decide whether to regulate other kinds of tobacco products, such as cigars.

24. Instead, Congress purported to delegate that authority to the Secretary of HHS, granting him complete authority to "deem[]" "any other tobacco products" subject to the Act's requirements by regulation. *Id.*

25. The Secretary redelegated that authority to the FDA, and the FDA, in turn, conferred it upon a career employee. *See* 2016 FDA Staff Manual Guide §§ 1410.10(1)(A)(1), 1410.21(1)(G)(1), https://bit.ly/2KGT7Ts (Aug. 26, 2016).

26. The TCA places no limits *at all*—much less intelligible ones—on the FDA's discretion to decide whether to "deem" tobacco products to be subject to the Act, which products to deem, or when to deem them.

27. Congress did, however, impose explicit limits on the kinds of restrictions that the FDA may impose on tobacco products covered by the Act, whether originally subjected to the Act by Congress or "deemed" to be subject to the Act by the FDA.

28. Among other things, the Act prohibits the FDA from banning tobacco products. Specifically, the Act authorizes the FDA to "require restrictions on the sale and distribution of a tobacco product," but imposes "[l]imitations" that make clear that the FDA may not ban tobacco products outright. 21 U.S.C. § 387f(d)(1), (3). The Act also specifically provides that the FDA may not "ban[] all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products." *Id.* § 387g(d)(3); *see also* H.R. Rep. No. 111–58, pt. 1, at 2 (2009).

B. The premarket-review process for new tobacco products

29. A central piece of the TCA's regulatory framework—and one of the most burdensome requirements for regulated parties and their products—is the premarket-review process for a "new tobacco product."

30. The FDA has expansively interpreted the term "new tobacco product." According to the FDA, any post–February 2007 change to a tobacco product is a modification that renders it a new tobacco product—even a change "so minor that it is not even capable of being quantified in the finished product." *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)*, FDA, at 16 (Dec. 2016), https://bit.ly/2IxH3RE.

31. As a result, many tobacco products that have been on the market for decades are considered by the FDA to be "new tobacco products." For example, Swisher's flagship Swisher Sweets, which have been on the market since 1958, are considered by the FDA to be "new tobacco products."

32. A new tobacco product that is marketed without FDA authorization is considered "adulterated" or "misbranded." 21 U.S.C. §§ 387b(6), 387c(a)(6). Marketing adulterated or misbranded products may lead to FDA enforcement actions, including the seizure of offending products, *id.* § 334, injunctions against manufacturers, distributors, and retailers, *id.* § 332, and criminal prosecution, *id.* §§ 331(a)–(c), 333(a), 335.

33. The Act's premarket-review provisions contemplate two main pathways that a manufacturer must follow before it may introduce a new tobacco product to the market.

34. *First*, the Act provides for a streamlined process pursuant to which a manufacturer may submit a substantial-equivalence "report" under Section 387e(j) demonstrating that a product is "substantially equivalent" to a "predicate tobacco product"—

meaning a product that was on the market prior to February 21, 2007. *See* 21 U.S.C. §§ 387e(j), 387j(a)(3). After a manufacturer files a substantial-equivalence report, the FDA must issue an order concluding that the product is (or is not) substantially equivalent to a predicate product. *Id.* § 387j(a)(2)(A)(i), (B)(ii). A manufacturer need not file a substantial-equivalence report when only "minor" modifications of "tobacco additive[s]" are at issue. *Id.* § 387e(j)(3). As noted above, however, the FDA has broadly construed the term "modify" to cover changes that cannot be quantified in the finished product.

35. *Second*, the Act provides for a more burdensome process for manufacturers to obtain authorization for a new tobacco product that is not substantially equivalent to any existing product. Under this pathway, manufacturers must submit a premarket-tobacco-product application (referred to by the FDA as a "PMTA"). A PMTA must establish that marketing the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). This pathway is required for products that differ substantially from tobacco products that were on the market as of February 15, 2007.

36. For premarket-tobacco-product applications, the Act expressly requires the FDA to issue an order allowing a product to be introduced into interstate commerce (or forbidding a product from being introduced) "[a]s promptly as possible, but in no event later than 180 days" after the manufacturer files an application. 21 U.S.C. § 387j(c)(1).

37. Thus, Congress plainly contemplated that the FDA would be able to complete even the most complex and time-consuming requests for premarket review

in a matter of months, and that the FDA would never withhold a decision for more than 180 days.

38. Congress also recognized that the Act's premarket-review requirements had the potential to cause significant market disruption if the FDA sought to apply them to tobacco products that were already on the market *before* manufacturers became required to seek the FDA's pre-approval. For example, when the statute was enacted in 2009, many existing cigarette and smokeless tobacco products qualified as "new tobacco products" because they had been modified (even if only in small ways) since February 2007. Immediately imposing premarket-review requirements on those products would have had the effect of banning them from the market until manufacturers could submit substantial-equivalence reports and get approval orders from the FDA. Because the FDA had not yet told manufacturers what to include in substantial-equivalence reports, that process would take years.

39. To avoid that disruption, the TCA provided that originally regulated products could remain on the market for 21 months after enactment (in March 2011), and indefinitely thereafter so long as manufacturers submitted timely substantial-equivalence reports and the FDA had not issued a final order determining that the products were *not* substantially equivalent to a predicate product. 21 U.S.C. § 387j(a)(2)(B)(i).

C. The initial round of substantial-equivalence reports for products that Congress subjected to the Act

40. When the TCA was enacted, the vast majority of the products that Congress subjected to its requirements—cigarettes, smokeless tobacco, and roll-your-own tobacco—were eligible for the substantial-equivalence pathway because similar products were on the market on February 15, 2007. But tobacco manufacturers did not know what information to include in their substantial-equivalence reports.

41. That is because the TCA says little about what information a substantial-equivalence report must include. Instead, the Act provides that the FDA "shall prescribe" the "form and manner" for regulated parties to submit substantial-equivalence reports. 21 U.S.C. § 387e(j)(1).

42. Yet the FDA waited until January 2011—two months before the statutory deadline for submitting substantial-equivalence reports—to issue a guidance document establishing even the baseline requirements. *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* ("January 2011 Guidance"), FDA (Jan. 5, 2011), https://bit.ly/2XQ2Qub.

43. Although that guidance document was short on details (the relevant portion was only six pages long), it made clear that substantial-equivalence reports require significant time and resources to prepare. Among other things, a manufacturer must: (1) include detailed lists of all design features, ingredients, and materials for the new and predicate products; (2) conduct laboratory testing to measure levels of harmful and

potentially harmful constituents ("HPHC") in the new and predicate products; (3) prepare an environmental assessment in accordance with the National Environmental Policy Act; and (4) provide clinical data if deemed necessary by FDA. *See* January 2011 Guidance at 7–13.

44. The FDA recognized that its bare-bones guidance did not provide sufficient information for manufacturers to submit high-quality reports. The agency pledged to "initiate a rulemaking that would establish requirements and standards for" such reports. January 2011 Guidance at 1–2. But manufacturers could not afford to wait. With the March 2011 statutory deadline fast approaching, manufacturers had to prepare reports based on their best estimations of the information and product-testing methods that the FDA would consider acceptable.

45. The result was a disaster. By March 2011, the FDA had received about 3,600 substantial-equivalence reports that, unsurprisingly, did not contain much of the information that the FDA later realized it wanted in order to make substantial-equivalence determinations. *See FDA Update on Provisional Substantial Equivalence (SE) Review Process*, FDA (Apr. 5, 2018), https://bit.ly/2wVvFJI. As a result, the FDA and manufacturers had to engage in an iterative information-gathering process over the course of many years. That process proved time-consuming and highly inefficient for both the FDA and manufacturers—so much so that, as of April 2018, the FDA had been able to issue final substantial-equivalence or non-substantial-equivalence orders for just 191 of the 3,600 reports. *Id.*

46. Swisher experienced this regulatory slog firsthand with its smokeless tobacco products. For example, Swisher submitted substantial-equivalence reports for two of its moist snuff products on March 2011. The FDA waited until August 2011 to even acknowledge receipt of the reports. After that, the FDA requested further information from Swisher five times—in April 2013, September 2013, August 2015, April 2016, and May 2017. The FDA finally issued orders approving the reports on April 30, 2018—*seven years* after Swisher submitted them. One of Swisher's 2011 reports remains pending to this day.

D. The Deeming Rule

47. As discussed, the TCA did not grant the FDA authority to regulate cigars. That was for good reason: One of the fundamental purposes of the Act was to curb "the use of tobacco by young people," Pub. L. No. 111-31 § 3, 123 Stat. 1776, 1781 (2009), and youth cigar-smoking rates have dramatically *decreased* over the past 20 years, *see, e.g.*, *Trends in the Prevalence of Tobacco Use National YRBS: 1991–2019*, Ctrs. For Disease Control and Prevention (Aug. 20, 2020), https://bit.ly/3ro9N5f (noting that high school user rates for cigars in 2019 were only a quarter of 1997 rates). In fact, when the FDA previously sought to regulate tobacco products in the 1990s, it decided to exclude cigars because "there is insufficient evidence of cigar … use by children and adolescents to support the inclusion of cigar[s] … within the scope of the final rule." 61 Fed. Reg. 44,396, 44,422–23 (Aug. 28, 1996). Again, youth use of cigars has declined dramatically since then.

48. Youth use of flavored cigars—another line of Swisher's products now deemed by the FDA to be subject to the Act—has similarly declined in recent years, as the FDA's own analysis reveals. *See* Karen A. Cullen et al., *Flavored Tobacco Product Use Among Middle and High School Students — United States, 2014–2018*, 68 Morbidity & Mortality Weekly Report 839, 840, 842 (2019) (showing significant declines in high school and middle school use of flavored cigars between 2014 and 2018); *see also* H. Dai, *Changes in Flavored Tobacco Product Use Among Current Youth Tobacco Users in the United States, 2014–2017*, JAMA Pediatrics (Jan. 7, 2019) (12 percent decline in youth use of flavored cigars between 2014 and 2016).

49. In 2016, however, the FDA promulgated the Deeming Rule and purported to indiscriminately subject *all* tobacco products to the TCA's requirements, including its premarket-review provisions. *See* 81 Fed. Reg. 28,974, 29,106 (May 10, 2016).

50. That decision flouted Congress's express determination *not* to apply the Act to all tobacco products.

51. The FDA believed that it had unlimited discretion to deem any (or all) tobacco products to be subject to the Act's requirements, boasting that it "is not required to meet a particular public health standard to deem tobacco products," and that the "only pertinent limitations on the scope of FDA's deeming authority are . . . definition[al]." 81 Fed. Reg. at 28,983.

52. The Deeming Rule was issued and signed by Leslie Kux, then the FDA's Associate Commissioner for Policy. 81 Fed. Reg. at 29,106. Despite the use of the

term "Commissioner," which is typically reserved for federal officers appointed by the President and confirmed by the Senate, the Associate Commissioner for Policy is actually a career FDA post.

53. In that role, Ms. Kux had been delegated broad authority by the FDA Commissioner to "issu[e] . . . proposed and final regulations of the Food and Drug Administration." 2016 FDA Staff Manual Guide § 1410.21(1)(G)(1). During her tenure at the FDA, Ms. Kux exercised her rulemaking authority to issue 385 regulations, including the Deeming Rule. *See* Angela C. Erickson & Thomas Berry, *But Who Rules the Rulemakers? A Study of Illegally Issued Regulations at HHS*, Pac. Legal Found. 25 & n. 18 (Table 1) (Apr. 29, 2019).

54. Then-FDA Commissioner Robert Califf issued a memorandum in September 2015 purporting to ratify actions taken by subordinates in the FDA in a single sentence. The attempted ratification did not go through the notice-and-comment process, nor did it purport to explain Commissioner Califf's reasons (if any) for ratifying the Deeming Rule.

55. Then-FDA Commissioner Scott Gottlieb separately purported to ratify the Deeming Rule in a one-paragraph statement in April 2019. This latest attempted ratification did not go through the notice-and-comment process either. Moreover, Commissioner Gottlieb's attempted ratification was contrary to the evidence before the agency at the time. In addition, Commissioner Gottlieb's attempted ratification failed to provide a reasoned explanation for his decision to ratify the Deeming Rule.

E. The Deeming Rule's impact on newly deemed products and the FDA's promises to manufacturers such as Swisher

56. The Deeming Rule threatened to force manufacturers of cigars and other newly deemed products to take millions of existing "new tobacco products," including thousands of cigars and millions of vaping products, off the market until manufacturers could submit substantial-equivalence reports or premarket-tobacco-product applications and then obtain FDA approval prior to enforcement.

57. Although the FDA had by this time specified in greater detail the requirements for substantial-equivalence reports for products such as cigarettes and smokeless tobacco, the agency had not yet articulated what information manufacturers would be required to include in substantial-equivalence reports for cigars and the other newly deemed products. The Deeming Rule itself said only that the FDA was "finalizing other guidance documents, regarding the evidence needed for SE reports" for the newly deemed products. 81 Fed. Reg. at 29,000–01; *see also id.* at 29,004, 29,012–13.

58. To avoid dealing with these problems, the FDA established a "compliance policy." Specifically, the FDA set forth timetables for manufacturers of newly deemed tobacco products to submit and obtain approval of substantial-equivalence reports and premarket-tobacco-product applications. 81 Fed. Reg. at 28,978.

59. For substantial-equivalence reports, the FDA told manufacturers that they would have until February 8, 2018—18 months from the Deeming Rule's effective date—to file reports, as well as another 12 months upon the timely filing of a re-

port, before the FDA would initiate any enforcement actions "for th[ose] products remaining on the market without FDA authorization." *Id.* The FDA apparently (but irrationally) believed that the compliance policy would give the agency time to finally establish its regulatory framework for substantial-equivalence reports and provide manufacturers with "sufficient time . . . to prepare high quality applications" that complied with the agency's yet-to-be-established requirements. *Id.* at 29,012. The FDA's timelines made little sense, given that the agency still had not finished its guidance concerning what should be included in substantial-equivalence reports for products such as cigars, and the FDA's prior experience with the originally regulated products showed that the FDA was incapable of getting through substantial-equivalence reports and PMTAs that quickly.

60. The FDA's compliance policy was fundamental to the rationality of the Deeming Rule. The FDA assumed that it would be able to review all substantial-equivalence reports for newly deemed products in just 12 months once manufacturers submitted them, and that the Deeming Rule would not force any products to be removed from the market simply because the FDA had not yet acted on timely filed reports. In addition, the compliance policy allowed the FDA to assure manufacturers, in accordance with the FDA's lack of statutory authority to ban tobacco products, that their products would not "be forced to be removed from the market" until they were "able to apply for premarket authorization." 81 Fed. Reg. at 28,993.

61. The FDA repeated this promise to manufacturers throughout the Deeming Rule, including in response to commenters who raised alarms about the massive

economic disruptions that would result from the FDA's decision to deem all tobacco products to be subject to the Act. Below are just a few examples:

- "FDA disagrees with comments stating that all newly deemed products will be forced to be removed from the market as . . . any that are not grandfathered will be able to apply for premarket authorization." 81 Fed. Reg. at 28,993.

- "As a result of FDA's compliance policy, we expect that many manufacturers will keep their products on the market beyond the effective date of this final rule." *Id.* at 28,977.

- "FDA's revised compliance policy for premarket review—resulting in products remaining on the market while manufacturers seek review . . . will . . . encourage high-quality premarket submissions from applicants." *Id.* at 28,978.

- "FDA is providing a compliance policy that will provide additional time for manufacturers of newly deemed products to comply with certain requirements, and which will reduce the burdens on manufacturers as they become regulated by FDA for the first time." *Id.* at 29,025.

62. History then began to repeat itself—the compliance policy did not give the FDA enough time to complete the regulatory framework for newly deemed products and, in particular, to promulgate its long-promised rule governing the content of substantial-equivalence reports.

63. As a result, the FDA twice extended the deadlines to give itself more time. In doing so, the FDA continued to promise manufacturers that it would not force them to remove their products from the market without providing them a meaningful opportunity to obtain premarket authorization, so long as they filed timely reports pursuant to the FDA's extended deadlines.

64. Ultimately, in August 2017, the FDA issued guidance announcing that it was extending the deadline for substantial-equivalence reports for cigars and other combustible tobacco products to August 8, 2021, and that it was further allowing manufacturers who timely filed substantial-equivalence reports to keep their products on the market indefinitely pending the FDA's decisions on the reports, as Congress had provided for the originally regulated products that were faced with a similar dilemma back in 2011. *See Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability*, FDA, at 3–4 (Aug. 2017), https://bit.ly/3eKjk1k.

F. The FDA's failure to provide sufficient guidance to manufacturers concerning the information required in substantial-equivalence reports

65. Throughout this period, the FDA acknowledged over and over that foundational guidance for premarket reports was still necessary. *See, e.g.*, Scott Gottlieb, Address at National Press Club, at 33:08–20 (Nov. 3, 2017), https://cs.pn/2WsYPPD; *Advancing Tobacco Regulation to Protect Children and Families*, FDA (Aug. 2, 2018), https://bit.ly/2XxxkB8; Defs.' Mot. to Dismiss at 2, *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-00883 (D. Md. Aug. 7, 2018), ECF No. 36-1.

66. In fact, the absence of a coherent process for manufacturers to submit and the FDA to review substantial-equivalence reports for newly deemed products was one of the reasons for the extended compliance periods.

67. The FDA did not publish a proposed rule "to establish requirements for the content and format of reports intended to establish the substantial equivalence of

a tobacco product (SE Reports)" until April 2019. 84 Fed. Reg. 12,740, 12,740 (Apr. 2, 2019). As the FDA explained: "The proposed rule would establish the information an SE Report must include so that FDA may make a substantial equivalence determination." *Id.*

68. The proposed rule gave manufacturers some guidance concerning what needed to be in their substantial-equivalence reports in advance of the submission deadline (that is, if one assumed the final rule would substantially mirror the proposed rule, notwithstanding the many questions and concerns raised by the industry in the comment period). But the proposed rule left open basic questions about the content of substantial-equivalence reports for cigars.

69. For example, the FDA's proposed rule says that substantial-equivalence reports must include the quantities of HPHCs (harmful and potentially harmful constituents) for new and predicate tobacco products. *See* 84 Fed. Reg. at 12,763–64. The FDA defines HPHCs as chemicals or chemical compounds in tobacco products or tobacco smoke that could cause harm to smokers or nonsmokers. *See id.* at 12,747. Identifying and quantifying HPHCs requires expensive laboratory testing, and it is difficult for manufacturers to know what to test for in advance.

70. But the FDA did not fulfill its statutory obligation to specify which HPHCs must be tested in cigars, 21 U.S.C. § 387d(e), as the agency has done for originally regulated products such as cigarettes, *see Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal*

Food, Drug, and Cosmetic Act ("HPHC Guidance"), FDA (Mar. 2012), https://bit.ly/2EPMQRp.

71. Nor has the FDA identified the methodologies that it wishes manufacturers to use when testing for HPHCs in cigars. And it is far from clear how the FDA expected that testing should be done. Standard cigarette-smoke testing machines, which replicate the act of smoking and include assumptions about the number of puffs and duration of each puff, do not yield accurate results for cigars, especially for large machine-made and hand-rolled cigars. Moreover, because the tobacco in cigars can vary substantially even among cigars within the same package, it is difficult to achieve the replication of testing results necessary for FDA-compliant HPHC testing. *See* HPHC Guidance at 9 (HPHC testing protocol must "measure HPHCs" in a manner that "provides reproducible results based on multiple measurements").

72. As another example, the FDA has not finalized the design parameters that cigar manufacturers must include in substantial-equivalence reports. The FDA's proposed rule on the content of substantial-equivalence reports says that the reports must include "a side-by-side comparison of each design parameter of the new and predicate tobacco products." 84 Fed. Reg. at 12,759. The proposed rule provides detailed lists of "the required design parameter information" for cigarettes, smokeless tobacco products, and the various components of roll-your-own tobacco products. *Id.* at 12,759–62. But for cigars, the FDA merely "invites comments and information on the parameters that may be needed to support an SE Report" without making *any* proposal. *Id.* at 12,762.

73. The FDA released a final rule on January 19, 2020, but then withdrew the final rule one day later. As of August 4, 2021, there *still* is no final rule establishing the requirements for substantial-equivalence reports.

G. The District of Maryland's decision vacating the August 2017 guidance

74. In May 2019, the U.S. District Court for the District of Maryland vacated the August 2017 guidance extending the compliance period for newly deemed products because the court determined that the guidance should have gone through notice-and-comment rulemaking. *See Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 494–98 (D. Md. 2019).

75. A few months later, the district court entered an order providing that manufacturers of new tobacco products on the market as of the effective date of the Deeming Rule (August 8, 2016) would have to file their reports or applications within 10 months. *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019). The court further ordered that products for which reports or applications were filed by the deadline "may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application." *Id.* The district court also made clear that after that date the FDA would retain the authority to defer enforcement "for good cause on a case-by-case basis." *Id.*

76. A subsequent order extended the deadline for manufacturers to file their reports and applications to September 9, 2020, and the safe harbor from enforcement

to September 9, 2021. *See* Order, *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-00883 (D. Md. Apr. 22, 2020), ECF No. 182.

H. Swisher submitted 171 timely substantial-equivalence reports.

77. Despite the glaring holes in the FDA's instructions concerning substantial-equivalence reports, Swisher had no choice but to submit reports for its newly deemed cigar products by the September 9, 2020 deadline.

78. Prior to preparing its reports, Swisher extensively consulted the FDA's generic guidance on the content of substantial-equivalence reports and gleaned what information it could from the FDA's proposed rule on substantial-equivalence reports, notwithstanding the many questions left open by that proposed rule as discussed above. Swisher also participated in FDA webinars and attended a public workshop on the topic of premarket filings. Importantly, beginning in 2018 (well prior to the District of Maryland's ruling), Swisher began working with an outside accredited laboratory to develop and execute an extensive HPHC testing program for its new and predicate products; this testing program ultimately generated a huge body of data that is included in Swisher's reports.

79. Swisher eventually filed 171 timely substantial-equivalence reports, for which the FDA assigned 267 distinct Submission Tracking Numbers ("STNs"). The difference reflects the FDA's decision to assign different STNs to packages selling different quantities of the same cigar (e.g., the same cigar sold in a 2-pack vs. a 5-pack). These efforts cost Swisher thousands of hours and millions of dollars.

80. Each report demonstrates that Swisher's "new tobacco products" are substantially equivalent to predicate products that were on the market in February 2007.

81. Among other things, each report includes: (1) the details necessary to identify the new and predicate products; (2) a detailed comparison of ingredients and HPHCs; (3) product-design characteristics; (4) manufacturing information; and (5) an environmental assessment. The reports fully document all differences between the new and predicate products—nearly all of which are insignificant differences in ingredients that are present in only minute quantities. And the reports include certifications attesting that no further differences exist.

82. Swisher received acceptance letters for all 267 STNs on November 20 and November 24, 2020—more than eight months ago. The FDA identified no errors or problems with Swisher's reports.

83. In large part because of Swisher's unilateral and substantial efforts and investments, each of Swisher's detailed reports contains more than sufficient information for the FDA to make a prompt substantial-equivalence determination under 21 U.S.C. § 387j(a)(2)(A)(i).

84. Nevertheless, as far as Swisher is aware the FDA has not done anything with its substantial-equivalence reports since November 2020.

85. The FDA has apparently not even begun so-called "substantive review," which the FDA describes as the "longest and most thorough" phase of the process. *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept.*

9, 2020 Deadline ("*February Perspective*"), FDA (Feb. 16, 2021), https://bit.ly/37hMtNn.

86. Accordingly, Swisher continues to face a lengthy and indefinite delay—potentially several years long—while it awaits final FDA action on its reports, and the September 9 deadline draws closer and closer.

I. The FDA is now explicitly threatening enforcement actions against Swisher and other manufacturers who submitted timely substantial-equivalence reports that the FDA has not reviewed.

87. Swisher was not alone in filing substantial-equivalence reports or premarket-tobacco-product applications ahead of the September 2020 deadline. The FDA received "thousands of tobacco products submissions covering *millions* of tobacco products." *Deemed Product Review: A Conversation with the Center for Tobacco Products Office of Science* ("*June 11 Conversation*"), FDA (June 11, 2021), Tr. at 6 (emphasis added), https://bit.ly/3jA0AUb. In total, the FDA received substantial-equivalence reports for 6,800 products; exemption requests for 350 products; and premarket-tobacco-product applications for 4.8 million products (primarily vaping products). *See February Perspective*. "[T]he submissions varied substantially in number of tobacco products contained in each submission, size, format and organization." *Id.*

88. This deluge of reports and applications was entirely predictable—indeed, commenters warned the FDA that it was coming even before the FDA adopted the Deeming Rule. The reason was obvious: in one fell swoop, the FDA was subjecting millions of products that were already on the market to a complex "premarket review"

process for which the FDA had failed to provide meaningful guidance to regulated parties.

89. Yet the FDA appears to have been caught totally unprepared for the flood of reports and applications. In February 2021, the FDA indicated that "given the unprecedented number of applications and other factors . . . , the likelihood of FDA reviewing all the applications by Sept. 9, 2021 is low." *February Perspective*. By that date—five months after receiving the reports, and almost halfway through the one-year period in which the FDA had assumed it could finish its review of *all* of the reports—the FDA had accepted 5,200 substantial-equivalence reports for filing, but had taken final action on only 50. *Id.* Still, the FDA cautioned regulated parties that if they sold any products that had not made it through the FDA's traffic jam by September 9, 2021, they could be subject to FDA enforcement.

90. A few months later, on June 11, 2021, the FDA held a live webinar featuring a presentation from the Center for Tobacco Policy's Office of Science Director, Matt Holman, and a question-and-answer session with Office of Science Staff.

91. With the September deadline for enforcement now even closer, the FDA admitted that it was woefully behind on its work. For example, the FDA admitted that "given the unprecedented number of applications"—a problem of the FDA's own making in the Deeming Rule—"the likelihood of FDA reviewing all of the applications received by September 9th, is extremely low." *June 11 Conversation*, Tr. at 19.

92. Although commenters had warned the FDA of this exact problem before the FDA even adopted the Deeming Rule, the FDA complained that the "number of

applications exceeds anything that we've ever seen by orders of magnitude," and that it has been "very challenging due to the size, complexity and diversity of these submissions." *Id.* at 8.

93. The FDA also informed regulated parties that it was reviewing substantial-equivalence reports in a "randomized" order, rather than reviewing the reports based on market share or a similar metric that would allow it to prioritize the most economically consequential applications. *June 11 Conversation*, Tr. at 7. This was a major deviation from the FDA's order-of-review for PMTAs. For those more complex applications, most of which involved newly deemed vaping products, the FDA gave priority to products with the "largest market share." *Id.* Had the FDA taken that same common-sense approach to substantial-equivalence reports, rather than one based on happenstance, Swisher's reports would have been at the front of the line.

94. As of June 11, the FDA had still taken final action on only *50* substantial-equivalence reports—less than 1% of what the FDA had accepted for filing, and indicating that the FDA had made no progress since February. *June 11 Conversation*, Slide 28.

95. Yet the FDA explicitly threatened manufacturers with enforcement actions if the FDA was unable to complete its review of their reports or applications. The FDA warned that "if products are not authorized by September 9th of 2021 and you [sell them on] the market at that time, they risk FDA enforcement." *June 11 Conversation*, Tr. at 37.

96. In light of the now imminent threat of enforcement and the increasingly unlikely and unrealistic prospect that the FDA would act on its substantial-equivalence reports in a timely manner, Swisher wrote the FDA on July 6, 2021. Ex. A (Letter from H. Walker to M. Zeller, *et al.*). Swisher explained that although its cigars have been on the market for decades, the company was now faced with catastrophe because the FDA had failed to act on Swisher's timely filed substantial-equivalence reports. Swisher noted that the FDA has authority to exercise case-by-case discretion to allow companies to keep their products on the market while they await the FDA's decision and asked the FDA to exercise that discretion for Swisher's products. As Swisher explained, a "temporary stay would simply preserve the status quo while the FDA completes its review." *Id.* Otherwise, Swisher warned, thousands of employees in Jacksonville, the Dominican Republic, and elsewhere could lose their jobs solely because of the FDA's inability to fulfill its obligations under the TCA.

97. As of the date of this filing, Swisher has received no response.

J. Inaction by September 9, 2021 will have swift, devastating, and existential consequences for Swisher and its employees.

98. Absent judicial intervention (or a miraculous turnaround by the FDA), Swisher will be forced, through no fault of its own, to remove *all* of its cigars from the market. Given that the Deeming Rule subjected virtually Swisher's entire cigar portfolio—representing about 89% of the company's revenue—to the TCA's premarket-review provisions, the indefinite removal of Swisher's cigars from the market will

cause devastating and irreparable harm to Swisher, its employees, and the communities they live and work in.

99. Among other things, Swisher would be forced to shutter its cigar business for the foreseeable future. Factory operations will screech to a halt, employees will be laid off—including many of Swisher's nearly 1,000 U.S. employees—and Swisher could lose billions of dollars in annual revenue and hundreds of millions more in unrecoverable investments.

100. Many of Swisher's employees work in specialized jobs and would be extremely difficult to rehire or replace even if the company were able to restart operations after a temporary shut-down.

101. In addition, Swisher would have to repurchase and collect hundreds of millions of cigars that it has already sold to retailers, which would be extremely expensive and by itself could pose an imminent threat to the company's financial viability. Nor would Swisher be able to simply resell the cigars once the FDA gets its act together. Swisher's cigars have a shelf life of approximately twelve months, and any delay would likely require throwing hundreds of millions of cigars out—a total loss to Swisher of hundreds of millions of dollars in product.

102. Even supposing that the FDA someday approves Swisher's substantial-equivalence reports, Swisher could not recover the revenue and investments lost in this period from any of the federal Defendants (or anyone else) due to sovereign immunity.

103. An indefinite shutdown of its cigar business will also cause other long-term, irreparable harm to Swisher. Even if the FDA approves Swisher's substantial-

equivalence reports months or years down the road, Swisher will not be able to simply pick up where it left off. Exiting and reentering the market is not as simple as flipping a switch.

104. For one thing, Swisher will have difficulty recapturing its highly sought-after retail space. Swisher's cigars are currently displayed in prime locations behind the counters of stores—locations that are key to driving revenue and increasing brand awareness. If Swisher exits the market, retailers will enter into contracts to fill those spaces with other products. It will be difficult for Swisher to get that retail space back even after those contracts expire, because retailers will be loath to incur the additional costs required to recreate cigar displays.

105. An indefinite shutdown will also sever relationships that Swisher has built over decades with retailers and customers that could take years to rebuild, if doing so is ever possible. Swisher has built a successful brand and reputation by marketing itself to retailers as a compliance leader and reliable business partner and to consumers as a maker of quality cigars. If Swisher's cigars are removed from the market indefinitely by the government, Swisher's hard-fought goodwill and reputation will be irreparably damaged. Going forward, retailers will be reluctant to enter into annual rebating contracts with Swisher. And many existing and potential customers who hear that the FDA has banned Swisher's cigars will wrongly conclude that the cigars are illegal or less safe than similar products.

106. If Swisher is forced to shut down its cigar operations, the federal government and state and local governments will lose hundreds of millions of dollars in annual tax revenue and will be forced to refund hundreds of millions more in taxes that have already been paid.

107. These are just a sample of the massive and irreparable economic and human costs of the FDA's threat to force Swisher's cigars off the shelf by sitting on the company's applications and, at the same time, threatening enforcement.

Count One:

The Deeming Provision violates the non-delegation doctrine.

108. Swisher incorporates by reference the allegations of paragraphs 1–3, 5–8, 11–39, 47–64, and 87–107.

109. The Vesting Clause of Article I of the U.S. Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. 1, § 1.

110. Section 387a(b) of the TCA, the Deeming Provision, purports to delegate legislative power to the Executive Branch by authorizing the FDA to "deem[]" products to be subject to its authority.

111. Thus, Section 387a(b) is unconstitutional under the non-delegation doctrine.

112. Because the TCA's Deeming Provision—the sole source of authority for the Deeming Rule—is an unconstitutional delegation of legislative power, the Deeming Rule, which was promulgated solely pursuant to that provision, is also invalid.

113. Swisher is therefore entitled to relief under Article I of the Constitution, the APA, and other applicable law.

Count Two:

The Deeming Rule violates the Appointments Clause.

114. Swisher incorporates by reference the allegations of paragraphs 1–3, 5–8, 11–39, 47–64, and 87–107.

115. Under Article II of the Constitution, principal officers must be appointed by the President and confirmed by the Senate, while Congress may authorize the appointment of inferior officers by "the President alone," "the Courts of Law," or "the Heads of Departments." U.S. Const. art. II, § 2, cl. 2.

116. Ms. Kux was an Officer of the United States when she issued the Deeming Rule.

117. Ms. Kux was not appointed by the President or confirmed by the Senate. Nor has Congress vested authority to appoint the Associate Commissioner for Policy in the President, the courts, or a Department head.

118. Thus, the Deeming Rule was issued by an unconstitutionally appointed official and is accordingly invalid.

119. The FDA's subsequent attempts to ratify the Deeming Rule were invalid.

120. Swisher is therefore entitled to relief under the Appointments Clause, the APA, and other applicable law.

Count Three:

The FDA's attempts to ratify the Deeming Rule are independently unlawful.

121. Swisher incorporates by reference the allegations of paragraphs 1–8, 11–76, 87–113, and 133–40.

122. Then-Commissioner Califf's September 2016 attempt to ratify the Deeming Rule independently violated the procedural and substantive requirements of the APA. Then-Commissioner Gottlieb's April 2019 attempt to re-ratify the Deeming Rule suffered from the same flaws.

123. For example, neither of the ratifications complied with the APA's notice-and-comment requirements. *See* 5 U.S.C. § 553.

124. Nor did either of the boilerplate ratifications satisfy the APA's requirement of reasoned decisionmaking.

125. To the extent that the FDA's attempted ratifications sought to incorporate by reference the reasoning of Ms. Kux in the original Deeming Rule, the ratifications were unlawful for all the reasons the Deeming Rule itself was arbitrary and capricious, contrary to law, and inconsistent with the procedural requirements of the APA and TCA, as described further in Counts 4–5.

126. Accordingly, the purported ratifications of the Deeming Rule are unlawful, and Swisher is entitled to relief under the APA and other applicable law.

Count Four:

The Deeming Rule exceeds the FDA's statutory authority.

127. Swisher incorporates by reference the allegations of paragraphs 1–8, 11–39, 47–64, and 87–113.

128. The TCA purports to authorize the FDA to deem particular tobacco products, or categories of products, to be subject to the Act's requirements.

129. The Act does not authorize the FDA to deem all tobacco products to be subject to the Act's requirements at once.

130. The Deeming Rule nonetheless purports to deem all tobacco products—even those coming into existence in the future—to be subject to the Act's requirements, rather than deeming particular products or categories of products.

131. Accordingly, the Deeming Rule exceeds the FDA's authority under the TCA.

132. Swisher is therefore entitled to relief under the APA, the TCA, and other applicable law.

Count Five:

The Deeming Rule is otherwise unlawful under the APA.

133. Swisher incorporates by reference the allegations of paragraphs 1–107 and 128–32.

134. In addition to the flaws identified above, the Deeming Rule is arbitrary and capricious, contrary to law, and inconsistent with the procedural requirements of the APA and TCA. *See* 5 U.S.C. § 706.

135. For example, and without limitation, to the extent the TCA includes an intelligible principle governing the FDA's exercise of its deeming authority, the FDA erroneously believed that there were *no* limits on its discretion beyond the expansive statutory definition of a "tobacco product." Similarly, to the extent the Act provides an intelligible principle limiting the FDA's power, the FDA failed to give sufficient consideration to the statutory criteria.

136. The FDA also arbitrarily subjected newly deemed products to the Act's premarket-review process without an administrable plan for processing substantial-equivalence reports and premarket-tobacco-product applications for the newly deemed products.

137. In doing so, the FDA failed to give sufficient consideration to the reliance interests of manufacturers of newly deemed products and other affected parties, including but not limited to wholesalers, retailers, and the budgets of federal, state, and local governments.

138. The FDA also failed to respond to the concerns of commenters, consider obvious alternatives, or adequately weigh the costs and benefits of the Deeming Rule. The FDA's decision was also contrary to the evidence before the agency, and the FDA relied on fundamentally flawed and irrational studies and models.

139. The FDA also violated the APA's procedural requirements. As one example, the APA failed to provide sufficient information to commenters in violation of 5 U.S.C. § 553.

140. Swisher is therefore entitled to relief under the APA, the TCA, and other applicable law.

Count Six:

The FDA's failure to act on Swisher's substantial-equivalence reports is unlawful.

141. Swisher incorporates by reference the allegations of paragraphs 1–6, 8–50, and 56–107.

142. The Due Process Clause forbids agencies from withholding or unreasonably delaying action that they are required to take.

143. The APA independently forbids agencies from withholding or unreasonably delaying action that they are required to take. *See, e.g.*, 5 U.S.C. §§ 555(b), 706(1).

144. For Swisher's substantial-equivalence reports, the TCA requires the FDA to issue orders determining whether Swisher's cigars are (or are not) substantially equivalent to a predicate product.

145. The Act requires the FDA to act on the reports within 180 days or less.

146. Swisher submitted the reports to the FDA more than 300 days ago.

147. Accordingly, the FDA is unlawfully withholding action on Swisher's substantial-equivalence reports.

148. Even if the Act does not impose an express deadline requiring the FDA to act on the reports within 180 days, Congress plainly contemplated that the FDA would complete its review in less than 180 days. That is because even for the more onerous and time-consuming premarket-tobacco-product applications, the FDA must act in 180 days or less.

149. The FDA's delay is the result of its own inability (or unwillingness) to act on Swisher's reports, not a reflection of any deficiencies in the reports themselves.

150. To the contrary, Swisher provided the FDA with more than enough information to promptly act on the reports.

151. The FDA's delay imposes devastating harm on Swisher, its employees, and others, including but not limited to wholesalers, retailers, and federal, state, and local governments.

152. Accordingly, the FDA is unreasonably delaying action on Swisher's substantial-equivalence reports.

153. Swisher is therefore entitled to relief under the Due Process Clause, the APA, the TCA, and other applicable law.

Count Seven:

The FDA's de facto ban on Swisher's cigars is unlawful.

154. Swisher incorporates by reference the allegations of paragraphs 1–6, 8–50, 56–107, and 142–53.

155. The TCA does not allow the FDA to ban cigars or categories of cigars.

156. The FDA's refusal to act on Swisher's substantial-equivalence reports, coupled with its explicit threat of enforcement action, will force Swisher to remove virtually all of its cigars from the market.

157. In practical effect, therefore, the FDA's failure to act is a de facto ban on Swisher's cigars.

158. Because the FDA lacks authority to ban Swisher's cigars even if it goes through the notice-and-comment process, its de facto ban through the indirect method of simply refusing to act on Swisher's substantial-equivalence reports is unlawful.

159. Even if the FDA did somehow have authority to ban some or all of Swisher's cigars, the FDA's de facto ban is still unlawful because the FDA failed to comply with the requisite procedures under the TCA and the APA.

160. Swisher is therefore entitled to relief under the APA, the TCA, and other applicable law.

Count Eight:

The FDA's threatened enforcement against Swisher's cigars is unlawful.

161. Swisher incorporates by reference the allegations of paragraphs 1–6, 8–50, 56–107, 142–53, and 155–60.

162. The FDA repeatedly assured manufacturers, implicitly and expressly, that it would not force newly deemed products off the shelves without providing manufacturers a meaningful opportunity to obtain premarket review.

163. The FDA also specifically promised Swisher and other cigar manufacturers that it would exercise its discretion to defer enforcement actions while their substantial-equivalence reports were pending, so long as they filed timely reports.

164. Swisher has made substantial investments in its cigar products since 2009, when Congress passed and the President signed the TCA, through the present.

165. Despite the lack of adequate guidance from the FDA, Swisher also made substantial investments in its process for submitting substantial-equivalence reports, including but not limited to millions of dollars of investments in HPHC testing.

166. Similarly, Swisher delayed filing its substantial-equivalence reports in reliance on the FDA's multiple promises that filing them was unnecessary until a future date.

167. Swisher diligently worked to comply with all relevant deadlines and instructions from the FDA.

168. Swisher lacked fair notice that its products would be subject to enforcement action before it received an answer from the FDA on its substantial-equivalence reports, even if Swisher complied with all of the FDA's relevant instructions and deadlines and timely submitted those reports explaining that its cigars are substantially equivalent to similar cigars that were on the market in February 2007.

169. For these reasons, the FDA's threatened enforcement of the TCA against Swisher's cigars violates the Due Process Clause, the APA, and other applicable law, and Swisher is therefore entitled to relief.

Prayer for Relief

170. Swisher prays for an order and judgment:

a. Declaring that the Deeming Rule is unlawful because the TCA's Deeming Provision, the sole source of statutory authority for the rule, delegates legislative power to the Executive Branch in violation of Article I of the U.S. Constitution; that the Deeming Rule is unlawful because it was issued by an

Officer of the United States who was not appointed in accordance with the Appointments Clause; that the Deeming Rule and the FDA's purported ratifications exceed the FDA's authority under the TCA; and that the Deeming Rule and the FDA's purported ratifications are otherwise arbitrary and capricious, contrary to law, and did not comply with the procedural requirements of the APA and TCA;

b. Declaring that the FDA's failure to act on Swisher's substantial-equivalence reports violates the Due Process Clause and the APA;

c. Declaring that any attempt by the FDA to enforce the TCA against Swisher or its employees with respect to Swisher's cigars violates the non-delegation doctrine, Appointments Clause, Due Process Clause, APA, and TCA;

d. Vacating and setting aside the Deeming Rule;

e. Granting preliminary and permanent injunctive relief prohibiting HHS, the FDA, and their officers, employees, and agents from enforcing the TCA against Swisher's cigars;

f. Granting preliminary and permanent injunctive relief requiring the FDA to act on Swisher's pending substantial-equivalence reports in a timely manner;

g. Issuing all other process necessary and appropriate to postpone further implementation of the Deeming Rule pending the conclusion of this case;

h. Awarding Swisher its reasonable costs, including attorneys' fees, incurred in bringing this action under 28 U.S.C. § 2412 or other applicable law; and

i. Granting such other and further relief as this Court deems just and proper.

Dated: August 4, 2021

Respectfully submitted,

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