IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILIP MORRIS USA INC.
6601 West Broad Street
Richmond, VA 23230

U.S. SMOKELESS TOBACCO COMPANY LLC
6603 West Broad Street
Richmond, VA 23230

R.J. REYNOLDS TOBACCO COMPANY
401 N. Main Street
Winston-Salem, NC 27101

AMERICAN SNUFF COMPANY, LLC
813 Ridge Lake Boulevard
Memphis, TN 38120

SANTA FE NATURAL TOBACCO COMPANY, INC.
One Plaza La Prensa
Santa Fe, NM 87507

LORILLARD TOBACCO COMPANY
714 Green Valley Road
Greensboro, NC 27408

Plaintiffs,

v.

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

Civil Action No. _____

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

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

and

STEPHEN OSTROFF, M.D., in his official capacity as Acting Commissioner of the Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs bring this lawsuit to challenge recent action by the United States Food and Drug Administration ("FDA") seeking to assert a broad power of prior restraint over Plaintiffs' marketing communications, even though the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, plainly denies FDA that power and the First Amendment bars it. Furthermore, FDA engaged in this unlawful action under the guise of a "guidance" to avoid the notice-and-comment requirements of the Administrative Procedure Act ("APA") and subsequent judicial review, even though this putative "guidance" sets forth FDA's final conclusions and creates specific legal obligations with clear and draconian consequences for violations.

2. In June 2009, Congress enacted the TCA, authorizing FDA to regulate the manufacture, marketing, and sale of tobacco products, including cigarettes and smokeless tobacco products manufactured by Plaintiffs.

3. The TCA differentiates between regulation of a "tobacco product" and regulation of a tobacco product's "label." With respect to a "tobacco product," manufacturers generally must obtain authorization from FDA before making a change to cigarettes, smokeless tobacco, or any other FDA-regulated tobacco product on the market. By contrast, with respect to a tobacco product's "label," Congress rejected giving FDA power to pre-approve changes except in two narrow circumstances: (1) where the label makes a "modified risk" claim; and (2) where FDA adopts a specific pre-approval regulation through notice-and-comment rulemaking.

4. On March 4, 2015, FDA issued a document entitled, "Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" ("SE Directive") [**Exhibit A**], that disregarded Congress's carefully calibrated statutory framework. Under the SE Directive, FDA in effect requires pre-approval of label changes despite Congress's intent to the contrary, which is unambiguously reflected in the structure and text of the TCA. Specifically, the SE Directive requires manufacturers to obtain FDA pre-authorization before making any change to a label that would render a tobacco product "distinct"—as defined under FDA's vague standards—from the predecessor version of the product, even though there is no change to the tobacco product itself.

5. Because the SE Directive is contrary to the TCA, exceeds the authority Congress delegated to FDA under the statute, lacks any reasoned or reasonable justification, and provides inadequate notice to manufacturers about which label changes will trigger FDA's new regulatory requirements, the SE Directive is arbitrary and capricious, an abuse of discretion, not in

accordance of law, and in excess of statutory jurisdiction, authority, and limitation. It therefore violates the APA.

6. The SE Directive also violates the APA because it was issued without observance of procedures required by law. Because it represents the Agency's final conclusions and imposes new legal obligations, the SE Directive is a substantive rule that was improperly adopted without notice-and-comment rulemaking. By failing to engage in notice-and-comment rulemaking, FDA not only violated the APA, but also the TCA itself, in which Congress required formal rulemaking before FDA could impose a prior restraint of tobacco product labels not making a "modified risk" claim. If FDA had conducted a rulemaking, commenters would have alerted the Agency to the fundamental statutory and constitutional flaws in its requirement for pre-approval of product labels, and the Agency would have been required to modify the requirement to address those flaws.

7. Moreover, by imposing this broad pre-approval requirement for label changes, the SE Directive also violates the First Amendment's strict limitations on prior restraints as well as its protections for commercial speech and the prohibition against vague speech restrictions. The SE Directive imposes a prior restraint on speech, yet contains none of the safeguards that the First Amendment requires to justify "the most serious and the least tolerable infringement on First Amendment rights." *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976); *see also Se. Promotions Ltd. v. Conrad*, 420 U.S. 546, 559 (1975) (emphasizing that "a free society prefers to punish the few who abuse rights of speech *after* they break the law [rather] than to throttle them and all others beforehand") (emphasis in original).

8. FDA's unlawful actions already have harmed Plaintiffs and threaten greater harms in the future by restricting Plaintiffs' ability to modify their product labels without FDA pre-authorization and by chilling and restricting protected speech.

9. This Court should declare the SE Directive unlawful, vacate it, and enjoin its implementation and enforcement.

JURISDICTION AND VENUE

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

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

12. The SE Directive is "final agency action" that is the culmination of FDA's decision-making process. It imposes new legal requirements and makes clear that manufacturers must comply with those requirements. In particular, the SE Directive effectively requires manufacturers to obtain pre-authorization from FDA before changing the labels of their tobacco products or altering the quantity of a tobacco product in a package, or else risk civil and criminal penalties. The SE Directive therefore determines legal rights and obligations of tobacco manufacturers, including Plaintiffs, and has significant legal consequences. In addition, the SE Directive chills and restricts protected speech by forcing Plaintiffs to choose between refraining

from such speech absent FDA authorization or risking civil and criminal penalties, including the removal of lawfully marketed products.

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

PARTIES

14. Philip Morris USA Inc. ("PM USA") is a Virginia corporation headquartered in Richmond, Virginia. PM USA manufactures cigarette products regulated by FDA.

15. U.S. Smokeless Tobacco Company LLC ("USSTC") is a Virginia limited liability company headquartered in Richmond, Virginia. USSTC manufactures smokeless tobacco products regulated by FDA. Prior to 2014, USSTC was known as U.S. Smokeless Tobacco Manufacturing Company LLC ("USSTMC"). In 2014, USSTMC was merged with, and renamed, USSTC.

16. Plaintiff R.J. Reynolds Tobacco Co., Inc. ("RJRT") is a wholly-owned subsidiary of Reynolds American, Inc. ("RAI"), a North Carolina corporation. RJRT's headquarters are located in Winston-Salem, North Carolina. RJRT manufactures cigarettes and smokeless tobacco regulated by FDA.

17. Plaintiff Santa Fe Natural Tobacco Company, Inc. ("Santa Fe") is a wholly-owned subsidiary of RAI. Santa Fe is a New Mexico corporation and its headquarters are located in Santa Fe, New Mexico. Santa Fe manufactures cigarettes regulated by FDA.

18. Plaintiff American Snuff Company ("ASC") is a wholly-owned subsidiary of RAI. ASC's headquarters are located in Memphis, Tennessee. ASC manufactures smokeless tobacco regulated by FDA.

19. Lorillard Tobacco Company ("Lorillard") is a Delaware corporation headquartered in Greensboro, North Carolina. Lorillard manufactures cigarette products regulated by FDA.

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

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

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

23. Defendant Stephen Ostroff, M.D. is Acting Commissioner of FDA and sued in his official capacity. The Acting Commissioner is directly responsible for FDA's administration of the TCA.

BACKGROUND

A. The Tobacco Control Act

24. The TCA includes provisions regulating the "tobacco product" and separate provisions regulating the "label" that appears on the package of the tobacco product.

1. Provisions Regulating the "Tobacco Product"

25. Under the TCA, FDA regulates the manufacture, marketing, and sale of "tobacco products," including "new tobacco products." TCA §§ 901(a), 910(a)(1). While Congress sought to prevent and reduce the use of tobacco products by minors and to ensure that consumers are better informed of the risks of such products, Congress also specifically provided for the continued availability and sale of tobacco products to adults. TCA § 3(6), (7); *see* 21 U.S.C. §§ 387g(d)(3), 387j. The TCA prohibits the Secretary from banning existing tobacco products—i.e., cigarettes, smokeless tobacco products, cigars, pipe tobacco, and roll-your-own tobacco

products. 21 U.S.C. § 387g(d)(3). Moreover, the statute "grandfathers" tobacco products that were on the market as of February 15, 2007, and makes clear that those grandfathered products do not require FDA's premarket review to remain on the market. 21 U.S.C. § 387j.

26. The TCA defines a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." *Id.* § 101(a)(rr)(1). The TCA defines a "new tobacco product" as:

> (A) any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007; or
>
> (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Id. § 910(a)(1).

27. A central component of the TCA is the requirement that, before commercially marketing a "new tobacco product," manufacturers obtain from FDA either (1) a premarket authorization order, or (2) an order finding that the "new tobacco product" is "substantially equivalent" to a predicate "tobacco product" commercially marketed in the United States as of February 15, 2007, or previously found to be substantially equivalent to such a product. *Id.* § 910(a)(2)(A).

28. To reach the market by the premarket authorization route, a manufacturer must submit a premarket tobacco application with extensive evidentiary support, including reports of investigations regarding the health risks of the new tobacco product; a "full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product"; and a "full description of the methods used in, and the

facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of" the product. *Id.* § 910(b)(1)(A)-(C).

29. To reach the market by the substantial equivalence ("SE") route, a manufacturer must submit a report demonstrating that the new tobacco product is "substantially equivalent" to a predicate tobacco product. *Id.* § 905(j)(1)(A)(i). A new tobacco product satisfies this standard if it has the "same characteristics" as the predicate, or, if it has different characteristics, it "does not raise different questions of public health." *Id.* § 910(a)(3)(A)(i)-(ii).

30. A manufacturer can commercially market a "new tobacco product" without a premarket authorization order or substantial equivalence finding, if the manufacturer (1) introduced the new tobacco product after February 15, 2007 and before March 22, 2011, and also (2) submitted an SE report before March 22, 2011. *Id.* § 910(a)(2)(B)(i)-(ii). Such a "provisional" product can remain on the market unless and until FDA finds it is not substantially equivalent. *Id.*

31. FDA deems tobacco products that are marketed without the appropriate FDA approval to be "misbranded" and "adulterated," *id.* §§ 903(a)(6), 902(6)(A); SE Directive at 3, exposing the manufacturer to substantial civil and criminal penalties. For example, FDA can seize products it contends are misbranded or adulterated, seek an injunction against marketing those products, seek civil penalties of up to $275,000 per violation or approximately $10.5 million in a single proceeding, with potential enhancements and multipliers, or pursue criminal penalties that could also include substantial fines, imprisonment of individuals, and significant collateral consequences. 21 U.S.C. §§ 331-34; 21 C.F.R. § 17.2.

2. Provisions Regulating the "Label" of Tobacco Products

32. The "label" of tobacco products is addressed in separate provisions of the FDCA and the TCA. A tobacco product "label" is defined as "a display of written, printed, or graphic

matter upon the immediate container of any article." 21 U.S.C. § 321(k). In this case, the term "article" refers to a tobacco product. Therefore, by definition, a change to the label by itself cannot create a new product under TCA § 910(a)(1), because that provision requires a change to the design, components, constituents, form of nicotine, additives, or ingredients of a tobacco product in order to create a new tobacco product.

33. Unlike changes to the tobacco product, the TCA generally does not require manufacturers to obtain pre-approval from FDA for label changes. Rather, the TCA directs manufacturers to file reports with FDA every six months reflecting material changes that have been made to the labeling of their tobacco products. TCA §§ 905(i)(1)(B), (i)(3)(D). If FDA finds a particular change false, misleading, or otherwise unlawful, FDA has authority to pursue the civil and criminal remedies discussed above, in addition to less formal regulatory measures, such as sending warning letters.

34. There are only two specific, narrowly circumscribed conditions under which the TCA requires manufacturers to obtain FDA approval before implementing a label change:

a. First, the TCA requires manufacturers to obtain FDA authorization before claiming in a label that a tobacco product presents a "modified risk." *Id.* § 911(a). To support this pre-approval requirement, Congress made specific findings in the TCA addressing the First Amendment standards applicable to restrictions on commercial speech. Congress found a "compelling governmental interest" in ensuring that statements about such "modified risk tobacco products" are accurate and complete, *id.* § 2(40), and that requiring pre-approval was "[t]he only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products," *id.* § 2(43).

b. Second, the TCA authorizes FDA to require "prior approval" of statements on tobacco product labels, but only for limited purposes and only by regulation, which under the APA requires notice-and-comment rulemaking:

> PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act).

Id. § 903(b).

35. The SE Directive is not limited to modified risk tobacco products and therefore no similar congressional findings apply. Nor has FDA promulgated a regulation through notice-and-comment rulemaking requiring prior approval of statements on tobacco product labels under § 903(b).

36. Instead, in a supposed "guidance," issued without public notice and comment, FDA purported to grant itself what amounts to broad new pre-authorization powers, requiring tobacco manufacturers to submit to the Agency's review before making any label change that would render the product "distinct" from its predecessor. For provisional products, the SE Directive imposes a 90-day waiting period before such label changes can proceed, allowing FDA an opportunity to reject changes it disfavors. Although styled as "guidance," the SE Directive in fact sets forth final agency conclusions and creates specific, binding legal obligations that Plaintiffs must either follow or face severe consequences. In asserting these powers, FDA overstepped its authority under the TCA, ignored the requirements of the APA, and violated the First and Fifth Amendments.

B. The Challenged SE Directive

1. FDA's "Draft Guidance"

37. In September 2011, FDA issued a "draft guidance" entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" ("Draft Guidance") [**Exhibit B**].

38. In the Draft Guidance, FDA claimed that the TCA requires manufacturers to submit to FDA review before changing the label of a tobacco product. That assertion rested on FDA's erroneous view that the label of a tobacco product "is considered a 'part' of that product." Draft Guidance at 3. According to FDA, "[a] change to any part of a tobacco product after February 15, 2007 makes that product a 'new tobacco product'" subject to FDA premarket review under the TCA. *Id.*

39. Plaintiffs submitted comments to FDA demonstrating that the TCA's structure and text precluded FDA's interpretation. *See, e.g.*, Altria Client Services Comments on Draft Guidance at 4-7 (Nov. 8, 2011) [**Exhibit C**]. Plaintiffs emphasized that the TCA provides for FDA pre-approval of tobacco product labels in only two narrow circumstances, neither of which was addressed in the Draft Guidance. *Id.* at 6-7. Plaintiffs also explained that requiring pre-approval of label changes would infringe on Plaintiffs' First Amendment rights. *Id.* at 8-10.

2. The SE Directive

40. On March 4, 2015, more than three years after issuing the Draft Guidance, FDA issued the SE Directive [**Exhibit A**]. The SE Directive requires FDA pre-authorization for a broad, but amorphously defined, set of changes to labels as well as for changes to the quantity of a tobacco product contained in a package.

a. Label Changes

41. In the SE Directive, FDA "reconsidered" its position in the Draft Guidance, and correctly concluded, contrary to its prior view, "that a label is *not* a 'part' of the tobacco product." SE Directive at 3 (emphasis added).

42. FDA instead offered up another novel, yet equally erroneous, interpretation, based on a different provision of the TCA, to claim for itself the same purported pre-authorization power over tobacco product label changes. In particular, FDA, "conclude[d] . . . that if a product's label is modified in any way that renders the product distinct from the predicate, even if its characteristics remain the same, the modified product is a new product under section 910(a)(1)(A) of the [FDCA] because that product was not commercially marketed in the United States as of February 15, 2007." *Id.* In reaching this "conclusion," FDA conveyed its final position rather than tentative or nonbinding guidance.

43. The SE Directive set forth vague and subjective criteria for determining whether a label change renders a tobacco product "distinct" and thus a "new tobacco product" requiring FDA pre-approval:

> Whether a product with a label change results in a distinct product *depends on the circumstances*. Some types of changes that might result in a distinct product are changes to logo, identifiable patterns of color, product descriptors, or any combination thereof. One consideration would be whether the label change would lead consumers to believe that the product is different from the predicate. Therefore, when a company changes the label of a tobacco product, *FDA believes it is a new product if consumers are likely to perceive it as "new" by virtue of the different label*.

Id. at 4 (emphases added).

44. As an example, the SE Directive states that changing the background color of a tobacco product's label from green to red "may result in a distinct product," but changing the background color from white to cream "may not result in a distinct product." *Id.* (capitalization

omitted). The SE Directive further states that changing the logo image on a label from a star to a lion "may result in a distinct product," but changing from a larger lion to a smaller lion "may not." *Id.* (capitalization omitted).

45. In addition, the SE Directive is silent regarding how FDA intends to review these label changes. This is not surprising, given that Congress did not contemplate such review of the product label as part of the substantial equivalence process and thus provided no criteria for it.

46. The SE Directive creates an entirely new regulatory framework to implement FDA's newly proclaimed authority to pre-approve changes to tobacco product labels. Among other requirements, it instructs Plaintiffs and other tobacco product manufacturers to submit a new type of substantial equivalence report when they change only the label of a tobacco product and not the tobacco product itself: "If a product is new because it is distinct, but the product has the same characteristics as the predicate tobacco product, then the manufacturer . . . may opt to submit a 'Same Characteristics SE Report' (e.g., the name or logo of the tobacco product is modified in a way that makes it distinct)." *Id.*

47. Neither the TCA nor any other statute or regulation mentions or otherwise contemplates a "Same Characteristics SE Report." Also, because the Draft Guidance never mentioned this reporting framework, the public did not have an opportunity to provide input on FDA's chosen regulatory approach.

48. The SE Directive contemplates that, after a Same Characteristics SE Report is filed, FDA will determine whether the relabeled product is "substantially equivalent" to the predicate product. Under the SE Directive, manufacturers cannot change a tobacco product label in a manner that makes the product "distinct" without first submitting a Same Characteristics SE Report and obtaining a substantial equivalence order from FDA.

49. The SE Directive sets forth two discretionary exceptions. First, for "provisional" tobacco products—i.e., products on the market pending FDA's decision on SE reports submitted before March 22, 2011—the SE Directive states, unless and until FDA finds the underlying provisional product to be not substantially equivalent, that "FDA does not intend to object to the commercial distribution of a new product, that is distinct from, but has the same characteristics as, a product subject to a 'provisional' SE Report" as long as the manufacturer submits a Same Characteristics SE Report and then waits 90 days before implementing the label change. *Id.* at 8. Second, a manufacturer that has already changed the label of a grandfathered or provisional product currently on the market can continue marketing the relabeled product, but only if the company submits a Same Characteristics SE Report within 30 days of issuance of the SE Directive—i.e., by April 3, 2015. *Id*. at 8-9

b. Product Quantity Changes

50. The SE Directive also announces that "FDA has determined that the introduction of a product for which the product quantity in the package has changed . . . , even if the per weight composition of additives, ingredients, and other features remains the same, renders it a new product . . . because the characteristics (*e.g.*, amounts of ingredients) have changed." *Id.* at 9-10 (footnote omitted). In reaching that "determination," FDA conveyed its final position rather than tentative or nonbinding guidance. That final position is new; FDA did not set it forth in the Draft Guidance or elsewhere. According to the SE Directive, absent a discretionary exception by FDA, the manufacturer cannot market this "new tobacco product" unless the Agency approves through the premarket authorization or substantial equivalence process.

51. The SE Directive requires another new report for these changes: "[W]e have determined that changes to product quantity (when all other product characteristics remain the same) will require a reduced set of information in order for FDA to determine whether the new

product is substantially equivalent within the meaning of section 910(a)(3)." *Id.* at 10. By reaching that "determination" and setting forth those "requirements," FDA conveyed its final position rather than tentative or nonbinding guidance.

52. The SE Directive goes on to describe in detail the information required in this "Product Quantity Change SE Report," including "[s]cientific data demonstrating that the change in product quantity is not likely to alter consumer use behavior of the new product compared to the predicate product." *Id.* at 11-13.

53. Neither the TCA nor any other statute or regulation mentions or otherwise contemplates a "Product Quantity Change SE Report." Also, because the Draft Guidance never mentioned this reporting framework, the public did not have an opportunity to provide input on FDA's chosen regulatory approach.

54. As with label changes, FDA stated that it "does not intend to object to the commercial distribution of a new product that has a different product quantity than, but is otherwise identical to" a provisional product, as long as the manufacturer does not implement the quantity change "until 90 days after FDA's receipt of the complete Product Quantity Change SE Report." *Id.* at 13-14. For grandfathered or provisional products with a changed product quantity already on the market, the manufacturer can continue marketing the product, with the changed quantity, conditioned on submission of a Product Quantity Change SE Report within 30 days after issuance of the SE Directive—i.e., April 3, 2015. *Id.* at 14-15.

VIOLATIONS OF LAW

A. The SE Directive Conflicts With the TCA's Structure and Text and With FDA's Prior Interpretations of the Statute

1. FDA's Position That Changes in the Label Can Render a Tobacco Product "New" Conflicts With the Structure of the TCA

55. The TCA authorizes FDA to require pre-authorization of tobacco product labels in two specific and narrow circumstances: first under TCA § 911 when a manufacturer proposes to claim in the label that the product presents a "modified risk"; and second under § 903 when FDA requires prior approval by regulation. The sweeping label pre-approval regime established in the SE Directive falls within neither of these circumstances. It is not limited to modified risk products under TCA § 911, the first statutory exception. And the SE Directive was not issued through a notice-and-comment rulemaking, which the APA requires for a regulation promulgated under § 903(b), the second statutory exception. In addition, FDA lodges this new regime for label changes in the substantial equivalence process, which was intended to deal with changes in the tobacco product, not in the product's label. FDA thus has upended Congress's carefully calibrated statutory structure. While the TCA addresses the physical characteristics of tobacco products and their labels in different provisions, and subjects them to different regulatory frameworks, the SE Directive commingles them in one amorphous process. At every juncture, the SE Directive is at odds with the statutory structure that Congress intended.

56. The SE Directive also purports to find authority for pre-market authorization of labels in TCA § 910, which requires marketing authorization orders for new products. If § 910 provided this claimed authority, then § 903(b)—which requires promulgation of a regulation for pre-market approval of labels—would be superfluous.

2. FDA's Position That Changes in the Label Can Render a Tobacco Product "New" Conflicts With the Text of the TCA

57. The SE Directive not only conflicts with the structure of the TCA, but also with the plain statutory text. The SE Directive conflates the "tobacco product" and the tobacco product's "label," even though FDA has conceded that the "label" is not part of a "tobacco product." SE Directive at 3.

58. Specifically, the SE Directive asserts that a product that is physically identical to a previous product but with a label change can fall within the definition of a "new tobacco product" under TCA § 910(a)(1)(A), which provides that a new tobacco product is "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007." SE Directive at 3. According to the SE Directive, a tobacco product with a label change that makes it "distinct" was not previously marketed and is therefore a "new tobacco product" subject to premarket review under the TCA. *Id.*

59. The words "distinct" and "label" appear nowhere in the definition of "new tobacco product." The part of the definition on which FDA now relies instead turns on whether a particular "tobacco product" was commercially marketed in the United States in 2007. TCA § 910(a)(1)(A). FDA has concluded that the term "tobacco product," as defined in the TCA, does not include the product's label. SE Directive at 3. A change in the label therefore does not change the "tobacco product." If a manufacturer changes the label of a "tobacco product" that was commercially marketed in the United States as of February 15, 2007, it is still the same "tobacco product" that was marketed on that date; the product simply has a different label. There is, accordingly, no basis in § 910(a)(1)(A) of the TCA for FDA to require pre-approval of that label change.

60. FDA's position also conflicts with the TCA's description of the substantial equivalence pathway to new product authorization. A new tobacco product is substantially equivalent to a predicate product if the new product has the "same characteristics" as the predicate. TCA § 910(a)(3)(A). Under the SE Directive, a label change that makes a product "distinct" renders it a new product and hence requires substantial equivalence review, even if the product's "characteristics remain the same." SE Directive at 3. But if the characteristics of the tobacco product itself remain the same, the products with the old label and the new label by definition are substantially equivalent. In other words, under FDA's theory, the label change would trigger a substantial equivalence process in which a finding of substantial equivalence is preordained. Congress did not authorize such a meaningless and superfluous regulatory exercise.

3. FDA's Position That Changes in the Label Can Render a Tobacco Product "New" Conflicts With FDA's Own Prior Interpretations of the TCA

61. FDA itself previously adopted different interpretations of the TCA's provisions that are fundamentally incompatible with its SE Directive:

a. FDA's November 2009 guidance, "Listing of Ingredients in Tobacco Products," stated that "packaging differences that do not affect the characteristics" of the tobacco product do not create "distinct products" requiring a separate listing of the product's ingredients, even if the brand or sub-brands were different. As FDA used the term in the November 2009 guidance, "packaging" plainly encompassed the product label. In contrast, the SE Directive now states that differences in the label can render a product "distinct," setting off a whole new regulatory process.

b. FDA's January 2011 guidance, "Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products," lists the information required in an SE report on pages 8 to 12. It does not include anything about the product's label. If FDA at that time had regarded review of the label as part of the SE process, the guidance at a minimum would have required the manufacturer to include a copy of the label in an SE report.

c. FDA's September 2011 Draft Guidance stated that the label was "part" of a tobacco product. The SE Directive, however, concedes that "FDA carefully reconsidered this policy" and has now "concluded that a label is not a 'part' of the tobacco product." SE Directive at 3.

4. Changes to the Product Quantity Do Not Render a Product "New"

62. The SE Directive asserts that a tobacco product that is offered for commercial distribution in a changed quantity is a "new tobacco product" because "the characteristics (e.g., amounts of ingredients) have changed." SE Directive at 9-10.

63. In FDA's view, when a manufacturer distributes samples of a smokeless tobacco product at a "qualified adult-only facility," using smaller cans containing a reduced quantity of smokeless tobacco as explicitly mandated by TCA § 102(a)(2)(G) and FDA regulations, 21 C.F.R. § 1140.16(d)(2)(iv), the company has created a "new tobacco product" requiring FDA pre-approval. *See* SE Directive at 11 (a change in product quantity "may occur where . . . the weight of [the] smokeless package would change, e.g., from 24 grams to 5 grams").

64. FDA's view is incorrect. While a product's ingredients and their relative proportions are encompassed within the term "tobacco product," a change in product quantity does not change the product's ingredients—identical ingredients are used in identical proportions to make the same "tobacco product." A change in quantity in and of itself likewise does not change any other characteristics of the product.

65. The SE Directive also improperly requires manufacturers to demonstrate in a Product Quantity Change SE Report that the product quantity change is not likely to alter consumer use of the product with the changed quantity compared to the product without a change in quantity. The TCA explicitly provides that manufacturers submit information on the behavioral aspects of tobacco use in applications for premarket authorization and for approval of modified risk products. *See* TCA §§ 910(c), 911(g)(2). But Congress did not require such

information with regard to the substantial equivalence pathway to market. That omission was purposeful and reflects Congress's intent that substantial equivalence be a more streamlined process than premarket authorization.

B. The SE Directive Improperly Imposes Legal Obligations Without the Requisite Notice-and-Comment Rulemaking

66. Even though it was issued as a "guidance" document, the SE Directive sets forth FDA's final positions, establishes legal obligations and makes them binding by subjecting tobacco product manufacturers to the risk of enormous penalties (including seizure of entire product lines found "adulterated" or "misbranded") and the credible threat of prosecution for non-compliance.

67. The SE Directive further promulgates a new regulatory scheme with new pathways to product approval and new reporting requirements with specific filing deadlines. The SE Directive emphasizes that manufacturers failing to meet the new requirements would be in violation of the FDCA, with the attendant risk of penalties. *See, e.g.*, SE Directive at 3 (emphasizing that a new tobacco product that does not satisfy the requirements of the FDCA will be considered adulterated and misbranded). In this respect and others, the SE Directive clearly reflects FDA's expectation that manufacturers will immediately conform to its requirements or face potential legal consequences. To the extent that the Same Characteristics SE Reports and Product Quantity Change SE Reports have been filed by the SE Directive's 30-day deadline, the coercive force of this threat is established despite FDA's lack of authority to impose that requirement. The SE Directive is therefore a substantive rule disguised as a guidance document.

68. Because the SE Directive is a substantive rule purporting to establish label pre-approval requirements, it should have been issued subject to notice-and-comment rulemaking as required by the APA and as contemplated by Congress's use of the word "regulation" in § 903(b)

of the TCA. Had FDA followed those procedures, tobacco manufacturers and other interested persons could have shared their views with FDA, and FDA could have assessed the shortcomings in its statutory interpretation, the serious First Amendment problems, the lack of clear standards, and the other fundamental flaws in the SE Directive.

69. Even on its own terms, the SE Directive violates the FDCA, 21 U.S.C. § 371(h), and regulations, 21 C.F.R. § 10.115, governing FDA's use of guidance documents. The changes between the 2011 Draft Guidance and the 2015 SE Directive were substantial. For example, the SE Directive abandoned FDA's prior erroneous interpretation of "new tobacco product" in the Draft Guidance and adopted a new (albeit equally erroneous) interpretation. The 2011 Draft Guidance also said nothing about Same Characteristics SE Reports or Product Quantity Change SE Reports. Because these changes were more than minor, the FDCA and regulations required FDA to issue the SE Directive as another draft guidance.

C. The SE Directive Violates the First Amendment

70. Product labels—which, by definition, are displays of written, printed or graphic matter—and brand names are speech protected by the First Amendment.

71. The SE Directive imposes an impermissible prior restraint on protected speech. Under FDA's view, if a manufacturer makes a label change that renders the product "distinct" from its predicate, the manufacturer cannot market the product without FDA's prior authorization. FDA is thus preventing manufacturers from communicating with consumers through the product label, unless FDA first grants permission.

72. FDA's prior restraint on speech lacks all of the safeguards the Constitution requires to obviate the dangers of censorship as well as arbitrary and irrational decision-making by FDA.

a. There is no deadline for FDA's substantial equivalence determination and thus no time limit on the prior restraint for communications on labels used with non-provisional products. For provisional products, the prior restraint lasts for at least 90 days.

b. For both provisional and non-provisional products, the SE Directive fails to provide the requisite narrow, objective, and definite standards to guide FDA's review.

c. For both types of products, the SE Directive does not describe at all the review FDA will undertake while the prior restraint is in force.

d. For both types of products, the SE Directive does not identify any standards FDA will apply in determining whether the label change ultimately should be approved.

e. For both types of products, the SE Directive places the burden on manufacturers to demonstrate that speech should be permitted, rather than on FDA to show that speech should be suppressed.

f. For both types of products, the SE Directive fails to provide an assurance of a prompt and final judicial determination, and fails to place the burden on FDA to institute judicial proceedings in which the constitutionality of the restraint is adjudicated.

73. FDA's restraint on speech does not advance a substantial, much less a compelling, government interest, is far broader and longer in duration than necessary, and lacks any meaningful procedural or substantive safeguards to cabin FDA's decision-making. The SE Directive does not explain why FDA believes these new pre-market requirements for label changes are necessary, particularly given that Congress chose to grandfather certain underlying tobacco products in the market when the TCA was enacted and exempt these products from FDA review, and to permit the continued marketing of underlying provisional products unless and until FDA determines them to be not substantially equivalent. Nor does the SE Directive explain what FDA intends to do with the newly required Same Characteristics SE Reports, or why

FDA's existing enforcement authority under the TCA is inadequate to address any concerns regarding product labels.

74. FDA's restraint on speech is speaker-based because it applies only to manufacturers of tobacco products. It is content-based because it applies only to specific label changes to tobacco products.

75. Nor does the SE Directive provide Plaintiffs notice of the standards FDA will apply in determining which label changes make a product "distinct" and therefore subject to FDA pre-approval. That determination, the SE Directive states, "depends on the circumstances," including consumers' perception of a label change. SE Directive at 4. While consumer perception is described as "[o]ne consideration," *id.*, the SE Directive does not disclose what other considerations FDA may apply. This unworkably vague and subjective standard leaves Plaintiffs to guess about whether a label change triggers FDA's pre-approval requirement.

76. If Plaintiffs guess incorrectly and fail to file a report for a label change that in FDA's view triggered the pre-approval requirement, FDA can treat subsequent sales of the product as illegal. This would subject Plaintiffs to severe penalties, including product seizure, injunctions, civil penalties with potential enhancements multiplying the impact, and criminal sanctions.

77. The SE directive both compounds the vagueness and escalates the potential penalties by requiring in every Same Characteristics SE Report a sworn certification from a "responsible official who is authorized to act on behalf of the company." SE Directive at 7. The responsible official must attest that "there is no modification, except for [the label or quantity change] from the predicate tobacco product, including any change in materials, ingredients, design features, heating source or any other features." *Id.* In addition, the certification must

acknowledge the official's and the company's exposure to criminal penalties under 18 U.S.C. § 1001 for any "materially false, fictitious, or fraudulent statement to the Government." *Id.* Yet despite requiring this intimidating recital, FDA admits that the TCA does not define some of the operative terms used in the certification, such as "materials," "design features" and "other features," which the official nonetheless must attest have not changed. *Id*. at 19.

78. The SE Directive thus injects intolerable uncertainty and risk into Plaintiffs' marketing of their products, which will chill Plaintiffs and other manufacturers from exercising their First Amendment right to communicate with consumers through product labels.

79. Because the SE Directive establishes vague and imprecise standards for FDA to apply in determining which label changes are subject to FDA pre-market review, the SE Directive vests FDA with intolerably vague and standardless discretion in making decisions that affect Plaintiffs' First Amendment rights.

D. The SE Directive Imposes Concrete Injury and Hardship on Plaintiffs

80. Plaintiffs manufacture hundreds of tobacco products. Depending on FDA's vague and unstated interpretation of what causes a label change to make a tobacco product distinct, Same Characteristics SE Reports purportedly would be required for many of them.

81. Plaintiffs, like other consumer product manufacturers, frequently modify the labels of their products to communicate with consumers about their products.

82. Plaintiffs currently have label changes in various stages of development, from those that are ready to be introduced to those anticipated for release in the coming months.

83. Plaintiffs collectively manufacture hundreds of "provisional" tobacco products that currently would be subject to a minimum 90-day ban on label changes. Plaintiffs therefore cannot make any label changes to those products that would render them "distinct" from the

product under substantial equivalence review without submitting a Same Characteristics SE Report to FDA and then waiting at least 90 days before introducing the label change.

84. With respect to grandfathered products and those provisional products for which FDA issues a substantial equivalence order, Plaintiffs are prohibited from commercially marketing those tobacco products with "distinct" label changes for an indefinite period of time, until FDA determines that the relabeled product that is the subject of the Same Characteristics SE Report is substantially equivalent.

85. If history serves as a guide, it could take FDA many months or years to rule on Same Characteristics SE Reports seeking FDA pre-approval for label changes. FDA has been criticized for its delays in acting on SE reports. *See* U.S. Gov't Accountability Office, GAO-13-723, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process* 22 (2013). To date, FDA has not ruled on thousands of SE reports submitted in 2011.

86. The SE Directive also harms Plaintiffs by subjecting them to a pre-authorization requirement and other unauthorized regulatory burdens whenever Plaintiffs change the quantity of tobacco product in a package, even when the TCA and FDA regulations mandate the change.

CLAIMS FOR RELIEF

COUNT I

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

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

88. The SE Directive is "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). The APA further

proscribes agency action "in excess of statutory jurisdiction, authority, or limitations." *Id.* § 706(2)(C).

90. The TCA differentiates between the regulation of the "tobacco product," on the one hand, and the tobacco product's "label," on the other hand. The "label" is not part of the "tobacco product." Changing a tobacco product's label therefore does not result in a "new tobacco product" subject to FDA pre-approval under the TCA. The TCA instead permits FDA to require pre-authorization of label changes in only two narrow circumstances, neither of which applies here.

91. The SE Directive broadly requires the pre-authorization of all label changes that supposedly render a non-provisional tobacco product "distinct" from its predicate because the label change results in a "new tobacco product." For provisional products, the SE Directive likewise requires that manufacturers submit a Same Characteristics SE Report and then wait at least 90 days before introducing such a label change.

92. The SE Directive is arbitrary, capricious, and contrary to the TCA, and also exceeds FDA's authority under the TCA, because it conflicts with the TCA's structure and text and with FDA's prior interpretations of the TCA. In addition, the SE Directive is arbitrary and capricious because it does not adequately inform manufacturers which label changes may render a product "distinct" and therefore subject to FDA pre-approval.

93. Similarly, the SE Directive is arbitrary, capricious, and contrary to the TCA, and also exceeds FDA's authority under the TCA, because changing the product quantity in a package does not result in a "new tobacco product" subject to FDA pre-approval under the TCA.

94. By requiring pre-authorization of product quantity changes on the theory that such changes result in a "new tobacco product," and by requiring that manufacturers submit data on

behavioral aspects of tobacco use, the SE Directive is arbitrary, capricious, and contrary to the TCA, and also exceeds FDA's authority under the TCA.

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

96. Plaintiffs have no adequate remedy at law.

97. The SE Directive has imposed harm on Plaintiffs, and also imposes definite impending future harm on Plaintiffs.

98. This Court accordingly should declare that the SE Directive is unlawful and set it aside. *See* 5 U.S.C. § 706(2).

COUNT II

(Violation of Administrative Procedure Act, Section 903(b) of the TCA, 21 U.S.C. § 371, and FDA's Good Guidance Practices: Failure to Comply with Procedures Required by Law)

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

100. The APA proscribes agency action that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D); *see id.* § 706(2)(A) ("not in accordance with law").

101. FDA issued the SE Directive without observing the procedure required by multiple laws:

a. The SE Directive sets forth final agency positions, imposes legal obligations, establishes severe consequences for non-compliance, and effects changes in existing law, and accordingly is a substantive rule that required FDA to conduct notice-and-comment rulemaking under the APA. *See* 5 U.S.C. § 553(b)(3)(A).

b. The SE Directive requires premarket authorization of statements made on the label of a tobacco product. Section 903 of the TCA provides that such requirements can be established only by regulation, which requires notice-and-comment rulemaking under the APA, 5 U.S.C. § 553(b)(3)(A).

c. The SE Directive sets forth "interpretations of statutory or regulatory requirements" and "changes in interpretation or policy that are of more than a minor nature," and therefore FDA was required under 21 U.S.C. § 371 and FDA's own Good Guidance Practices regulations, 21 C.F.R. §§ 10.115(c)(i), (ii), to provide an opportunity for public comment.

102. FDA violated the statutory and regulatory requirements governing guidance documents by making material changes to its 2011 Draft Guidance without issuing the SE Directive as a draft subject to public comment. 21 U.S.C. § 371; 21 C.F.R. §§ 10.115(c)(i), (ii).

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

104. Plaintiffs have no adequate remedy at law.

105. Because FDA promulgated the SE Directive without observing procedures required by law, this Court should vacate it as unlawful.

COUNT III

(Violation of First Amendment to the U.S. Constitution: the SE Directive Impermissibly Restricts Protected Speech)

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

107. Product labels contain commercial speech protected by the First Amendment.

108. The SE Directive prohibits manufacturers from changing the label of a tobacco product without first obtaining FDA's pre-authorization (or, with respect to "provisional" tobacco products, without submitting a Same Characteristics SE Report and then waiting at least 90 days). This is an unconstitutional violation of Plaintiffs' First Amendment right to communicate with consumers through product labels. The SE Directive does not directly serve a substantial, much less compelling, government interest, is far broader and longer in duration than necessary, and lacks any meaningful procedural or substantive safeguards to cabin FDA's decision-making authority.

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

110. Plaintiffs have no adequate remedy at law.

111. As a result, the SE Directive violates the First Amendment to the U.S. Constitution and should be set aside. See 5 U.S.C. § 706(2)(B).

COUNT IV

(Violation of First and Fifth Amendments to the U.S. Constitution: the SE Directive Is Unconstitutionally Vague)

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

113. The SE Directive restricts communications in tobacco product labels "if a product's label is modified in any way that renders the product distinct from the predicate." SE Directive at 3. The SE Directive does not give manufacturers fair notice of the label changes that may result in a "distinct" product subject to FDA pre-approval. Nor does the SE Directive articulate clear standards that prevent arbitrary and discriminatory enforcement by FDA officials applying the SE Directive.

114. The uncertainty generated by the SE Directive chills Plaintiffs' exercise of their First Amendment right to communicate with consumers through product labels because, if Plaintiffs make a label change without submitting it for FDA pre-approval and FDA thereafter concludes that the change rendered the product "distinct," they will be subject to significant civil and criminal penalties.

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

116. Plaintiffs have no adequate remedy at law.

117. As a result, the SE Directive violates the First and Fifth Amendments to the U.S. Constitution and should be set aside. See 5 U.S.C. § 706(2)(B).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter judgment in their favor and:

a. Declare that the SE Directive is arbitrary, capricious, or otherwise not in accordance with law, and exceeds FDA's authority, in violation of the APA;

b. Declare that the SE Directive impermissibly restricts protected speech in violation of the First Amendment to the Constitution;

c. Declare that the SE Directive establishes restrictions on protected speech that are vague, overbroad, and lacking in procedural safeguards, in violation of the First and Fifth Amendments to the Constitution;

d. Declare that the SE Directive was issued without notice-and-comment rulemaking, in violation of the APA and the TCA, and in violation of the statutory and regulatory requirements governing guidance documents;

e. Vacate and set aside the SE Directive;

f. Enter a permanent injunction restraining Defendants from implementing or enforcing the SE Directive;

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

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

Dated: April 14, 2015

Respectfully Submitted,

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