IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

U.S. SMOKELESS TOBACCO COMPANY LLC 6601 West Broad Street Richmond, VA 23230 Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, MD 20993 UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES 200 Independence Avenue SW Washington, DC 20201 ALEX M. AZAR, Secretary of Health and Human Services Office of the Secretary 200 Independence Avenue SW Washington, DC 20201 and SCOTT GOTTLIEB, M.D., in his official capacity as Commissioner of Food and Drugs 10903 New Hampshire Avenue Silver Spring, MD 20993 Defendants. _____	Civil Action No. 18-cv-251

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. This lawsuit challenges the U.S. Food and Drug Administration's ("FDA") misapplication of the substantial equivalence standard in the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 ("TCA"). This Court previously rejected an FDA interpretation of the TCA's substantial equivalence standard as "illogical." *Philip Morris USA Inc. v. FDA*, 202 F. Supp. 3d 31, 53 (D.D.C. 2016) (Mehta, J.). In recently denying substantial equivalence applications submitted by Plaintiff U.S. Smokeless Tobacco Company ("UST") for Copenhagen Bold Wintergreen Flavor Packs ("Copenhagen Bold"), FDA applied a similarly flawed interpretation of the standard that is inconsistent with this Court's ruling and, for multiple reasons, is arbitrary, capricious, and contrary to the TCA.

2. The TCA grants FDA authority to regulate tobacco products. The statute requires manufacturers to obtain FDA authorization to market any "new tobacco product"—defined as one not on the market as of February 15, 2007, the date the TCA was originally introduced in Congress. The TCA thus "grandfathered" tobacco products that were on the market as of February 15, 2007, allowing the continued sale of such products without FDA authorization. In so doing, the TCA essentially freezes in place the range of risks presented in the tobacco market as of that date.

3. The steps required to obtain FDA authorization to market a new product vary depending on the product. A new product that differs substantially from products on the market as of February 15, 2007, must undergo an arduous premarket approval process to establish that allowing the new product is appropriate for the protection of public health. This pathway to market requires a thorough inquiry into the health risks of the new product compared to those in the overall market. FDA has estimated that manufacturers will spend approximately 5,000 hours

to prepare each application for premarket approval. FDA, Draft Guidance for Industry, *Applications for Premarket Review of New Tobacco Products; Availability; Agency Information Collection Activities; Proposed Collection*, 76 Fed. Reg. 60055, 60057 (Sept. 28, 2011).

4. The TCA creates an exception to this demanding process: a streamlined pathway to market a new product that is "substantially equivalent" to a "predicate tobacco product." A "predicate tobacco product" is either a grandfathered product that was on the market as of February 2007 or a product previously found substantially equivalent to one. To obtain a substantial equivalence ("SE") finding, the manufacturer must show that the new product *either* (1) has the "same characteristics as the predicate tobacco product," *or*, if not, (2) does not raise "different questions of public health." 21 U.S.C. § 387j(a)(3)(A)(i)–(ii). Congress intended the SE process to be far less burdensome than premarket approval. FDA estimated that manufacturers would spend approximately 300 to 360 hours to prepare each SE report. FDA, Final Rule, *Tobacco Products, Exemptions from Substantial Equivalence Requirements*, 76 Fed. Reg. 38961, 38971 (July 5, 2011) (360 hours); FDA, Final Rule, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act*, 81 Fed. Reg. 28973, 29087-88 (May 10, 2016) (300 hours); *see Philip Morris USA Inc.*, 202 F. Supp. 3d at 38 (describing "less rigorous" SE pathway).

5. Moist smokeless tobacco can be manufactured in either a loose form (where the user places a pinch of loose tobacco between the cheek and gum) or a portioned form in pouches (where the user places a pouch containing tobacco between the cheek and gum). UST seeks to market a new, portioned form moist smokeless product, Copenhagen Bold Wintergreen Flavor Packs ("Copenhagen Bold"). Copenhagen Bold would take the *exact* same loose tobacco that UST sold in February 2007—and therefore can still sell today as a grandfathered product—and

would put that loose tobacco in mesh pouches. UST submitted SE reports showing that putting the grandfathered loose tobacco product in a pouch *decreases* the release of nicotine and certain carcinogens, without any indication of an increase in harmful constituents. The reports further show that the risks of the new product are in line with those prevalent in the market for moist smokeless tobacco products as of February 2007. As a result, Copenhagen Bold presents no new health risks as compared to moist smokeless products marketed in February 2007, and it should readily have satisfied the second prong of the SE standard because it "does not raise different questions of public health." 21 U.S.C. § 387j(a)(3)(A)(ii). In fact, under the SE process that Congress intended, Copenhagen Bold would be the paradigmatic substantially equivalent product.

6. Nonetheless, FDA rejected UST's applications—issuing orders that found Copenhagen Bold Not Substantially Equivalent ("NSE Orders") and affirming them on supervisory review ("Agency Appeal Order"). In FDA's view, the fact that a new product falls within the range of risks in the market for that type of product as of February 2007 is irrelevant in determining whether the new product raises "different questions of public health." Instead, FDA applied an extraordinarily restrictive test limited *exclusively* to a characteristic-by-characteristic comparison of the new product with a single "predicate," *i.e.*, a single "grandfathered" product. As part of this narrow application, FDA required that the new product had to be in the same format as the predicate. For this reason, FDA refused to consider data regarding the identical grandfathered loose tobacco product because it comes in a loose format, even though (1) it is the exact same tobacco as in Copenhagen Bold, and (2) when wrapped in the pouches and sold as Copenhagen Bold, this identical tobacco would release less nicotine and certain harmful constituents. FDA thus reached its counterintuitive NSE determination here only

by confining the assessment of any "questions of public health" *solely* to a comparison between Copenhagen Bold and a separate grandfathered pouch product, which FDA steered UST to use as the lone predicate.

7. As explained in detail below, FDA's misapplication of the SE standard not only defies common sense, but also conflicts with the plain language of the TCA. While the first prong of the SE test expressly requires a characteristic-by-characteristic comparison between the new and predicate products, the substantive standard in the second prong mentions neither the "predicate product" nor "characteristics," and requires a broader inquiry with "public health" as the touchstone. The second prong mandates an appraisal of "questions of public health"—an inherently broad inquiry that necessarily considers context, including the range of risks presented in the overall market for the type of tobacco product—instead of tethering review exclusively to a single predicate product. FDA's unduly restrictive approach also ignores the structure of the statute, discounts the role of the Medical Device Amendments ("MDA") as the template for the TCA's SE standard, and thwarts the central function of the SE process.

8. The frequent shifts in FDA's views and the lack of transparency regarding the TCA's requirements have compounded these errors and are independently unlawful under the Administrative Procedure Act and the Due Process Clause. In the nearly nine years since the TCA was enacted, FDA has never defined "different questions of public health" for purposes of the SE standard or otherwise shed light on what this test requires. Likewise, in the nearly 18 months since this Court's decision, FDA has offered no revised interpretation of the SE standard's first prong. When FDA occasionally has made public statements about the SE process, they have been convoluted and contradictory, creating confusion rather than clarity, and prejudicing UST's SE submissions. This, too, is far from what Congress had in mind in

providing a streamlined, alternative pathway to market for substantially equivalent tobacco products.

9. FDA's errors and omissions in interpreting the SE standard have imposed, and continue to impose, serious and irreparable harm on UST. This Court should declare unlawful and vacate FDA's orders of July 13, 2017 and January 2, 2018, which find Copenhagen Bold not substantially equivalent, and enjoin their implementation and enforcement. This Court should remand the NSE Orders to FDA to consider the Copenhagen Bold SE reports under the correct standard.

JURISDICTION AND VENUE

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

11. Venue is proper in this district under 28 U.S.C. § 1391. Defendants FDA and the Department of Health and Human Services ("HHS") reside in this judicial district, and a substantial part of the events giving rise to this action occurred in this judicial district.

12. The NSE Orders and the Agency Appeal Order constitute "final agency action" that marks the culmination of FDA's decision-making process. They determine UST's legal rights and obligations with respect to Copenhagen Bold, and impose new substantive legal requirements regarding UST's ability to market Copenhagen Bold.

13. An actual and justiciable controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant declaratory and injunctive relief. *Id.* §§ 2201-2202; 5 U.S.C. §§ 705-706.

PARTIES

14. UST is a Virginia corporation headquartered in Richmond, Virginia. UST manufactures moist smokeless tobacco products regulated by FDA and seeks to manufacture Copenhagen Bold, which is the subject of the NSE Orders and the Agency Appeal Order.

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

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

17. Defendant Alex M. Azar is Secretary of HHS and sued in his official capacity. Secretary Azar oversees FDA's activities with respect to the TCA.

18. Defendant Scott Gottlieb, M.D. is Commissioner of Food and Drugs and sued in his official capacity. Commissioner Gottlieb is directly responsible for FDA's administration of the TCA.

BACKGROUND

A. TCA Provisions Regulating "Tobacco Products"

19. Enacted in 2009, the TCA amended the Food, Drug, and Cosmetic Act ("FDCA") to grant FDA regulatory authority over "tobacco products," including the moist smokeless tobacco products at issue here. 21 U.S.C. § 387a(b).

20. Under the TCA, manufacturers must obtain FDA authorization to introduce a "new tobacco product" into the market. The Act defines "new tobacco product" as either (A) "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007," or (B) "any modification . . . of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." *Id.* § 387j(a)(1). The TCA thus "grandfathered" tobacco products on the market as of February 15, 2007—the date the

TCA was originally introduced. In other words, the TCA treats the market for tobacco products on February 15, 2007 as a baseline, ensuring that new products will not introduce health hazards different in type or magnitude from those present on that date.

21. The TCA establishes three pathways to obtain FDA authorization to market a new tobacco product, modeled on the parallel processes for medical devices under the Medical Device Amendments ("MDA"). *Id*. § 387j(a)(2), (a)(3)(A); *id.* § 387e(j)(3). The three pathways are: a full application for FDA premarket approval; a substantial equivalence report (the pathway at issue here); and an exemption to the substantial equivalence pathway.

22. The first pathway, premarket approval, applies to products significantly different from those on the market as of the February 2007 baseline. This pathway requires an exhaustive, meticulously documented application to introduce such a new product. *Id*. § 387j(a)(2), (b); *see Philip Morris USA Inc.*, 202 F. Supp. 3d at 38-39 (describing the "more rigorous" premarket pathway). Among other things, the applicant must show "that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). This showing must be made "with respect to the risks and benefits to the population as a whole," and must take into account "the increased or decreased likelihood that existing users of tobacco products will stop using such products . . . [and] that those who do not use tobacco products will start using such products." *Id.* § 387j(c)(4). FDA recommends that applicants provide data from "well-controlled investigations" on a wide range of issues, "so as to ensure that the study findings are generalizable to the population of U.S. tobacco users and non-users as a whole." FDA, Draft Guidance for Industry, *Applications for Premarket Review of New Tobacco Products* at 19 (Sept. 2011).

23. The TCA created a second, streamlined pathway for new tobacco products that do not need to go through the premarket approval process because they are found to be "substantially equivalent."

24. To establish "substantial equivalence," the manufacturer must submit an SE report showing that the new product has either:

> (1) "[T]he same characteristics as the predicate tobacco product";
>
> or
>
> (2) "[D]ifferent characteristics and the information submitted contains information . . . that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health."

Id. § 387j(a)(3)(A)(i)–(ii). A new product is substantially equivalent if it satisfies either prong. "Characteristics" means "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." *Id.* § 387j(a)(3)(B).

25. FDA originally estimated that manufacturers will spend approximately 300 to 360 hours to prepare each SE report. FDA, Final Rule, *Tobacco Products, Exemptions from Substantial Equivalence Requirements*, 76 Fed. Reg. at 38971 (360 hours); FDA, Final Rule, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act*, 81 Fed. Reg. at 29087-88 (300 hours); *see Philip Morris USA Inc.*, 202 F. Supp. 3d at 38 (describing "less rigorous" SE pathway). This is *only 6 to 7 percent* of the 5,000 hours FDA estimated for a full premarket approval application.

26. The third pathway to market exempts from review "minor" modifications of "tobacco additive[s]" in products. 21 U.S.C. § 387e(j)(3). That pathway is not at issue here.

B. The Prior Successful Challenge to FDA's Interpretation of the SE Standard

27. This case is not the first time it has been necessary for a court to correct FDA's misapplication of the SE standard. From the outset after enactment of the TCA, FDA sought

improperly to narrow the standard and to transform what Congress intended as a streamlined pathway into a duplicate of the full-blown process for premarket approval. Worse, in many respects, FDA has made the streamlined substantial equivalence process *more difficult* than the exhaustive premarket approval process.

28. In 2011, FDA announced that a new tobacco product could satisfy the first prong of the SE standard, the "same characteristics" prong, only if the product's characteristics were *identical* to those of the predicate product. *See, e.g.*, FDA, Guidance for Industry and FDA Staff, *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* at 13 (Jan. 2011); FDA, Draft Guidance for Industry and Staff: *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* at 6 (1st ed. Sept. 2011). In 2015, the Agency reaffirmed in a final guidance document that "the 'same characteristics' prong of the SE standard describes products whose physical attributes are identical to those of the predicate." *See* FDA, Guidance for Industry and Staff, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)* at 6 (Sept. 2015).[1] At that point, UST and other regulated companies filed suit challenging FDA's approach.

29. In 2016, this Court rejected FDA's interpretation as "illogical" and contrary to the TCA. *Philip Morris USA Inc.*, 202 F. Supp. 3d at 53. As the Court explained, because a "new tobacco product" is one that was introduced or modified after February 15, 2007, by definition it will not have characteristics identical to those of a grandfathered product. Otherwise, it would be the same grandfathered product, not a "new" product. Thus, no new product could satisfy

[1] *Available at* https://web.archive.org/web/20151014100118/http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf.

FDA's version of the "same characteristics test," with the result that "all non-exempt physical modifications [would be channeled] past the 'same characteristics' prong" to be decided instead through the "different questions of public health" prong. *Id.* The Court found this result "not reasonable." *Id.* The function of the "same characteristics" prong, the Court held, is to determine whether any differences in characteristics between the new and predicate products are sufficiently material to warrant evaluating the new product under the second, "different questions of public health" prong. FDA did not appeal this ruling nor otherwise challenge it. Instead, in December 2016, FDA issued a new edition of the final guidance that, among other things, removed the statements regarding identical characteristics. FDA, Guidance for Industry, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (3rd ed., Dec. 2016). However, neither in that guidance nor in any subsequent pronouncements has FDA said what the first prong means.

C. FDA's Determination That UST's Copenhagen Bold Pouch Tobacco Products Are Not Substantially Equivalent

30. On November 13, 2015, UST submitted SE Reports SE0012626 and SE0012633 for Copenhagen Bold Wintergreen Flavor Packs. The two new products differed only as to portion size (1.55g and 2.0g), and are referred to jointly here as "Copenhagen Bold."

31. Relying on FDA's public statements in several "webinars" permitting manufacturers to use multiple predicate products, UST demonstrated that Copenhagen Bold is substantially equivalent to two products that were marketed as of February 15, 2007. The first, the grandfathered loose tobacco product, used the identical tobacco blend and product formula as Copenhagen Bold, but loose rather than in pouches. The second, a grandfathered portioned product, was a product with the same format as Copenhagen Bold (*i.e.*, the tobacco was contained in pouches), but with a different tobacco blend and formula.

32. After UST submitted these SE Reports, FDA changed its views as to the requirements manufacturers had to meet in the SE process. First, in communications with UST, FDA made clear that it would find that products are NSE when their SE reports—like the ones UST had submitted for Copenhagen Bold—identify more than one predicate product. Second, FDA conveyed in informal industry updates and multiple Advice/Information Requests and Preliminary Finding Letters for other products of UST and its affiliates, a strong "preference" that the new and predicate products have the same format (*e.g.*, a new pouch product would require a predicate pouch product, and a new loose product would require a predicate loose product). *See, e.g.*, FDA, *Update on Review of Substantial Equivalence Reports (SE Reports)* at 15 (Apr. 10, 2013) (identifying a difference in product category between the predicate and new products as a factor elevating an SE report to a higher Public Health Impact tier);[2] Ltr. from M. Holman to Altria Client Services[3] at 2 (June 26, 2015) ("By comparing a portioned new product to a non-portioned predicate product, no meaningful scientific comparison of the design characteristics of the new and predicate products themselves can be performed to demonstrate that the new product does not raise different questions of public health."). In other words, FDA communicated to UST that its SE reports should use only a single predicate with the same format, or FDA would reject them.

33. FDA, however, suggested that UST could use so-called "surrogate" products to convey additional information it wants FDA to consider in an SE report. The term "surrogate" does not appear in the TCA, any regulation promulgated under the TCA, or any draft or final

[2] *Available at* https://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM347933.pdf.

[3] Altria Client Services ("ALCS"), like UST, is a wholly owned subsidiary of Altria Group, Inc. ALCS provides a range of services to UST and other Altria Group subsidiaries, including regulatory affairs support.

guidance document about the TCA. To determine the possible uses of surrogate products in SE reports, UST had to rely on communications with FDA staff (including communications by affiliates of UST regarding other tobacco products). Importantly, while FDA staff stated that manufacturers could use data from surrogate products when data for a predicate product was unavailable, they did not limit the use of surrogate data to those circumstances. To illustrate, the Director of the Division of Product Science at FDA stated in a letter involving the product of a UST affiliate that—to establish "substantial equivalence" under the second prong— companies could use as a "surrogate" a grandfathered product that shared some of the characteristics of the new product but not the predicate product. Ltr. fr. M. Holman to PM USA, Nov. 4, 2016, at 3 (emphasis added).

34. On December 22, 2016, after discussions with FDA staff, UST provided substantial additional data. Response to Scientific Advice/Information Request for - SE0012626, SE0012633, SE0012891, and SE0012892 (Dec. 22, 2016). As UST explained, based on its communications with FDA about "surrogate products," and in light of FDA's demand for a single predicate product in the same format as the new product, the Company had amended the SE Reports to designate the grandfathered portioned product as the lone predicate. *Id.* at 5. The amended SE Reports designated the grandfathered loose tobacco product with the exact same tobacco blend and formula as Copenhagen Bold, as a "surrogate" product. Proceeding only under the second prong of the SE standard, UST demonstrated that Copenhagen Bold does not "raise questions of public health that are different from questions already posed in the marketplace by existing products." Specifically, UST showed that Copenhagen Bold uses the identical tobacco blend and formula as the grandfathered surrogate product, merely portioned in

mesh pouches, and that putting this identical tobacco in a mesh pouch would *lower* its release of nicotine and certain carcinogens. *See, e.g.*, *id.* at 11 n.14, 14-15, 17.

35. On March 16, 2017, FDA sent UST a "preliminary determination" that the Company had not demonstrated substantial equivalence for Copenhagen Bold. Ltr. fr. M. Walters to UST (Mar. 16, 2017) (the "Preliminary Finding Letter"). In the Preliminary Finding Letter, FDA contradicted the key point previously conveyed regarding "surrogate products." FDA now insisted that UST could use surrogate product data *only* where the predicate product was not available to be tested. Because data on the predicate product was available, FDA shut its eyes to the information regarding the grandfathered surrogate loose tobacco product. The Preliminary Finding Letter concluded that UST had failed to show the absence of "different questions of public health." FDA, however, still did not define the term nor identify the different questions of "public health" that Copenhagen Bold supposedly had raised. *See id.*

36. On April 14, 2017, UST responded to FDA's preliminary determination. Response to Preliminary Finding for SE0012626, SE0012633, SE0012891 and SE0012892 (Apr. 14, 2017). UST explained that it had converted the grandfathered loose tobacco product from a predicate to a surrogate in reliance on its discussions with FDA and had left the grandfathered portioned tobacco product as the sole predicate based on FDA's virtually determinative "strong preference" that the new and predicate products have the same format—here, portioned in pouches. *Id.* at 5. UST again sought to focus FDA on the critical fact—that Copenhagen Bold is nothing more than the identical loose moist smokeless tobacco product on the market in 2007, distributed in a pouch format, which *reduces* the amount of nicotine and certain carcinogens released. In any event, UST noted, Copenhagen Bold is within the industry range of moist

smokeless tobacco products on the market as of February 15, 2007, for all the characteristics identified in the Preliminary Finding Letter. *See, e.g.*, *id.* at 5-6, 16; *see also id.* at 39 n.33.

37. Despite the additional data and explanations UST provided, FDA issued the NSE Orders for Copenhagen Bold on July 13, 2017.

38. In the NSE Orders, FDA did not dispute that the risks of Copenhagen Bold were within the industry range for the well-known risks prevalent in the market for moist smokeless tobacco products as of February 15, 2007. Nor did FDA dispute that putting the identical grandfathered loose tobacco product in mesh pouches reduces the amount of nicotine and harmful constituents released. Instead, the NSE Orders hinged on FDA's purely legal opinion that the "different questions of public health" standard for the second prong of the SE test looks *exclusively* at a comparison between the single predicate product—the one FDA drove UST to use, the grandfathered portioned product—and the new product. NSE Orders at 2, 3, 4.

39. The NSE Orders reiterated, contrary to FDA's earlier assurances, that manufacturers could use data from "surrogate products" only in lieu of, but not in addition to, predicate data. The Orders stated that "marketplace surrogate products" are not an appropriate comparator in SE reports. Although FDA did not define "marketplace surrogate products," FDA appears to have imposed a categorical bar on using surrogate products to provide information about the market for tobacco products that the manufacturer wants FDA to consider. Here, that bar excluded information that Copenhagen Bold was merely a grandfathered loose tobacco product wrapped in a mesh pouch, and that in this format, it released less nicotine and harmful constituents.

40. As a result of FDA's misapplication of the second prong of the SE test, FDA limited its evaluation only to a comparison between Copenhagen Bold and the grandfathered

portioned tobacco product—the single predicate UST was left little choice but to use—and found that UST had failed to show that differences in certain individual characteristics between the two products do not raise different questions of public health. FDA neither identified the "questions of public health" that the changes in individual characteristics supposedly raised, nor explained how those questions could be "different." *See id.*

41. On August 8, 2017, UST requested supervisory review of the NSE Orders. Ltr. fr. UST to M. Zeller (Aug. 8, 2017). UST explained that the Orders had misapplied the second prong of the SE standard by constricting the assessment of "different questions of public health" to an examination of a single predicate. *Id.* at 8-10. UST further explained that FDA had erred by making this comparison for each characteristic in isolation without assessing whether the new product as a whole raised different questions of public health. *Id.* at 11. And UST stressed the difficulty of meeting an SE standard where the Agency had failed to define "different questions of public health" or otherwise to establish clear SE requirements, and where it had provided inconsistent interpretations of "surrogate tobacco products." *Id.* at 14-16.

42. On January 2, 2018, FDA issued the Agency Appeal Order, denying UST's appeal and affirming FDA's erroneous application of the second, "different questions of public health" prong of the SE test. The Agency Appeal Order did not dispute UST's showing that, by putting the grandfathered loose tobacco product in mesh pouches, Copenhagen Bold reduces the release of nicotine and certain carcinogens, or that the risks of Copenhagen Bold are comparable to the risks of moist smokeless products on the market as of February 15, 2007. Instead, FDA's affirmance of the NSE Orders was based on its legal determination that the Agency can consider only a comparison between the new product and the single predicate product, and that an examination of the market for moist smokeless tobacco products as a whole is irrelevant to the

assessment of "different questions of public health." With regard to the use of surrogate products, FDA found the SE reports deficient "because the surrogate data was not being used *in place of* data for the identified predicate." *Id.* at 7 (emphasis added). Finally, FDA paid lip service to the notion that "the relevant inquiry" related to the product as a whole and not individual characteristics. *Id.* at 8. FDA claimed that it had analyzed individual characteristics to determine that the differences "*caused* the product" to raise different questions of public health. But FDA did not explain how the characteristics it analyzed made any difference to the product as a whole. In other words, FDA did not say how those characteristics *caused* the new product to raise "different questions of public health." And, again, FDA also failed to identify what those "different questions" supposedly were.

VIOLATIONS OF LAW

A. FDA's NSE Orders Misapplied the "Different Questions of Public Health" Prong of the SE Inquiry

43. The NSE Orders are based on FDA's flawed application of the second, "different questions of public health" prong of the TCA's SE standard. FDA reached its erroneous conclusion by comparing the health risks of Copenhagen Bold *only* to those of a single predicate product, disregarding context, and in particular, refusing to consider whether the new product falls within the range of the risks presented by moist smokeless tobacco products on the market as of February 15, 2007.

44. FDA's granular approach conflicts with the text and structure of the TCA, complicates the SE process, and obscures the fundamental purpose that the SE process is designed to serve. By the time the TCA was adopted, the questions of public health tobacco products raise were well-recognized. The TCA's statutory findings cataloged those risks. Pub. L. No. 111-31 § 2 (21 U.S.C. § 387 note). The purpose of the "different questions of public

health" prong is to identify and channel to the full-blown premarket approval process those new products that raise questions of public health beyond those already recognized. In other words, the "different questions" prong was intended to identify products that have risks distinct in type or magnitude from the known risks prevalent in the market as of the designated baseline date of February 15, 2007. In constricting the "different questions of public health" prong to a comparison of one new product to one predicate product, FDA has abandoned the broad perspective of a "public health" inquiry.

45. FDA's flawed approach is the direct consequence of its erroneous interpretation of the first, "same characteristics" prong of the SE test, which this Court rejected more than a year ago. As this Court held, the function of the "same characteristics" prong is to determine whether any differences are sufficiently material to warrant evaluating the new product under the second, "different questions of public health" prong. *Philip Morris USA Inc.*, 202 F. Supp. at 53-54.

46. Since this Court issued its opinion in September 2016, FDA has not communicated its current interpretation of the "same characteristics" prong. And, as noted, even while continuing to assess whether products raise "different questions of public health," FDA has *never* defined the term. However, the Agency appears to be applying the "different questions" test the same way it did before the Court rejected its interpretation of the "same characteristics" prong. Specifically, FDA continues to base its decision under the second prong exclusively on a characteristic-by-characteristic comparison between the new and predicate products. In so doing, FDA replicates the "same characteristics" inquiry delineated by the Court for the first prong of the SE test—a comparison of the characteristics of the new and predicate products to determine the materiality of any differences—rather than considering the new product as a whole

in the context of the market as of the February 15, 2007 baseline date. By failing to adjust its interpretation of the "different questions" prong in light of this Court's decision, FDA has conflated the two parts of the SE standard, rendering one part redundant, in violation of the canon directing courts to construe a statute "so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Hibbs v. Winn*, 542 U.S. 88, 101 (2004). That canon has particular force here, as the SE analysis is supposed to reach the second prong only if the product does not satisfy the first.

1. The Text of the TCA Shows That the "Different Questions of Public Health" Prong Requires an Assessment of the New Product With Regard to the Known Risks of the Type of Tobacco Product

47. A textual analysis of the TCA makes clear that the analysis under the SE standard's second prong should not be confined to a narrow comparison of the new product exclusively with a single grandfathered predicate product, as FDA did here.

48. The starting point of this textual analysis is a comparison between the language of the first and second prongs. The first prong explicitly requires the manufacturer to compare the new and predicate product; that is, it requires a determination whether the new product has the "same characteristics *as the predicate tobacco product*." 21 U.S.C. § 387j(a)(3)(A)(i) (emphasis added). The second prong casts a wider net. It requires the manufacturer to "demonstrate[] that it is not appropriate to regulate the product under this section because the product does not raise different questions of *public health*." *Id.* § 387j(a)(3)(A)(ii) (emphasis added). The second prong does not mention the "predicate product." Instead, it ends with the words "different questions of public health"—omitting, importantly, the trailing phrase that appears in the first prong, "*as the predicate tobacco product*." If Congress had intended a parallel comparison restricted exclusively to the predicate product, as FDA now posits, it could have said so

specifically, just as it did in the "same characteristics" prong. Given this omission, it is implausible that Congress intended to confine the comparison solely to the term omitted.

49. The second prong's central phrase "different questions of public health" mandates this broad public health focus, in language that contrasts sharply with the first prong's concrete characteristic-by-characteristic comparison of the new and predicate products.

a. To raise a "different *question*," the new product must prompt a new inquiry or broach a new "matter or concern." Oxford Dictionaries, "question," https://en.oxforddictionaries.com/definition/question (last visited Jan. 26, 2018). While FDA, unhelpfully, has not said what a "different question" is, well-known risks falling within the range presented by the same type of tobacco products on the market as of February 15, 2007, do not prompt new or different inquiries.

b. To implicate "*public health*," the new inquiry must relate to "[t]he health of the population as a whole, especially as monitored, regulated, and promoted by the state." Oxford Dictionaries, "public health," https://en.oxforddictionaries.com/definition/public_health (last visited Jan. 26, 2018). A public health inquiry, then, is necessarily broad. It takes into account the relative risks of marketed products. The FDA Commissioner and the Director of the Center for Tobacco Products have recognized that, "[t]o truly protect the public, the FDA's approach must take into account the continuum of risk for nicotine containing products," Scott Gottlieb and Mitchell Zeller, "*A Nicotine-Focused Framework for Public Health*," 377 New Eng. J. Med. 1111, 1113 (Sep. 21, 2017); in other words, an inquiry involving public health must focus on the relative risks of tobacco products in the overall market. Commissioner Gottlieb and Director Zeller also have highlighted the broad compass of the term "public health" when they described "*public health* benefits," in expansive terms such as "smoking-related morbidity" and

"premature mortality." *Id.* at 1113 (emphasis added). Limiting "questions of public health" exclusively to those generated by a comparison of discrete characteristics of the new product and one product selected from the entire market shrinks the public health inquiry past recognition.

c. Given the well-known risks of tobacco products at the time the TCA was introduced, a "different" question of "public health" would necessarily be a risk to the public of a different type or magnitude from the risks present in the market for the particular category of tobacco product (*e.g.*, moist smokeless tobacco or cigarettes) as of the baseline date of February 15, 2007.

50. FDA bases its narrow interpretation of the second prong not on the language in the second prong itself, but rather on the definitional introduction to the TCA's SE provision, 21 U.S.C. § 387j(a)(3)(A) (Section 910(a)(3)(A)). The introduction defines substantial equivalence to mean, "*with respect to the tobacco product being compared to the predicate tobacco product*, that the Secretary by order has found that the tobacco product" satisfies one of the prongs of the SE test. *Id.* (emphasis added). According to FDA, because the introduction refers to the "predicate," this must mean that both prongs of the SE test are confined to a comparison between the new and predicate products. Agency Appeal Order at 3.

51. FDA's interpretation of the introduction is incorrect. The introductory clause merely describes the threshold comparison of "characteristics" that occurs at the start of any SE analysis, regardless of prong. The characteristics of the new and predicate products are compared, and if they are "the same," the analysis ends with the first prong. If they are materially different, then the analysis proceeds under the second prong. That is all the introduction does. It does not modify or restrict the broader inquiry into "different questions of public health" under the second prong once the threshold is passed. If the preamble in fact

restricted the comparison exclusively to the predicate product for *both* prongs of the SE test, as FDA claims, it would not have been necessary for Congress to include the language expressly limiting the inquiry to the predicate in the first prong, while omitting it in the second. Yet Congress did refer to the "predicate tobacco product" in the first prong. Under FDA's view, that language is superfluous.

52. FDA's erroneous approach in the orders challenged here did not merely limit the SE inquiry to comparison with a single predicate. It narrowed the focus even further by making clear that it would reject any application in which the predicate did not have the same format as the new product. This additional constraint accomplishes nothing more than preventing manufacturers from providing, and FDA from considering, information that clearly would be useful in the assessment of "different questions of public health." There is no basis in the TCA, any regulation under the TCA, or any FDA guidance, for this additional restriction, and it cannot be reconciled with the essential function of SE review.

2. The Text of the Progenitor SE Provision in the MDA Also Refutes FDA's Interpretation

53. The statutory progenitor of the TCA's SE provisions further confirms that FDA has misapplied the "different questions of public health" prong of the TCA's SE standard.

54. Congress modeled the SE provisions in the TCA on the SE provisions in the Medical Device Amendments ("MDA") to the FDCA, "incorporating [the device provisions], with some modifications." *Philip Morris USA Inc.*, 202 F. Supp. 3d at 53; *see* S. Rep. 105-180, at 23-24 (1998) (explaining that "substantial equivalence" in the TCA largely tracked the MDA).

55. Critically, the MDA uses different language in articulating the second prong of its SE inquiry. Under the MDA, the second prong evaluates whether the new product "is as safe and effective as a legally marketed device, and . . . does not raise different *questions of safety*

and effectiveness than the predicate device." 21 U.S.C. § 360c(i)(1)(A)(ii) (emphasis added). FDA has explained that a "different question" of safety and effectiveness is one "that was not applicable to the predicate device, and poses a significant safety or effectiveness concern for the new device." FDA, Guidance for Industry and Staff, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* at 20 (July 28, 2014).

56. The TCA, while still including the term "different question," modified the test in two ways. First, Congress changed "different questions of *safety and effectiveness*" in the MDA to "different questions of *public health*" in the TCA. Some modification of the MDA standard was necessary, because effectiveness, while an issue for medical devices, is not an issue for tobacco products. But Congress simply could have dropped the word "effectiveness" and referred in the TCA to "different questions of safety." Instead, Congress substituted the sweeping term "public health." As explained, an inquiry focused on "public health" is pitched at a higher level than a comparison between the new product and one product out of the entire market, and involves an assessment whether the risks of the product are within the range of the well-known risks prevalent on the market as of February 15, 2007.

57. Second, Congress in the TCA omitted the comparative phrase "than the predicate [product]," which is present in the MDA. Thus, the TCA only requires a showing that "the product does not raise different questions of public health," *full stop*. 21 U.S.C. § 387j(a)(3)(A)(ii). Particularly given the conjunction with the TCA's newly introduced focus on "public health," the difference between the language of the "different questions" prong in the TCA as compared to the MDA is deliberate. *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) ("[W]here Congress includes particular language in one section of a statute but omits it in

another . . . , it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotation marks omitted).

58. In the Agency Appeal Order, FDA offers no explanation for why the MDA includes the words "than the predicate" in the second prong but the TCA does not. Nevertheless, FDA contends that this omission in the TCA is irrelevant. FDA states that, "In the different characteristics prong, neither the tobacco nor the device provisions explicitly states what the comparison is to regarding whether the characteristics are different, although the overall structure of each makes clear what the comparator—the predicate." *Id.* at 4. In explaining what it means by "overall structure," FDA stresses that "sections 910(a)(3)(A) and 512(i)(1)(A) say that substantial equivalence is with respect to the product 'being compared to its predicate.'" *Id.* This argument merely rehashes FDA's flawed reliance on the definitional introduction as the sole justification for its determination that the second prong comparison must be limited to the predicate. But, as noted, the introduction of the SE provision in the MDA also referred to the "predicate," yet the MDA's second prong still expressly confines the comparison to the "predicate device." The reference to the "predicate" in the introduction thus does not limit the inquiry. If it did, there would have been no reason for the MDA to specify in the second prong that the comparison was with "the predicate device."

3. FDA's Interpretation Is Incompatible With the Structure of the TCA's Market Authorization Provisions

59. FDA's interpretation of the TCA also ignores the structure and purpose of the market authorization provisions. Congress designed the premarket approval process to be a demanding pathway to market for new tobacco products, requiring a detailed, comprehensive showing that the new product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A), (c)(2)(4). That means introduction of the new product must further public

health, which the TCA defines with respect to the marketplace as a whole. *Id.* § 387j(c)(4) (public health determination must be made "with respect to the risks and benefits to the population as a whole").

60. FDA's approval of the premarket application for another moist smokeless tobacco product, Swedish Match snus (a moist powder tobacco product), reflects how the Agency interprets the premarket approval standard. There, FDA allowed Swedish Match to market new products based on its determination that the new products contain levels of harmful and potentially harmful chemicals that are "similar or lower than levels of [moist smokeless tobacco] *products currently on the U.S. market*." *See* Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review, Swedish Match North America, Inc., PM0000010–17 at 6 (Nov. 2, 2015) (emphasis added).[4] As FDA concluded, "the results analyzed indicate these products fall in the normal range, and the actual design feature values do not appear to raise concerns related to how these products might adversely impact public health through risk to the user, increased initiation or decreased cessation as compared to the existing [moist smokeless tobacco] market." *Id.* at 15. In other words, the new products are "appropriate for the protection of public health" because the risks they present are in the normal range seen in the market as a whole.

61. Congress enacted the SE pathway to be a less demanding alternative to premarket approval, designed to mirror the SE process under the MDA, which "is a faster and less stringent method to obtain clearance to market medical devices than the Premarket Approval (PMA) process." Office of Inspector General, Department of Health and Human Services, *FDA's Clearance of Medical Devices Through the 510(k) Process* 1 (Sep. 2013), OEI-04-10-00480.

[4] *Available at* https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472123.pdf.

Thus, rather than a full application, the SE process under the TCA requires only a "report" explaining why the new product is substantially equivalent and describing the company's efforts to comply with the TCA. 21 U.S.C. § 387e(j)(1)(A).

62. The "different questions of public health" prong of the SE standard requires the manufacturer to provide "information . . . that demonstrates that it is not appropriate to regulate the product under *this section*." 21 U.S.C. § 387j(a)(3)(A)(ii) (emphasis added). "This section" refers to Section 910 of the TCA (*id.* § 387j), which sets forth the premarket approval process. Such an inquiry makes sense in the context of Section 910 only if the assessment of "different questions of public health" considers the February 2007 market as a whole, and is not confined to a single predicate product. Indeed, Congress placed the definition of the SE standard in Section 910—rather than in Section 905 (which creates the SE process and specifies the content of SE reports)—precisely because it is an exception to the requirement that a new product must satisfy the more rigorous premarket authorization process. *Id.* § 387j(a)(2)(A)(i)(I).

63. As FDA applied the SE standard here, however, small changes in the values for individual characteristics as compared to a single predicate may raise "different questions of public health," requiring that the new product meet the more rigorous premarket authorization standard before it can be sold. That is so even if the new product presents risks no different from the well-known ones posed by other tobacco products marketed as of February 15, 2007—and therefore present no different question of public health. In essence, FDA's interpretation of the SE test decouples it entirely from the screening function it is supposed to serve as part of a cohesive market authorization process.

64. Given that Congress designed the SE process to be less demanding than the premarket approval route, it also makes no sense for the SE standard to be more difficult to meet

than the premarket approval standard. Yet that is the result of FDA's approach. FDA can find a new product NSE if a single characteristic is different from that characteristic in the predicate product. For purposes of premarket approval, as illustrated by FDA's assessment of the Swedish Match application, that difference would not matter if the product as a whole presents risks in the range of those presented in the market for the same type of tobacco product as of February 15, 2007. In this respect, too, FDA's application of the SE standard clashes with the essential role of the SE pathway in the market authorization process the TCA enacted.

65. In the final analysis, the second prong's inquiry—whether a new product raises "different questions of public health"—is a screen for the premarket approval pathway. If a new product raises a "different question," the full premarket approval process seeks to answer it to determine if marketing the product is "appropriate for the protection of *public health*." The law is clear that, absent a contrary definition, a term has the same meaning each time it appears in a statute. *See Ratzlaf v. United States*, 510 U.S. 135, 143 (1994); *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990). "Public health" means the same thing under the premarket authorization process as it does under the SE process. Thus, given the structure of Section 910, the question of public health asked (by the second prong) and the question of public health answered (by the premarket authorization pathway) must be the same. The assessment of the public health thus should consider the 2007 market for moist smokeless tobacco products as a whole.

66. FDA initially indicated that the SE process should take only 6-7 percent of the hours FDA estimated were required to complete an application for premarket approval. As a result of FDA's inflation of the SE process far beyond its intended function, the time UST has been required to spend on the Copenhagen Bold SE Reports alone has dwarfed the Agency's

estimate. The complexity and burdens engendered by FDA's interpretation of the SE provision provide strong evidence that the interpretation is incorrect.

4. FDA's Interpretation Conflicts with the Structure of the SE Provision Itself

67. FDA's approach conflicts with this Court's prior interpretation of the first, "same characteristics" prong. *See Philip Morris USA Inc.*, 202 F. Supp. 3d at 53. So long as FDA took the position that the "same characteristics" test required identical characteristics in the new and predicate product, identifying an independent function for the second prong was straightforward. When the characteristics of the two products were not identical, FDA would evaluate the materiality of those specific differences under the second prong. But once the Court rejected FDA's interpretation and held that FDA's task under the first prong is to determine whether the differences in characteristics between the new and predicate products are material—essentially the test FDA now applies to the second prong—FDA should have rethought its approach to *both* prongs. It did not.

68. Since this Court's ruling in September 2016, FDA has failed to articulate any substitute for its discredited interpretation of the first prong "same characteristics" test. Nor has FDA publicly communicated how it applies the "different questions of public health" prong. However, whatever that phrase means, FDA's decisions—including the one challenged here—suggest that the Agency is continuing to apply the second prong the same way it did before this Court rejected its interpretation of the first. That is, FDA continues under the second prong to undertake a characteristic-by-characteristic comparison confined exclusively to the new and predicate products, rather than considering the new product in the context of the market as of the February 15, 2007 baseline. As a result, under FDA's approach, the two prongs now do the

same thing, in violation of the longstanding canon of construction against superfluous language. The TCA mandated a two-step analysis of substantial equivalence, not one step performed twice.

5. FDA Improperly Evaluated Whether Variations in Individual Characteristics, Rather than the Product as Whole, Presented Different Questions of Public Health

69. FDA required UST to establish that each difference *in a characteristic* of Copenhagen Bold did not raise different health risks as compared to the corresponding characteristic in the predicate product. Even aside from improperly constricting the SE analysis to the predicate product, this characteristic-by-characteristic comparison in the second prong of the SE test is incorrect, and it provides another reason why the NSE Orders and the Agency Appeal Order violate the APA and the TCA.

70. The first prong of the SE test expressly focuses on the *characteristics* of both the new and predicate tobacco products. By contrast, the second prong, after establishing at the threshold that the product has "different characteristics," does not even mention "characteristics" in the substantive standard. Instead, that standard requires a showing that "*the product* does not raise different questions of public health." The second prong thus focuses on the public health issues raised by the "*product*" as a whole, rather than by any particular "characteristic."

71. When UST pointed out this error in its administrative appeal, FDA agreed that the analysis of "different questions" had to focus on the product as a whole, but claimed to have done that by examining "whether the differences in characteristics *cause* the new ***product*** to raise different questions of public health." Agency Appeal Order at 8 (first emphasis added; second emphasis in original). Despite this lip service to examining the product as an integrated whole, FDA did not actually apply this standard. To the contrary, in evaluating individual characteristics of the new and predicate products here, FDA frequently omitted the "cause the product" language and assessed only whether the single characteristic itself raised "different

questions of public health." *See, e.g.*, FDA, Second Engineering Review at 6 (Feb. 6, 2017) ("the differences in the tobacco particle size of the new and predicate products do not raise any different questions of public health," because "loose filler dissolution release rate testing show[s] that the new products have a similar or lower nicotine release rate"); *id.* at 7 ("any differences in the portion thickness of the new and predicate products do not raise any different questions of public health"); *id.* at 10 ("This supports the applicant's assertion that the differences in tobacco particle size distribution do not raise different questions of public health"); FDA, Second Chemistry Review at 27 (Feb. 3, 2017) (requesting UST "[p]rovide adequate evidence that the differences in nicotine release between the new and predicate products do not raise different questions of public health," or that "the differences in free nicotine between the new and predicate products do not raise different questions of public health"); FDA, Third Addiction Review at 11 ("provide evidence that the differences in free nicotine content between the new and predicate products do not raise different questions of public health"). Nor was this new. From its earliest guidance documents on the SE process in 2011, FDA has often blurred the distinction it cites here as to whether a characteristic raised different questions of public health or caused the product to do so. FDA, Guidance for Industry and FDA Staff, *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* at 11, 13, 15 (Jan. 5, 2011) (5 references); FDA, Draft Guidance for Industry and FDA Staff, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* at 5 (Sept. 2011).

72. The NSE and Appeal Orders here confirm what these telltale lapses convey—FDA's professed agreement that it should consider the product as a whole does not reflect its practice. To consider whether the product as a whole raises different questions of public health

requires an assessment of the combination of all the product's characteristics, in the aggregate, and evaluating whether, in the context of the entire product, a variation in a particular characteristic is significant. Of course, it is possible that a single characteristic could *cause* a product to present a materially higher risk. But in order to determine that, FDA would have to assess the *causal* linkage. There is no indication that FDA has undertaken this assessment.

B. Copenhagen Bold Satisfies the Substantial Equivalence Standard

73. Copenhagen Bold presents no public health questions that differ in type or magnitude from the questions presented by moist smokeless tobacco products that were on the market on February 15, 2007. Indeed, the tobacco in Copenhagen Bold is the *identical* tobacco blend and formula used in the surrogate grandfathered loose tobacco product. UST documented this in its SE Reports and in multiple responses to FDA inquiries.

74. UST demonstrated further that the pouch technology in the new Copenhagen Bold products actually *reduces* the rate and amount of nicotine and certain harmful constituents released as compared to the grandfathered loose tobacco product on the market as of February 15, 2007. There was no indication that any harmful constituent increased when the *identical* grandfathered loose tobacco blend was put in a mesh pouch. And the rate and amount of nicotine and harmful constituents released by the new products are within the range of such values for moist smokeless tobacco products on the market as of that date. FDA has never questioned any of these findings.

75. As a result, had FDA applied the correct standard, it would have determined that Copenhagen Bold is substantially equivalent because the product as a whole does not raise different questions of public health.

C. FDA's Vague, Inconsistent, and Ad Hoc Standards for Substantial Equivalence Are Arbitrary, Capricious, and in Violation of Due Process

76. FDA has failed to provide fair notice of the standards applicable to SE reports, as due process under the Fifth Amendment to the U.S. Constitution requires. Thus, FDA cannot now assert that UST has failed to meet any such standards in the NSE Orders.

77. Due process requires that agencies provide regulated parties "fair warning of the conduct a regulation prohibits or requires." *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (alterations omitted). Conversely, due process precludes an agency from punishing a regulated entity when the agency did not afford the entity "fair notice" that the challenged conduct could result in punishment. *FCC v. Fox Television Stations, Inc*., 67 U.S. 239, 258 (2012).

78. More than six years ago, FDA recognized that "interested parties need clarity as to FDA's expectations regarding [SE] reports and sufficient time to prepare submissions in advance of the statutory deadline." SE Guidance (Sep. 2011), at 2. To that end, FDA pledged "to initiate a rulemaking that would establish requirements and standards for substantial equivalence." SE Guidance at 1. Since 2013, FDA repeatedly has included SE regulations on its annual "Unified Regulatory Agenda. *See*, *e.g.*, Office of Information and Regulatory Affairs, Format and Content of Reports Intended to Demonstrate Substantial Equivalence, RIN 0910-AG96 (Fall 2013), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201310&RIN=0910-AG96; Office of Information and Regulatory Affairs, Format and Content of Reports Intended to Demonstrate Substantial Equivalence, RIN 0910-AG96 (Fall 2016), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201610&RIN=0910-AG96. Nevertheless, FDA still has not issued a rule or otherwise provided comprehensible direction—that is, fair notice—regarding the standards applicable in the SE process.

79. In fact, even aside from regulations, FDA has never in any other way suggested *any* standard under the "different questions of public health" prong, despite many opportunities to do so over the last seven years, including multiple guidance documents where it would have been natural and logical for the Agency to shed light on the issue. *See, e.g.*, FDA, Guidance for Industry and FDA Staff, *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* (Jan. 5, 2011) ("SE Guidance"); FDA, Draft Guidance for Industry and Staff—*Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (Sep. 2011); FDA, Guidance for Industry and Staff—*Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (Mar. 2015; rev'd Sept. 2015) ("2015 FAQ Guidance"); FDA, Guidance for Industry, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (ed. 3, Dec. 2016).

80. FDA's prior SE and NSE orders provide scant insight into the Agency's thinking on SE standards actually applied in reaching those decisions. FDA does not adequately explain its conclusions in SE orders, and the redactions of proprietary information from the SE and NSE orders for competitors' products make those materials even less informative. Further, FDA does not make NSE orders available in the first instance, and parties thus far have been forced to submit FOIA requests in order to obtain the heavily redacted reports for its competitors' products.

81. FDA's failure to provide useable interpretations of the "different questions" prong of the SE test (as well as the "same characteristics" prong) has left manufacturers like UST with no practical guidelines.

82. Compounding the confusion, when FDA has spoken about the SE process, its statements have been inconsistent and illogical. FDA's conflicting positions on the use of multiple predicate products in SE reports illustrate the chaotic, *ad hoc* nature of the Agency's pronouncements. In guidance issued in 2011, FDA ruled out the use of more than one predicate, stating that "a meaningful scientific comparison intended to determine whether the characteristics of the products are the same or are different but present no different questions of public health cannot be made between a new tobacco product and multiple predicate products." FDA, Guidance for Industry and FDA Staff, *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* (Jan. 5, 2011). As of March 2012, FDA's website answered the question, "What is a predicate product?" by noting that FDA's guidance interprets a predicate "to mean a single tobacco product." FDA, *Overview Questions: Substantial Equivalence.*[5]

83. A month later, FDA shifted its position and suggested that manufacturers might be able to submit multiple predicates. FDA, Webinar: *Reports on Substantial Equivalence (905(j)(1)(A)(i) Reports): One Year Later* (Apr. 24, 2012). FDA sounded a different note on August 7, 2012, when it cited as a "common deficienc[y] in SE Reports. . . listing numerous predicate products," and noted that "[t]he SE guidance recommends one predicate." FDA, *Common Issues Identified During FDA's Scientific Evaluation of SE Reports.* Five days later, on August 12, 2012, FDA changed its position yet again. The Director of the Office of Science and the Director of its Product Sciences Division in FDA's Center for Tobacco Products reiterated in a webinar that "Multiple predicates [are] allowed." FDA, Webinar, *Reports on Substantial*

[5] *Available at* https://web.archive.org/web/20120302084117/http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForIndustry/ucm237528.htm

Equivalence (905(j)(1)(A)(i) Reports): An Update (Aug. 21, 2012), at slide 23.[6] The confusion as regards FDA's public position continued over the ensuing years. In litigation filings in 2016, FDA suggested that there "may be limited circumstances" warranting multiple predicates. FDA, Reply in Sup. of Mot. to Dismiss at 10 n.9, *Philip Morris USA Inc. v. FDA* (D.D.C. No. 15-cv-1590), 2016 WL 634119. But in December 2016, FDA issued a guidance that presupposed the use of a single predicate. FDA, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Reponses to Frequently Asked Questions (Edition 3)* (*E.g.*, p. 4: FDA determines whether the new product is substantially equivalent to "*an* appropriate predicate product" (emphasis added); p. 6: change in product quantity results in tobacco product "having different characteristics from *the* predicate product" (emphasis added); p. 9: requiring full identification of "*a* predicate tobacco product" (emphasis added)). And today, FDA's website seems to revert to the position articulated back in July 2011: "FDA interprets a predicate product to mean *a single tobacco product* that the manufacturer will compare to its new tobacco product." FDA, *Questions and Answers on SE* (emphasis added).[7] At the same time as FDA was making these varied public pronouncements, FDA staff was advising that manufacturers *could* submit SE reports with multiple predicates, but the Agency would almost certainly reject them. FDA's dizzying mix of conflicting signals left UST uncertain as to what FDA expected the Company to submit.

84. FDA only exacerbated the confusion by providing conflicting information about the use of "surrogate products" as vehicles for data that the manufacturers otherwise might have

[6] *Available at* https://www.fda.gov/downloads/tobaccoproducts/guidancecompliance regulatoryinformation/ucm316450.pdf.

[7] *Available at* https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProduct ReviewEvaluation/ SubstantialEquivalence/ucm304517.htm.

sought to include through an additional predicate. FDA has never issued a regulation, guidance document, or other policy statement addressing this concept, but instead has relied on non-public communications with individual manufacturers during the SE process. Thus, it comes as no surprise that FDA's views on "surrogate" products have been an elusive moving target and a proving ground for *ad hoc* regulation.

85. The result of this approach is that FDA has willfully blinded itself to useful information. The Agency's narrowing of review to a single predicate in the "same format" has no grounding in any statutory provision, regulation or guidance. It is entirely *ad hoc*, made possible only because FDA has failed to define the applicable standard under *either* prong of the SE test.

86. FDA's "history of *ad hoc* and inconsistent judgments on a particular question" displaces any presumption of regular agency decision-making. *Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1049 n.23 (D.C. Cir. 1979) (internal quotation marks omitted). By failing to define either "same characteristics" or "different questions of public health," by regulating through *ad hoc* decisions, punctuated with vague, inconsistent guidance documents, not to mention unreliable private advice, FDA has made the SE provisions of the TCA indecipherable to regulated entities like UST. In these circumstances, it would be fundamentally unfair—and would violate due process—to uphold the NSE Orders and the Agency Appeal Order. *See Christopher*, 567 U.S. at 158-59 ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an [administrative] proceeding . . . .").

CLAIMS FOR RELIEF

COUNT I
(Violation of the Administrative Procedure Act: the NSE Orders and Agency Appeal Order Are Arbitrary, Capricious, and Not in Accordance with the TCA, and FDA's Action Is Unsupported by, and Lacks a Rational Connection to, the Evidence in the Administrative Record)

87. UST incorporates the preceding paragraphs as if fully set forth herein.

88. The NSE Orders and Agency Appeal Order are "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704.

89. The APA proscribes agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A).

90. In requiring UST to show that the new Copenhagen Bold products do not raise different question of public health solely by reference to a single predicate product, excluding from the evaluation any consideration of where the new product fits in the range of known risks prevalent in the market as of February 15, 2007, the NSE Orders and Agency Appeal Order are arbitrary, capricious, and contrary to the TCA.

91. By focusing on a comparison of individual characteristics of the predicate product to individual characteristics of the new product, rather than focusing on whether the new product "as a whole" raises different questions of public health, the NSE Orders and Agency Appeal Order are arbitrary, capricious, and contrary to the TCA.

92. By excluding from its analysis any information other than data on a single predicate in the same format as the new product, without any statutory or regulatory basis for this limitation, FDA has acted arbitrarily, capriciously, and contrary to the TCA.

93. UST has exhausted its administrative remedies. In the alternative, UST has no adequate or available administrative remedy, and any effort to obtain any administrative remedy would be futile.

94. This Court accordingly should set aside and declare unlawful the NSE Orders and Agency Appeal Order, and remand the matter to FDA to apply the correct legal standard. *See* 5 U.S.C. § 706(2).

COUNT II
(Violation of the Administrative Procedure Act: the NSE Orders and Agency Appeal Order Are Arbitrary, Capricious, and Not in Accordance with the TCA, and the Agency's Action Is Unsupported by, and Lacks a Rational Connection to, the Evidence in the Administrative Record)

95. UST incorporates the preceding paragraphs as if fully set forth herein.

96. Under the APA, an agency action is arbitrary and capricious when the agency acts counter to the evidence in the record or when its action lacks a rational connection to the facts in the record. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43–44 (1983); *Haselwander v. McHugh*, 774 F.3d 990, 998–99 (D.C. Cir. 2014).

97. In requiring UST to show that Copenhagen Bold does not raise different questions of public health solely by comparing the new product's characteristics to the characteristics of a single predicate product in the same format as the new product, rather than determining whether the risks raised by the new product as a whole were different in type or magnitude from the risks prevalent in the market as of February 15, 2007, the NSE Orders and Agency Appeal Order are arbitrary, capricious, and contrary to the TCA.

98. Because the administrative record lacks evidence supporting a conclusion that Copenhagen Bold raises different questions of public health, and because FDA unjustifiably

excluded information that would have been important in formulating such a conclusion, FDA did not make a reasoned decision based on reasonable extrapolations from reliable evidence.

99. UST has exhausted its administrative remedies. In the alternative, UST has no adequate or available administrative remedy, and any effort to obtain any administrative remedy would be futile.

100. This Court accordingly should set aside and declare unlawful the NSE Orders and Agency Appeal Order, and remand the matter to FDA to apply the correct legal standard. *See* 5 U.S.C. § 706(2).

COUNT III
(Violation of the Fifth Amendment to the U.S. Constitution: Denial of Due Process)

101. UST incorporates the preceding paragraphs as if fully set forth herein.

102. Due process requires that agencies provide regulated parties "fair warning of the conduct a regulation prohibits or requires." *Christopher*, 567 U.S. at 156 (alterations omitted); *see also Fox Television Stations*, 132 S. Ct. at 2317–18.

103. FDA failed to provide fair notice of the standards applicable to SE reports. It did not define or otherwise give content to key operative parts of the statutory requirements UST and other manufacturers had to meet.

104. Such instructions as FDA provided to regulated companies were contradictory and confused. For example, FDA's position on the use of multiple predicates and surrogate products has fluctuated. This vacillation denied UST fair notice of the applicable requirements. UST cannot know what FDA requires when FDA itself does not know. FDA's erratic pronouncements shaped the SE reports here and then constrained even further the information in the SE reports that the Agency would consider. FDA's SE procedures fall below the

rudimentary prerequisites of a fair administrative process. The NSE and Agency Appeal Orders that these procedures produced and that rest on erratic, fluctuating "standards" violate due process.

105. UST has exhausted its administrative remedies. In the alternative, UST has no adequate or available administrative remedy, and any effort to obtain any administrative remedy would be futile. Moreover, UST need not exhaust administrative remedies to raise claims of constitutional harm.

106. As a result, this Court should set aside the NSE Orders and Agency Appeal Order and declare that they violate the Fifth Amendment to the U.S. Constitution. *See* 28 U.S.C. § 2201(a).

PRAYER FOR RELIEF

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

a. Declare that the NSE Orders and Agency Appeal Order are arbitrary and capricious, not in accordance with law, all in violation of the APA and the TCA, because the NSE Orders and Agency Appeal Order misconstrue the SE standard in Section 910 of the TCA;

b. Declare that the NSE Orders and Agency Appeal Order failed to give UST fair notice of the applicable SE standards, depriving UST of due process of law, in violation of the Fifth Amendment to the U.S. Constitution;

c. Vacate and set aside the NSE Orders and Agency Appeal Order under 5 U.S.C. § 706.

d. Remand the matter to FDA to apply the correct legal standard;

e. Enter a permanent injunction restraining Defendants from implementing or enforcing the NSE Orders and Agency Appeal Order;

f. Award UST its costs and reasonable attorneys' fees; and

g. Order such other relief as this Court may deem just and proper.

Dated: February 2, 2018

Respectfully submitted,

/s/ Robert N. Weiner

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