UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Philip Morris USA Inc., *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil No. 15-cv-1590 (APM)**
United States Food and Drug Administration, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

In 2009, Congress passed the landmark Family Smoking Prevention and Tobacco Control Act ("TCA" or "the Act"). Under the TCA, Congress made the United States Food and Drug Administration ("FDA") the "primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." It granted the FDA the authority to "set national standards" regarding tobacco, gave the agency "new and flexible enforcement authority," and aimed to "ensure that the FDA has the authority to address issues of particular concern to public health officials."

One of the central features of the TCA is the requirement that a tobacco company secure approval from the FDA before it commercially markets a "new tobacco product," as defined by the Act. A tobacco company can obtain such premarket approval through one of two pathways. First, a sponsor of a "new tobacco product" can show that its new product is "substantially equivalent" to an existing, "predicate" product, which has been grandfathered under the Act. Or, a sponsor can submit a premarket approval application with the FDA. That process, which is more

rigorous than substantial equivalence review, requires the product sponsor to submit a bevy of information about the product, including its health risks, to the agency.

The issue of what constitutes a "new tobacco product" rests at the heart of this matter. Specifically, the case presents two questions:

- First, does a modification of an existing product's label that renders the product label "distinct" from its predecessor create a "new tobacco product," such that the newly labeled product is subject to FDA approval through the substantial equivalence review pathway?
- Second, does a change in the quantity of an existing product create a "new tobacco product," such that the new-quantity product is subject to FDA approval through the substantial equivalence review pathway?

In September 2015, the FDA issued a final industry Guidance which answered both questions "yes." According to the FDA, a distinct labeling change or a quantity change to an existing product results in a "new tobacco product," which triggers the need for a showing of substantial equivalence before the product can be commercially marketed.

Plaintiffs—the country's leading tobacco companies[1]—say the FDA is wrong. In their view, neither a label modification nor a quantity change creates a "new tobacco product" and therefore neither type of alteration triggers the substantial equivalence review process. Further, Plaintiffs contend that the Guidance must be vacated because the FDA failed to adopt it through the appropriate public notice-and-comment process.

The court agrees with Plaintiffs in part and disagrees with them in part. The court concludes that, under the TCA, a modification to an existing product's label does not result in a

[1] Plaintiffs include Philip Morris USA Inc.; U.S. Smokeless Tobacco Company LLC; R.J. Reynolds Tobacco Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; and ITG Brands, LLC.

"new tobacco product" and therefore such a label change does not give rise to the Act's substantial equivalence review process. Accordingly, the FDA's Guidance as it relates to labeling changes is contrary to the law and cannot stand. On the other hand, the court concludes that a change to an existing product's quantity does result in a "new tobacco product" and therefore does trigger the Act's substantial equivalence review process. The court further finds that the FDA's Guidance is not a legislative rule and thus was not subject to the demands of notice-and-comment rulemaking. Accordingly, in regards to quantity change, the court concludes that the Guidance need not be vacated.

The court therefore (1) denies Defendants' Motion to Dismiss, (2) grants in part and denies in part Defendants' Motion for Summary Judgment, and (3) grants in part and denies in part Plaintiffs' Motion for Summary Judgment. The FDA's industry Guidance shall be vacated insofar as it interprets a labeling change as creating a "new tobacco product" under the TCA. The Guidance will stand in all other respects. This matter is remanded to the FDA to effectuate the court's decision.

II. BACKGROUND

A. Factual Background

1. The Family Smoking Prevention and Tobacco Control Act

Over fifty years ago, Congress began to regulate the production, advertisement, and sale of tobacco products. *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 518 (6th Cir. 2012) (providing an overview of major legislation regarding tobacco industry practices). Not until the last decade, however, did the FDA become a significant part of that framework.

The FDA's regulatory role began with a misstep. In 1996, the FDA attempted to bring the tobacco industry within its jurisdiction by asserting that nicotine was a "drug" as defined under

the Food, Drug, and Cosmetic Act. That endeavor failed, however, when the Supreme Court determined that the FDA had exceeded its statutory authority and struck down its attempts at regulation. *See generally FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

Thirteen years later, in 2009, Congress granted the FDA the power it lacked. The Family Smoking Prevention and Tobacco Control Act ("TCA or "the Act") amended the Federal Food, Drug, and Cosmetic Act to make the FDA the "primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31 (2009) [hereinafter TCA], § 3(1). Congress passed the TCA after finding, among other problems, that "Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products." *Id.* § 2(7). Congress further noted that, "[b]ecause past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed." *Id.* § 2(6). By enacting the TCA, Congress hoped to deal with these issues, in part, by allowing the FDA to "set national standards" regarding tobacco, providing it with "new and flexible enforcement authority," and ensuring that it had "the authority to address issues of particular concern to public health officials." *Id.* § 3(2)-(4).

The statutory scheme established by the TCA is quite comprehensive. It addresses a broad variety of issues—*e.g.*, the standards governing the adulteration of tobacco products, *id.* § 902; the standards governing the flavors and additives in tobacco products, *id.* § 907; the availability of judicial review, *id.* § 912; the jurisdiction of the Federal Trade Commission, *id.* § 914; and the establishment of a scientific advisory committee, *id.* § 917. Only a few of the Act's provisions are

at issue here. They concern the various obligations and restrictions imposed on tobacco companies in regard to introducing new products into the commercial market, as well as the FDA's authority to regulate such products. The court turns first to the pertinent statutory definitions and then explains the TCA's relevant premarket approval-related regulatory scheme.

2. Key Definitions

Tobacco Product. At its core, the TCA revolves around a single object: a "tobacco product." All of the regulatory authority granted to the FDA under the TCA was based on Congress' desire to control the production, sale, and distribution of that single item. Its definition, therefore, is critical to the functioning of the Act. Per the TCA, a "tobacco product" is defined as:

> [A]ny product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

Id. § 101(a). The definition of "tobacco product" is notable in that it refers only to the product's physical characteristics. As discussed below, Congress separately defined the related—and often integrated—elements of a "package" and a "label."

New Tobacco Product. If a tobacco product is at the core of the TCA, the definition of a "new tobacco product" is at the core of this case. That term's definition is critical to the regulatory powers granted to the FDA because, if a tobacco product is "new," it cannot be commercially marketed unless first approved by the FDA. *Id.* § 910. A "new tobacco product" is defined under the TCA 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). Thus, Congress placed beyond the FDA's premarket approval authority any tobacco product that was commercially marketed before February 15, 2007. In this opinion, such products shall be referred to as "existing" or "predicate" products. Modifications to such products, as will be seen, may be subject to the TCA's premarket approval requirements, depending on the nature of the modification.

Package. The TCA also defines, and thus treats as distinct from a "tobacco product" itself and its "label," the product's "package." The Act defines "package" to mean "a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers." TCA § 900(13).

Label. Congress did not define the term "label" under the TCA, because Congress already had defined it under the Federal Food, Drug, and Cosmetic Act, which the TCA amends.

> The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

21 U.S.C. § 321(k). The related term "'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). The word "article," as used in the definition, refers to the "tobacco product" itself.

3. Key Statutory Sections

Having set out the definitions central to the parties' dispute, the court turns to the pertinent statutory provisions.

Premarket Review. Under Section 910 of the TCA, unless exempted under the statute, a "new tobacco product" must first receive FDA approval before it can be introduced or delivered into interstate commerce. *See generally* TCA § 910. The Act sets forth two pathways—one more rigorous than the other—by which a new tobacco product can secure such premarket approval.

The less rigorous route for a new tobacco product to receive premarket approval requires the tobacco product sponsor to file a "report" that the new tobacco product is "substantially equivalent" to an existing product. The existing or "predicate" product must have been "commercially marketed . . . in the United States as of February 15, 2007," and be "in compliance with the requirements of [the] Act." *Id*. § 910(a)(2)(A); *see also id.* § 905(j) (describing report requirements). A new tobacco product is "substantially equivalent" to the predicate tobacco product if it:

> (i) has the same characteristics as the predicate tobacco product; or
>
> (ii) has different characteristics and the information submitted [in the substantial equivalence report] contains information, including clinical data if deemed necessary by the Secretary, 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. § 910(a)(3)(A)(i)-(ii). The TCA defines "characteristics" to mean "the materials, ingredients, design, composition, heating source, or other features of a tobacco product"—in other words, the physical characteristics of the product. *Id.* § 910(a)(3)(B). If the FDA finds that the new tobacco product is substantially equivalent to the predicate, it must issue an order allowing the product to be commercially marketed.

Section 905 sets forth the timing for filing a substantial equivalence report. If a company seeks approval for a new tobacco product through the substantial equivalence process, it must submit a report demonstrating that the product is "substantially equivalent, within the meaning of section 910," to a predicate product, "at least 90 days prior" to commercially marketing the new product. *Id.* § 905(j)(1). The report shall be "in such form and manner as the [FDA] shall prescribe." *Id.*

If a product cannot qualify for the substantial equivalence pathway, it must traverse a more rigorous pathway known as "premarket review" to obtain FDA approval. Although that process is not directly implicated in this case, the court describes it for purposes of completeness. The premarket review process requires the sponsor of the new tobacco product to submit an application that describes, among other details, the physical makeup of the tobacco product, the manufacturing process used to create it, and the health risks of such product. *Id.* § 910(b). The application also must contain samples of the tobacco product and its components, as well as "specimens of the labeling proposed to be used for such tobacco product." *Id.* § 910(b)(1)(E)-(F).

Upon receipt of the application, the FDA on its own initiative, or based upon the applicant's request, may refer the application to a Tobacco Products Advisory Committee for a recommendation. *Id.* § 910(b)(2). The FDA must act within 180 days of receiving a premarket review application. *Id.* § 901(c)(1)(A). If the FDA decides to deny a premarket review application, it be must for one of four reasons delineated in the statute. Those reasons include: (1) a failure to show that the marketing of the product would be appropriate for public health; (2) a manufacturing, processing, or packing process that does not conform to statutory requirements; (3) a false or misleading label; or (4) a lack of conformity with standards set for tobacco products under Section 907 of the TCA. *Id.* § 910(c)(2).

Finally, the TCA vests the FDA with discretion to exempt a new tobacco product from the need to obtain regulatory approval if the new product "would be a minor modification" of an existing product. *Id.* §§ 910(a)(2)(ii), 905(j)(3)(A)(i). To qualify for the exemption, the new tobacco product must have been created "by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive." *Id.* § 905(j)(3).

Preapproval of Label Modifications. In two different sections, the TCA addresses the FDA's authority to preapprove tobacco label—as distinct from tobacco product—modifications. The first such grant of authority is found in Section 903, which generally concerns the misbranding of tobacco products. Much of Section 903 addresses the labeling and packaging required to prevent tobacco products from being deemed "misbranded"—the information required, the appropriate conspicuousness of such information, etc. *See generally id.* § 903. The section also grants the FDA the authority to require tobacco companies to submit certain types of label changes for approval. *Id.* § 903. Specifically, Section 903(b) states that

> [t]he Secretary [of Health and Human Services] 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 [TCA].

Section 903(b) (emphasis added). All parties agree that the term "by regulation" means a regulation promulgated through notice-and-comment rulemaking. *See, e.g.*, Dr. Tr. of June 9, 2016 Oral Arg., ECF No. 42 [hereinafter Dr. Tr.], at 7:11-7:16, 7:24-8:4, 8:16-8:19, 24:1-24:4, 68:14-68:22.

The second section of the TCA that authorizes the FDA to preapprove a label change is Section 911, which addresses "modified risk tobacco products." TCA § 911. A "modified tobacco product" refers to those tobacco products "sold or distributed for use to reduce harm of the risk of

tobacco-related disease associated with commercially marketed tobacco products." *Id.* § 911(b)(1). More specifically, this includes tobacco products

> (i) the label, labeling, or advertising of which represents explicitly or implicitly that
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> (I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
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> (II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
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> (III) the tobacco product or its smoke does not contain or is free of a substance;
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> (ii) the label, labeling, or advertising of which uses the descriptors 'light', 'mild', or 'low' or similar descriptors; or
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> (iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the [TCA], respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

Id. § 911(b)(2)(A)(i)-(iii). Essentially, therefore, a "modified risk tobacco product" is defined by the content of its label. And the FDA is mandated to "require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information." *Id.* § 911(h)(1). No modified risk product can be sold unless the FDA grants approval of the label after reviewing an application for the sale of such product. *See id.* § 911(a), (g).

Registration and Product Listing Requirements. The TCA also provides in Section 905 a mechanism by which the FDA can identify the companies and products involved in tobacco-related

commerce. First, every individual or company that produces a tobacco product must register with the FDA. *Id.* § 905(a)-(i). Each registered entity must provide a list of all tobacco products which they "manufacture[ ], prepare[ ], compound[ ], or process[ ] . . . for commercial distribution." *Id.* § 905(i)(1). For any product on the list that is subject to a tobacco product standard under Section 907 or is a new tobacco product under Section 910, "a copy of all labeling for such tobacco product" must accompany the list. *Id.* § 905(i)(1)(A). For any other product on the list, "a copy of all consumer information and other labeling for such tobacco product" must accompany the list. *Id.* § 905(i)(1)(B).

Twice yearly, in June and in December, registered tobacco companies must provide an updated list of products to the FDA. That list must include any previously unreported products; any discontinued products; any previously discontinued products once again being produced; and "any material change in any information previously submitted [in a report under the section]." *Id.* § 905(i)(3). As noted, if an updated list includes a "new tobacco product" under section 910, a copy of the labeling must be included. *See id.* §§ 905(i)(1)(A), 905 (i)(3)(A).

4. The FDA's Industry Guidances

The 2011 Draft Guidance. The seeds of this lawsuit were planted nearly five years ago. In September 2011, the FDA issued a document entitled "Draft Guidance for Industry and FDA Staff: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" ("Draft Guidance"). *See generally* Joint Appendix [hereinafter J.A.], ECF No. 41, at 083-095. The Draft Guidance was intended to address frequently received questions regarding the term "new tobacco product" and the consequences flowing from that designation. *Id.* at 085.

Perhaps most significantly, according to the Draft Guidance, "[a] change to *any part* of a tobacco product after February 15, 2007 makes that product a 'new tobacco product.'" *Id.* at 087 (emphasis added). The FDA based its interpretation on the second half of the definition of "new tobacco product," *id.* at 087, which covers "any modification (including a change in design, any component, any part, or any constituent . . . or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product," TCA § 910(a)(1)(B). "The label and packaging of a tobacco product," the FDA concluded, "is considered a 'part' of that product." J.A. at 087. Thus, according to the FDA, a change to a product's label created a new tobacco product. *Id.* at 087-089.

In response to that interpretation of the Act and the FDA's invitation for comment, some of the Plaintiffs submitted comments disputing the validity of the FDA's conclusions. *See, e.g.*, *id.* at 121-127 (submitting comments on behalf of Philip Morris USA and US Smokeless Tobacco Company LLC, and arguing that the FDA's position was foreclosed by the "text, context, and purpose" of the TCA).

The First Substantial Equivalence Guidance. Three and a half years after issuing the Draft Guidance, on March 4, 2015, the FDA issued a new version, entitled "Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" ("First SE Guidance"). *See generally id.* at 061-082 The First SE Guidance varied significantly in two ways from the Draft Guidance.

First, the First SE Guidance abandoned its original position that the word "part," as used to define "tobacco product," included a product's label and packaging. *Id*. at 065 ("After reviewing the comments and information submitted in response to the September 2011 draft guidance, FDA has carefully considered this policy . . . . [and] concluded that a label is not a 'part' of the tobacco

product."). The FDA did not, however, change its view that a distinct label change resulted in a "new tobacco product." Instead, it changed its logic. The FDA reasoned 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 [TCA] because that product was not commercially marketed in the United States as of February 15, 2007." *Id.* at 065. The FDA provided minimal additional explanation regarding its newly advanced interpretation, except to say that "[t]his interpretation is consistent with provisions throughout the [Food, Drug & Cosmetic Act], in which individual tobacco products are distinguished primarily on the basis of brands and subbrands." *Id.* at 066 (footnotes omitted).

The First SE Guidance did attempt to explain how its interpretation should be applied. It noted that "[w]hether a product with a label change results in a distinct product depends on the circumstances." *Id.* It provided examples of alterations that might result in a distinct, new tobacco product, including "changes to logo, identifiable patterns of color, product descriptors, or any combination thereof." *Id.* It further advised companies to consider "whether the label change would lead consumers to believe that the product is different from the predicate"—*i.e.*, whether consumers would believe that the product was new. *Id.* And it included in the First SE Guidance a chart with several examples of "distinct" and "non-distinct" changes. *Id.* For instance, the chart stated that a change in background color from green to red "may result" in a distinct product, but a change from white to cream "may not." *Id.* Similarly, changing the object depicted in a tobacco product's logo from a star to a lion "may result" in a distinct product, but merely reducing the size of the logo "may not." *Id.*

As a consequence of its position that a "distinct" labeling change results in a "new tobacco product," the FDA made clear that tobacco companies would be required to demonstrate the

substantial equivalence of the new tobacco product before marketing it commercially. The First SE Guidance explained how a company could obtain such approval. If a product was "distinct" due to its label, but retained the same physical characteristics as a predicate tobacco product, the First SE Guidance gave tobacco companies the option to submit a newly created type of substantial equivalence report—a "Same Characteristics SE Report"—as an alternative to a full substantial equivalence report. *Id.* at 066. The Same Characteristics SE Report would require the company to submit, among other things, the name, type, and size of both the new tobacco product and the predicate tobacco product; a health information summary; information about any other related substantial equivalence reports; and a certification, signed by a tobacco company official, stating that the only modification was a change to the label and describing that change. *Id*. at 067-069. A tobacco company would not, however, have to submit information about the specific physical characteristics of the new tobacco product or its predicate product. And, critically, nor would it have to submit either the original or the modified label. *Id.*

In addition to addressing the impact of a labeling change, the First SE Guidance also addressed a completely new issue: the impact of a change in product quantity. Like a distinct label change, the FDA stated that a change in product quantity would constitute a "new tobacco product," as defined by the TCA. *Id.* at 071-072. Such a "change in product quantity" could include a change in "the number of portioned parts per package" or a change in the weight of a product, "even if the per weight composition of additives, ingredients, and other features remains the same." *Id.* (footnote omitted). The FDA explained that such changes created a new product "because the characteristics [of the tobacco product] (e.g., amounts of ingredients) have changed." *Id.* at 072.

Similar to the scheme it established for label changes, the First SE Guidance also established an alternative substantial equivalence report for product quantity changes. *Id.* Under this report, called a "Product Quantity Change SE Report," a company would be required to submit nearly the same information as required by the Same Characteristics SE Report, except the certification would have to attest that the only modification to the product was a change in quantity. *Id.* at 073-075. In addition, a company would have to submit "[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 074.

The FDA again indicated that it would accept comments about the latest version of its guidance. *Id.* at 061. And once again, some of the Plaintiffs sent comments disagreeing with the FDA's conclusions. *See generally id.* at 096-120 (submitting comments on behalf of RAI Services Company, which is affiliated with Plaintiffs R.J. Reynolds Tobacco Company, American Snuff Company, LLC, and Santa Fe Natural Tobacco Company, Inc.).

Plaintiff's Challenge to the First SE Guidance. A little over month after the FDA had issued the First SE Guidance, on April 14, 2015, Plaintiffs filed a Complaint in this court, challenging the First SE Guidance on statutory and constitutional grounds. *See* Compl., *Philip Morris USA Inc., et al. v. US FDA, et al.*, No. 15-cv-00544 (APM) (D.D.C. filed Apr. 14, 2015). On May 29, 2015, the FDA announced that it was evaluating comments made in response to the First SE Guidance and would not enforce the First SE Guidance until it either had issued a revised guidance or announced that it would not make revisions. J.A. at 040. As a result, several days later, on June 2, 2015, Plaintiffs voluntarily dismissed their Complaint without prejudice. Compl., ECF No. 1, ¶ 53.

The Second (and Final) Substantial Equivalence Guidance. On September 8, 2015, the FDA released a revised, final version of the First SE Guidance, titled "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)" ("Second SE Guidance" or "Guidance"). J.A. at 001. Although the revised version reached the same conclusions as the First SE Guidance as to how label and quantity changes could result in a "new tobacco product," the revised version offered new justifications for the FDA's position.

The FDA for the first time relied on Section 910(a)(3)(A) of the TCA to assert that a label change could result in a new tobacco product. *Id*. at 007-008. Section 910(a)(3)(A) provides that a product may be found substantially equivalent to a predicate product where the two have the "same characteristics" or where they have "different characteristics . . . and . . . the [new] product does not raise different questions of public health." TCA § 910(a)(3)(A)(i-ii). The TCA, however, defines "characteristics" in terms of a product's physical traits only. *See id.* § 910(a)(3)(B).

Because the process set forth by Congress to determine substantial equivalency distinguishes between "same characteristics " and "different characteristics," the FDA reasoned that Congress must have determined that there would be some new products with *identical* physical attributes as earlier predicate products—that is, the "same characteristics"—that nonetheless would need to be cleared for marketing. J.A. at 008 ("Accordingly, Congress must have contemplated that there would be 'new tobacco products' that were physically identical to predicate products that would be cleared for marketing under the 'same characteristics' prong."). The FDA further reasoned that products with a distinct labeling change—but with physical attributes identical to those of a predicate product—would fall into the "same characteristics" category. *Id.* ("Products that carry new names or label modifications that render the product

distinct, but otherwise have the same physical attributes as a predicate product [would] fall into this category.").

By contrast, the FDA interpreted the "'different characteristics prong of the SE criteria to refer to changes in the physical attributes of the product." *Id.* The FDA claimed that its interpretation was consistent with other provisions of the TCA. *Id*. at 008. With respect to product quantity changes, the FDA's position and rationale remained generally the same as originally stated in the First SE Guidance. *Compare id.* at 018-20 *with id.* at 071-072.

The FDA also announced the manner in which it would enforce the requirement that companies file the newly developed substantial equivalence reports. As relevant here,[2] the FDA stated that it would not take enforcement action against a new tobacco product marketed without agency approval so long as the manufacturer submitted a Same Characteristics SE Report or a Product Quantity Change SE Report and did not commercially distribute the product until 90 days after the FDA's receipt of such report. *Id.* at 015-016, 025. Additionally, for new tobacco products already on the market, the FDA stated that it would not take enforcement action as long as it received a Same Characteristics SE Report or a Product Quantity Change SE Report within 30 days of the Second SE Guidance's issuance date. *Id.*

B. Procedural Background

On September 30, 2015, three weeks after the FDA issued the Second SE Guidance, Plaintiffs filed a new Complaint before this court alleging that the Second SE Guidance is inconsistent with the TCA, violates the substantive and procedural requirements of the Administrative Procedure Act ("APA"), and infringes the First Amendment. *See generally* Compl. One month later, on October 30, 2015, Plaintiffs followed their Complaint with a Motion for

[2] The FDA also addressed how it would exercise its enforcement discretion with respect to other new tobacco products, but those particulars are not material here.

Summary Judgment. *See* Pls.' Mot. for Summ. J., ECF No. 21 [hereinafter Pls.' Mot.]. In response, on December 8, 2015, Defendants filed a Motion to Dismiss, or in the Alternative, Motion for Summary Judgment. *See generally* Defs.' Mot. to Dismiss, or in the Alternative, Mot. for Summ. J., ECF. 29. The court now turns to the merits of the parties' motions.

III. LEGAL STANDARD

A. Motion to Dismiss

In evaluating a motion to dismiss under Rule 12(b)(6), the court must accept a plaintiff's factual allegations as true and "construe the complaint 'in favor of the plaintiff, who must be granted the benefit of all inferences that can be derived from the facts alleged.'" *Hettinga v. United States*, 677 F.3d 471, 476 (D.C. Cir. 2012) (quoting *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979)). The court need not accept as true "a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), or "inferences . . . unsupported by the facts set out in the complaint," *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The factual allegations in the complaint need not be "detailed"; however, the Federal Rules demand more than "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (citing *Twombly*, 550 U.S. at 555). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S.

at 555). If the facts as alleged fail to establish that a plaintiff has stated a claim upon which relief can be granted, a court must grant defendant's Rule 12(b)(6) motion. *See Am. Chemistry Council, Inc. v. U.S. Dep't of Health & Human Servs.*, 922 F. Supp. 2d 56, 61 (D.D.C. 2013).

B. Motion for Summary Judgment

The parties have filed cross-motions for summary judgment. Cross-motions for summary judgment ordinarily are reviewed under the standard set forth in Federal Rule of Civil Procedure 56, which requires a court to grant summary judgment when the pleadings and the evidence demonstrate that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). However, in cases such as this one that involve the review of a final agency action under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.*, the Rule 56 standard does not apply. *See Stuttering Found. of Am. v. Springer*, 498 F. Supp. 2d 203, 207 (D.D.C. 2007). Instead, "the district judge sits as an appellate tribunal" and "[t]he 'entire case' on review is a question of law." *Am. Biosci. Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (citing cases). "[T]he [c]ourt's review is limited to the administrative record," *Fund for Animals v. Babbitt*, 903 F. Supp. 96, 105 (D.D.C. 1995) (citing *Camp v. Pitts*, 411 U.S. 138, 142 (1973)), and its role is limited to "determin[ing] whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did," *see Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (citations and internal quotation marks omitted).

IV. DISCUSSION

A. Ripeness

Before the court turns to the merits of this case, it first must resolve a threshold issue: whether the controversy is "ripe" for judicial resolution. To make this determination, the court

must evaluate (1) the fitness of the issues for judicial consideration and (2) the hardship to the parties if judicial consideration is withheld. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967).

In *Abbott Laboratories*, the Court considered two factors when evaluating whether, as here, a pre-enforcement challenge to an agency action is fit for judicial review. First, it considered whether "the issue tendered is a purely legal one." *Id.* at 149. In this case, "the principal issue presented to the [court is] one of statutory interpretation." *Ciba-Geigy Corp. v. US EPA*, 801 F.2d 430, 435 (D.C. Cir. 1986). Neither side has sought to root their interpretation of the Second SE Guidance in the facts of any specific application of the Guidance; rather, their arguments are premised on the Act's text and structure. *See id.* Nor would factual development help the court decide the issues in question. *See id; see also CSI Aviation Servs., Inc. v. US Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011) ("In the absence of disputed facts that would bear on the statutory question, there [i]s no benefit in waiting for the agency to develop a record before granting judicial review."). Accordingly, the purely legal nature of the issues weighs in favor of judicial review.

Second, the Supreme Court in *Abbott Laboratories* asked whether the issue presented was a "final agency action" under the APA. *Abbott Labs*., 387 U.S. at 149-50; *see also CSI Aviation Svcs.*, 637 F.3d at 412 (describing and applying factors to be considered by the court when determining if the government action at issue constitutes "final agency action"). An action is deemed to be final under the APA when it "mark[s] the 'consummation' of the agency's decisionmaking process" and is "not . . . of a merely tentative or interlocutory nature." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citation omitted). The action must also "be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Id.*

at 178. The Court has described the question of "finality" under the APA as a "pragmatic" one. *Abbott Labs.*, 387 U.S. at 149.

Defendants do not seriously argue that the Second SE Guidance is anything other than "the consummation of the agency's decisionmaking process." *See* Dr. Tr. at 72:15-72:18 (conceding that that FDA has no plans modify the "current thinking as reflected in the [Second SE] Guidance"). Instead, they contend that the Second SE Guidance does not constitute a final agency action because it does not fulfill the second requirement of finality: it does not determine rights or obligations or establish legal consequences. *See* Def.'s Mot. to Dismiss, or in the Alternative for Summ. J., Defs.' Mem. of P&A in Supp., ECF No. 30-2 [hereinafter Defs.' Mot.], at 13-15. The court disagrees.

Defendants' argument starts with the text of the Second SE Guidance itself, which states that the Second SE Guidance "do[es] not establish legally enforceable responsibilities . . . and should be viewed only as [a] recommendation[ ]." J.A. at 004; *see also* Defs.' Mot. at 6, 13 (referencing J.A. at 004). The Guidance further states, within a bolded text box, that it "does not establish any rights for any person and is not binding on FDA or the public." J.A. at 003. Such boilerplate language, however, cannot dictate whether the Second SE Guidance is a final agency action fit for review. *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022-23 (D.C. Cir. 2000) (rejecting the argument that "boilerplate" language in an agency guidance is dispositive as to whether an agency action has legal consequences). Instead, the court must consider the context and form in which the agency action arises.

Non-legislative agency statements of the type at issue here generally do not qualify as a final agency action. *See Am. Tort Reform Ass'n v. Occupational Safety & Health Admin.,* 738 F.3d 387, 395 (D.C. Cir. 2013); s*ee Pharm. Research & Mfrs. of Am. v. US HHS*, 138 F. Supp. 3d 31,

41 (D.D.C. 2015) ("Admittedly, interpretive rules, guidance policies, and other general agency statements that lack the force of law 'generally do not qualify' as a final agency action." (quoting *Am. Tort Reform*, 738 F.3d at 395)). That does not mean, however, that such statements can *never* constitute final agency action. *See Appalachian Power*, 208 F.3d at 1023; *see also Pharm. Research*, 138 F. Supp. 3d at 41. They "'can, as a practical matter, having a binding effect' which contributes to a finding that the action is 'final.'" *Pharm. Research*, 138 F. Supp. 3d at 41 (quoting *Appalachian Power*, 208 F.3d at 1021-22). Courts within this Circuit have undertaken pre-enforcement review of non-legislative rules on a multitude of occasions. *Id.* at 40-41 (collecting cases).

To determine if an agency's interpretive rule or guidance is sufficiently final to warrant pre-enforcement review, the court may consider a host of factors. *Id.* at 41-43. The three most important factors are: (1) whether the agency has taken a "definitive legal position" regarding its statutory authority; (2) whether the case presents a "purely legal question of statutory interpretation;" and (3) whether the action "imposes an immediate and significant practical burden on the regulated entity." *See id.* at 42 (quoting *Ciba-Geigy*, 801 F.2d at 435-437) (internal quotation marks omitted). Here, as discussed, *supra*, the first two factors are easily met.

Slightly more complicated is whether the action imposes a significant burden on tobacco companies. In this case, that factor affecting finality substantially overlaps with the second prong of the ripeness inquiry: hardship on the parties. Defendants contend that the Second SE Guidance creates no significant burden or hardship because it merely provides the FDA's "current thinking" regarding the interpretation of certain sections of the TCA. Defs.' Mot. at 13. Accordingly, Defendants argue, the Guidance places no new obligations on tobacco companies, but rather simply provides information about their preexisting duties under the statute. *Id.*

The fact that the FDA is purporting merely to interpret a statute that vests it with regulatory authority does not mean, however, that its action is not final and therefore unfit for judicial review. *See CSI Aviation Svcs.*, 637 F.3d at 412 (finding final agency action where the Department of Transportation interpreted one of its governing statutes); *see Ciba-Geigy Corp.*, 801 F.2d at 438 ("As this court has repeatedly held before, . . . an agency's interpretation of its governing statute, with the expectation that regulated parties will conform to and rely on this interpretation, is final agency action fit for judicial review." (citation and internal quotation marks omitted)); *Indep. Bankers Ass'n of Am. v. Smith*, 534 F.2d 921, 929 n.29 (D.C. Cir. 1976) (collecting cases). And the "distinction" between whether the statute or the guidance is the actual source of binding authority is "a hollow one without any meaningful difference." *Pharm. Research*, 138 F. Supp. 3d at 44.

Nor is it dispositive that the FDA has not yet pursued or threatened an enforcement action against anyone for failure to comply with the Guidance. Def.'s Mot. at 14-15. Like the regulations challenged in *Abbott Laboratories*, the Second SE Guidance "purport[s] to give an authoritative interpretation of a statutory provision that has a direct effect on the day-to-day business of all" tobacco companies. *Abbott Labs.*, 387 U.S. at 151. Plaintiffs must decide if they can make label and quantity changes without first seeking FDA approval. If they elect not to seek approval, they do so with some risk that the FDA might view their changes as violating the TCA and thus pursue an enforcement action. Because of this dilemma created by the Second SE Guidance, several Plaintiffs have decided to postpone label changes. *See* Pls.' Opp'n to Defs.' Mot. to Dismiss, or in the Alternative, for Summary Judgment, ECF No. 36, at 8-9; Pls.' Mot., Heather Newman Decl., ECF No. 22-2, ¶¶ 6-7; Pls.' Mot., J. Brice O'Brien Decl., ECF No. 23-1, ¶¶ 8-14, 16-18.

The FDA argues that such enforcement is unprecedented and unlikely. Defs.' Mot. at 14-15. Yet the risk of such enforcement is not as remote as Defendants would have the court believe. The FDA described the First SE Guidance "as an interim enforcement policy," and stated that "[t]his policy will be in effect as we consider new comments to the guidance." J.A. at 040 n.1. The First SE Guidance also stated that, "[d]uring the interim enforcement period, FDA does not intend to issue any warning letters or take steps to initiate any judicial or administrative adversarial proceedings for marketing a new tobacco product without required premarket authorization under Section 910" for labeling and quantity changes. *Id.* The clear implication of that statement is that, when the interim enforcement period ends, companies that fail to comply with the Guidance can reasonably expect to receive warning letters from the FDA and face possible enforcement action.

Now that the Guidance is final, the FDA has left no doubt that it intends to rely on its interpretation of the TCA for enforcement purposes. The Second SE Guidance states that the FDA "will not take *enforcement action* against a new tobacco product that is marketed without a required authorization" as long as the product manufacturer delays commercial distribution of the product until 90 days after the FDA has received a Same Characteristics SE Report or a Product Quantity Change SE Report from the company. *Id.* at 016, 025 (emphasis added). For new tobacco products already on the market, the FDA has said that it will not take enforcement action if the product manufacturer files the appropriate abbreviated SE Report within 30 days of the date of the issuance of the Second SE Guidance. *Id.* at 016, 025.

Plainly, in light of the Guidance, tobacco companies are given a choice: either comply with the FDA's interpretation of the TCA by filing the required SE report when making a label or quantity change to their product, or risk a possible "enforcement action." But, of course, that is no real choice at all. The Guidance thus poses an immediate and significant practical hardship to

Plaintiffs. *See CSI Aviation Svcs.*, 637 F.3d at 412 (holding that the DOT's cease and desist letter "put the company to the painful choice between costly compliance and the risk of prosecution at an uncertain point in the future" and that the "conundrum" was "'the very dilemma the Supreme Court has found sufficient to warrant judicial review.'") (citation and internal quotation marks omitted); *see also Pharm. Research*, 138 F. Supp. 3d at 47.

The hardship that Plaintiffs face here is further magnified because the Guidance, at least as it relates to labeling modifications, arguably "chills" their commercial speech rights, *see* Pls.' Mot. at 34-43—a constitutional implication that Defendants do not dispute, Defs.' Reply, ECF No. 38, at 5 (conceding that "courts may apply a more permissive standard for ripeness when violations of the First Amendment are alleged"). *See Chamber of Commerce of the U.S. v. FEC*, 69 F.3d 600, 603-04 (D.C. Cir. 1995) ("A party has standing to challenge, pre-enforcement, even the constitutionality of a *statute* if First Amendment rights are arguably chilled, so long as there is a credible threat of enforcement."). Accordingly, the court finds that "the impact of [the Guidance] upon the petitioners is sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage." *Abbott Labs.*, 387 U.S. at 151.

* * *

Because this case involves final agency action that is fit for judicial consideration, and involves issues of law that, if left unaddressed, would cause significant hardship to Plaintiffs, the court finds that the case is ripe for disposition.

B. Product Label Changes

Having disposed of the threshold question of ripeness, the court now turns to Plaintiffs' challenge to FDA's position that a distinct labeling change renders a tobacco product "new" and

therefore requires its manufacturer to demonstrate substantial equivalence before putting the newly labeled product on the market.

1. The Parties' Positions

Plaintiffs' primary contention is that the FDA's position on labeling changes is inconsistent with the plain text and structure of the TCA. They argue that Congress carefully and narrowly outlined the two circumstances in which the FDA may require premarket approval of a labeling change: (1) where the label presents a modified risk claim, and (2) where a specific preapproval regulation is adopted under notice-and-comment rulemaking. Pls.' Mot. at 6-7, 19. Beyond those two expressly stated instances, Plaintiffs contend, Congress did not allow the FDA to exercise premarket authorization power with respect to a labeling change. *Id.* at 19.

For their part, Defendants defend their interpretation of the TCA on the same grounds set forth in the Second SE Guidance. To recap, Defendants' argument starts with the premise that "new tobacco product" and "substantial equivalence" are related concepts under the TCA that must be construed in tandem. Defs.' Mot. at 23 ("'New tobacco product' and 'substantial equivalence' are related concepts that are defined in the same section of the TCA. . . .Substantial equivalence is relevant only to new tobacco products."). From that premise, Defendants contend that "[t]he definition of 'substantial equivalence' shows that Congress must have contemplated that there would be tobacco products that have the same physical attributes as predicate products"—that is, the "same characteristics"—"but would nonetheless be 'new tobacco products.'" *Id.* at 23.

Defendants reach their conclusion from the fact that the TCA (1) distinguishes between "same characteristics" and "different characteristics" for purposes of defining the two ways in which a manufacturer can show that its new product is substantially equivalent to an existing product, and (2) defines "characteristics" in terms of a product's physical attributes only. *Id.* The

FDA, according to Defendants, "reasonably interpreted 'same characteristics' to mean that the new and predicate products must have identical physical attributes." *Id.* Such an interpretation is reasonable, Defendants urge, in order to give meaning to both the "same characteristics" and "different characteristics" prongs of the substantial equivalence test. A new tobacco product that shares the "same characteristics" as a predicate product—*i.e.*, is physically identical but nonetheless still must be found substantially equivalent—must differ from the predicate product in some way other than its physical characteristics. Such a non-physical-attribute-based difference, according to Defendants, must include a distinct labeling change. *Id.* If it did not, the "same characteristics" prong would be rendered superfluous. Thus, in order to give meaning to the "same characteristics" prong, and therefore the rest of the substantial equivalence section, Defendants argue that Congress must have contemplated that a non-physical-attribute difference, like a labeling change, would create a "new tobacco product."

2. Standards of Statutory Interpretation

When, as here, a court is "asked to rule on an agency's interpretation of a statute it is charged with administering, [the court is required to] undertake the two-step *Chevron* analysis." *R.G. Johnson Co., Inc. v. Apfel*, 172 F.3d 890, 894 (D.C. Cir. 1999) (citing *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-45 (1984). Under the *Chevron* doctrine, courts "have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *United States v. Mead Corp.*, 533 U.S. 218, 228-29 (2001) (quoting *Chevron*, 467 U.S. at 844). However, before a court can determine the deference to be granted an agency's interpretation of a statute it administers, it must first consider "whether Congress has directly spoken to the precise question at issue. If the intent

of Congress is clear, that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43.

If, however, "the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute," *id.*, 467 U.S. at 843, as long as it "appears that Congress delegated authority to the agency generally to make rules carrying the force of law" and the agency exercised this authority when making the rule at issue, *Gonzales v. Oregon*, 546 U.S. 243, 255-56 (2006) (quoting *Mead*, 533 U.S. at 226-27) (citation and internal quotation marks omitted). An interpretation is permissible if it is a "'reasonable' explanation of how an agency's interpretation serves the statute's objectives." *Northpoint Tech., Ltd. v. FCC,* 412 F.3d 145, 151 (D.C. Cir. 2005); *see also Dist. of Columbia v. Dep't of Labor*, No. 14-5132, 2016 WL 1319453, at *4 (D.C. Cir. Apr. 5, 2016) ("[U]nder *Chevron* . . . the fundamental question is not whether we think the [agency]'s interpretation is correct, but whether the [agency]'s interpretation of the [a]ct is at least reasonable in light of any ambiguities in the statute."). "If the agency's construction is reasonable, [courts] defer." *Council for Urological Interests v. Burwell*, 790 F.3d 212, 219 (D.C. Cir. 2015) (citing *Chevron,* 467 U.S. at 842-43). "[A]n explanation that is 'arbitrary, capricious, or manifestly contrary to the statute,' however," cannot be found to be a reasonable explanation. *Northpoint Tech.*, 412 F.3d at 151 (quoting *Chevron*, 467 U.S. at 844).

3. The Court's Interpretation of the TCA

Applying the foregoing framework, the court determines that it need not go beyond *Chevron* step one because Congress' intent is clear from the plain text and structure of the TCA. The court agrees with Plaintiffs that the FDA's interpretation of the TCA, which would permit the

agency to demand a showing of substantial equivalence when a distinct labeling change is made to a product, is foreclosed by the TCA itself.

a. The text of the TCA

"[I]t is elementary that 'no deference is due to agency interpretations at odds with the plain language of the statute itself.'" *Smith v. City of Jackson, Miss.*, 544 U.S. 228, 266 (2005) (citation omitted). The court therefore starts, as it must, with the plain text of the TCA.

Congress clearly knew how to use the word "label" in the TCA. After all, the word "label" or "labeling" appears no less than 150 times in the headings and text of the Act.[3] *See generally* TCA. Yet despite referring to labels throughout the TCA, Congress did not once use that term in the TCA's definition of "new tobacco product" or in the provisions governing substantial equivalence. The court must presume that that omission was purposeful. *See Am. Forest & Paper Ass'n v. FERC*, 550 F.3d 1179, 1181 (D.C. Cir. 2008) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same [a]ct, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983))).

That omission appears all the more purposeful when, in other instances in the very same Act, Congress explicitly required labels to be submitted to the FDA. For instance, Congress required a manufacturer who could not secure approval through a substantial equivalence showing, but instead had to traverse the more rigorous premarket review pathway, to include as part of its premarket review application "specimens of the labeling proposed to be used." TCA

[3] To obtain this count, the court searched for the word "label" as it appears in the text of the TCA. The word "label," or a derivation thereof, appears in the bill's text, including headings, 153 times. Among these references is a section which requires labels on tobacco products that are sold in the U.S. to declare "Sale only allowed in the United States." TCA § 920(a). There are multiple provisions regarding the appropriate labeling for "modified risk" tobacco products. *Id.* § 911(b). There is even an entire title of the TCA wholly dedicated to setting forth a regulatory scheme addressing, in great detail, the restrictions governing the size, style, and content of tobacco product labels. *See id.*, Title II, §§ 201-206.

§ 910(b)(1)(F). Congress also expressly empowered the FDA to reject a premarket review application if "the proposed labeling is false or misleading in any particular," a power that is noticeably absent in connection with substantial equivalence review. *Id.* § 910(c)(2)(C).

Elsewhere, Congress required manufacturers to submit labels and label changes to the FDA so that it could monitor tobacco products entering and exiting the marketplace. For example, the TCA requires tobacco companies when they first register with the FDA to submit a list of products "manufactured, prepared, compounded, or processed" for commercial distribution. *Id.* § 905(i)(1). For most products on that list, the tobacco companies also must submit a copy of the product's label. *Id.* § 905(i)(1)(A)-(C). The original list of products must be updated bi-annually, *id.* § 905(i)(3), and if a tobacco company adds a new tobacco product to the list, it must include a copy of the new product's label, *id.* § 905(i)(3)(A) (requiring that the listing of a new tobacco product "be accompanied by the other information required by paragraph 1"). The fact that Congress used the word "label" and required the submission of labels in various provisions of the TCA in order to enable the FDA to approve and monitor tobacco products—but not in connection with substantial equivalence review—demonstrates that Congress did not mean for a labeling change to trigger such review.

Finally, it is important that none of the actual terms that Congress used to define the term "new tobacco product"—and thus to initiate substantial equivalence review—can be read to encompass anything other the physical attributes of the product itself, as distinct from its label or the package in which it is contained. Section 910(a)(1)(A) defines a new tobacco product as "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007." *Id.* § 910(a)(1)(A). A "tobacco product," in turn, is defined only by the product's physical traits. *See* 21 U.S.C. § 321(rr)(1) (defining 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"); *see also* J.A. at 065 (stating that the FDA has concluded that a label is not a "part" of a tobacco product). Section 910(a)(1)(B) defines "new tobacco product" also to include "any modification" to a tobacco product commercially marketed after February 15, 2007. The term "modification" is described parenthetically to "include[e] 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." TCA § 910(a)(1)(B). Again, all of those terms refer only to the physical attributes of a tobacco product—not its labeling or packaging.

Simply put, if a Congress that used the words "label" and "labeling" over 150 times in the TCA wanted a substantial equivalency report to be submitted when changes were made to a tobacco product's label, it easily could have made that clear by using the defined term "label" that otherwise appears throughout the Act. That the term does not appear even once in the Act's "new tobacco product" definition or its substantial equivalence provisions—Sections 905(j) and 910(a)—can only be construed to mean that Congress did not intend for a label change to trigger a substantial equivalence showing.

b. The context and structure of the TCA

Although the court's inquiry "begins with the text" of the statute, *W. Minn. Mun. Power Agency v. FERC*, 806 F.3d 588, 591 (D.C. Cir. 2015) (citing *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004)), it may also consider "the specific context in which th[e] language [at issue] is used, and the broader context of the statute as a whole," *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). *See also Boumediene v. Bush*, 553 U.S. 723, 776 (2008) ("When interpreting a statute, [the court] examine[s] related provisions in other parts of the U.S.

Code."). The structure of the TCA only confirms the conclusion compelled by the plain text of the statute.

Congress clearly delegated to the FDA the authority to regulate label changes in other sections of the Act. Section 903(b) of the TCA gives the FDA broad power to, "by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate . . . provisions of the [TCA]." TCA § 903(b). Congress thus enabled the FDA, through notice-and-comment rulemaking, to require a tobacco company that changes its product's name or logo to submit the change to the FDA for premarket approval. Yet these are the same types of changes that the Guidance asserts must trigger substantial equivalence review, or otherwise render the FDA powerless in the face of a label change. Additionally, under Section 911, Congress gave the FDA similar authority over the labels placed on "modified risk tobacco products," which are those "sold or distributed for use to reduce harm of the risk of tobacco-related disease associated with commercially marketed tobacco products." *Id.* § 911(b)(1). No modified risk product can be sold unless the FDA grants approval of its label. *Id.* § 911(a), (g)-(h).

It is significant that Congress expressly spelled out in two different sections—Sections 903 and 911—the power that the FDA has with respect to premarket approval of tobacco product labels. Yet, Section 910—the very section from which the FDA claims to derive its authority in this case—is utterly silent regarding the FDA's ability to subject a labeling change to substantial equivalence review. Surely that was purposeful. It is simply too far-fetched to believe, as Defendants insist, that the same Congress that expressly made labeling changes trigger FDA review in some sections of the TCA, at the same time intended to provide the same or similar authority through an unintuitive, creative reading of Section 910. As the Supreme Court has stated, "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or

ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (citations omitted).

4. Defendants' Interpretation Does Not Withstand Scrutiny

Defendants' reading of Section 910 is unconvincing for yet another reason. As discussed above, Defendants' interpretation is rooted in the Act's definition of "substantial equivalence." Recall, under Section 910, a tobacco company can demonstrate substantial equivalence by showing that the new tobacco product and its predicate either (1) have the "same characteristics" or (2) have "different characteristics" and the new product does not raise different questions of public health. All parties agree that the Act defines "characteristics" only in terms of the physical elements of a tobacco product. The nub of the parties' disagreement is whether, as Defendants argue, Congress intended "same characteristics" to mean "identical characteristics." Pls.' Mot. at 13-14; Defs.' Mot. at 23-24. That assumption cannot, however, be squared with another provision of the Act.

Under Section 905(j), the FDA "may exempt" a new tobacco product from making a substantial equivalency showing if the product is "modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive," and the FDA determines that

> (i) such modification would be a minor modification of a tobacco product that can be sold under [the TCA];
>
> (ii) a [substantial equivalence] report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and
>
> (iii) an exemption is otherwise appropriate.

TCA § 905(j)(3)(A)(i)-(iii). This exemption for "minor modifications" cannot be squared with Defendants' reading of "same" characteristics as meaning "identical" characteristics. Congress

plainly meant to exclude from a substantial equivalence showing some new products that, although possessing *different* physical characteristics than their predicate product, did not raise sufficient health risks to warrant an FDA review. That being so, Congress surely did not intend, as Defendants argue, for products with *identical* physical characteristics, and thus with previously known effects, to be subject to a more intensive substantial equivalency showing under the "same characteristics" prong. To conclude otherwise would be illogical.

Further, it is not reasonable to think that Congress intended to channel all non-exempt physical modifications through the "different characteristics" prong. If it had wanted such a result, it would have said so expressly. Instead, it created a less burdensome "same characteristics" prong that seemingly was intended for physical changes that were more than "minor," but yet not so significant so to require a showing, through clinical data if demanded, that "the product does not raise different questions of public health." *Compare id.* § 910(a)(3)(A)(i), *with id.* § 910(a)(3)(A)(ii).

Such a reading finds support in the provenance of TCA's substantial equivalence provision. Congress incorporated into the TCA, with some modifications, the substantial equivalence provisions of the Medical Device Amendments to the Food, Drug & Cosmetic Act (the "Medical Device Amendments"). *See* S. Rep. No. 105-180, at 23 (1998) (stating that the definition of "substantial equivalence" "is largely the same as in [the Medical Device Amendments] with a few modifications"). The Medical Device Amendments, like the TCA, created two tiers of substantial equivalence review, one for products with the "same technological characteristics" and the other for products with "different technological characteristics." 21 U.S.C. § 360c(i)(1)(A). The term "different technological characteristics" was defined to mean "a *significant change* in the materials, design, energy source, or other features of the device from those of the predicate device."

Id. § 360(c)(i)(1)(B) (emphasis added). "When Congress uses the same language in two statutes having similar purposes, particularly when one is enacted shortly after the other, it is appropriate to presume that Congress intended that text to have the same meaning in both statutes." *City of Jackson*, 544 U.S. at 233 (citation omitted)). Accordingly, the court finds it is reasonable to conclude, as Plaintiffs have argued, that Congress intended for "different characteristics" as used in the TCA likewise to mean a "significant" change in characteristics.

Defendants take issue with this reading. They contend that Congress made two substantive changes to the TCA that make it inapt for the court to derive meaning from the Medical Device Amendments. First, Congress eliminated the adjective "technological" to modify "characteristics." And, second, unlike the Medical Device Amendments, Congress chose not to expressly define "different characteristics" in the TCA. Defs.' Mot. at 29. Neither of those arguments is persuasive. True, Congress eliminated the modifier "technological" from the TCA; but it made clear that the word "physical," though not explicitly used, was the intended substitute modifier for "characteristics." After all, the TCA defines "characteristics" only in terms of a tobacco product's physical elements.

Additionally, the fact that Congress did not specifically define "different characteristics" in the TCA—it only defined the term "characteristics"—does not compel the conclusion that Congress intended the term to have a wholly different meaning than the term "different technological characteristics" as used in the Medical Device Amendments. Rather, because Congress (1) used the identical words "same" and "different" to modify "characteristics" and (2) used those words to distinguish between the two substantial equivalence pathways in both the TCA and the Medical Device Amendments, it is reasonable to conclude that Congress intended for the term "different" to have a similar meaning in both statutes. *See City of Jackson*, 544 U.S.

at 233. Accordingly, the "same characteristics" prong may encompass similar, but not necessarily identical, products, while the "different characteristics" prong may cover significantly different products.

5. The Purported Gap in FDA's Oversight

Defendants also contend that the court must reject Plaintiffs' reading of the TCA because otherwise there would be a gap in the FDA's oversight authority. Specifically, Defendants argue that, under Plaintiffs' reading, a tobacco company simply could rename, repackage, and relabel an existing product and begin to commercially market it and "FDA would have no means of knowing that the product is intended to be physically identical to a lawful predicate." Defs.' Mot. at 27. Furthermore, the FDA might not even come to learn of the commercial marketing of such a "new" product until the seller files its bi-annual report with the FDA. Thus, Defendants' argue, "Plaintiffs' interpretation of the statute would thwart what even they concede is a 'central feature' of the TCA." *Id.* at 28 (quoting Pls.' Mot. at 4).

Defendants' argument, though not without some appeal, ultimately fails. The purported gap in oversight that would be created by adopting Plaintiffs' reading is not as great as Defendants contend. After all, the TCA itself provides a mechanism for the FDA to oversee the kind of wholesale name and labeling changes it fears that tobacco companies could undertake without regulatory approval. Rulemaking under Section 903(b) would enable the FDA to preapprove such name and logo changes and thereby avoid the surprise of a refashioned existing product hitting the market with the FDA's knowledge. Plaintiffs generally concede that the FDA has such authority under Section 903(b). Dr. Tr. 23:2-24:10. Admittedly, under the statutory scheme, the FDA might not be able to demand that such a refashioned product demonstrate substantial equivalence before becoming commercially available. But that gap is not fundamentally at odds with the statutory

scheme. Indeed, Congress did not even require that every change to an existing tobacco product's *physical* components would trigger a substantial equivalence review. TCA § 905(j)(3). It is thus consistent with the TCA's broad regulatory scheme to permit a labeling change—even a distinct one—to go without substantial equivalence review.

* * *

Accordingly, for the reasons stated, the court concludes that the Second SE Guidance's interpretation of the TCA as mandating substantial equivalence review for a distinct labeling change is contrary to the TCA and is thus unlawful. Because the court has found in favor of Plaintiffs at *Chevron* step one, it need not address their remaining arguments under the APA or the First Amendment.

C. Quantity Changes

The court next turns to Plaintiffs' challenge to the FDA's position in the Second SE Guidance that a change in product quantity results in a new tobacco product that is subject to premarket review under Section 910. J.A. at 018-020. For example, according to the Guidance, if the number of cigarettes in a pack is increased from 20 to 24, the resulting 24-pack constitutes a new tobacco product. *Id.* at 018-019. Much like its actions involving label changes, the FDA created a new, streamlined "Product Quantity Change SE Report" for such product quantity changes. *Id.* at 018-024.

Plaintiffs contest Defendants' conclusions regarding quantity changes on two grounds. Pls.' Mot. at 43-45. First, Plaintiffs argue that the FDA's interpretation conflicts with the text and structure of the TCA. They focus on each individual portion within a tobacco product and argue that none of these portions is changed when the overall quantity is altered. To illustrate their point, they offer the following example: "*A* cigarette included in a package of 20 cigarettes has the

identical 'amount of ingredients, materials, and other features' as an identical cigarette that comes in a package of 24 cigarettes." *Id.* at 44 (emphasis added). They further argue that the fact that the Product Quantity Change SE Report requires information regarding consumer use of the new tobacco product is inconsistent with Congress' decision not to collect such information regarding the behavioral aspects of tobacco use in substantial equivalence reports. *Id.* And, finally, they contend that the FDA's interpretation is at odds with the statutory requirement that smokeless tobacco samples are to be distributed in smaller packs. *Id.* at 45.

Second, Plaintiffs contend that the product-quantity change requirement is arbitrary and capricious under the APA. *Id.* In particular, they argue that the Second SE Guidance improperly imposes binding legal obligations on the tobacco companies through a guidance document, rather than through notice-and-comment rulemaking. *Id.* The court considers each argument in turn.

1. Interpretation of the TCA

a. The text of the TCA

The court's evaluation of the FDA's product-quantity change interpretation is relatively straightforward and merely requires looking to the plain text of the TCA. Section 910 states that a "new tobacco product" is created when there is "*any* modification . . . of a tobacco product." TCA § 910(a)(1)(B) (emphasis added). Congress' use of the word "any" suggests that even the slightest change to the physical components of an existing tobacco product would create a new tobacco product. Thus, any alteration to a predicate product's quantity would modify that product and therefore result in a new tobacco product that, unless subject to the exemption under Section 905(j)(3), would have to show substantial equivalence before being commercially marketed.

Further, Section 910 specifically provides that a modification may include "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." *Id.* The statute does not define the words "design" or "content," so the court will apply their ordinary meaning. *See Smith v. United States*, 508 U.S. 223, 228 (1993) ("When a word is not defined by statute, [the court] normally construe[s] it in accord with it ordinary or natural meaning.") (citations omitted). "Design" means "the way something has been made: the way the parts of something . . . are formed and arranged for a particular use, effect, etc."[4] "Content" means "the amount of specified material contained: proportion."[5] Based on these definitions, a plain reading of the text makes clear that a change in quantity constitutes a "modification" to a tobacco product's "design" and its constituent parts, including the "content" of nicotine.

Simple examples are illustrative. Say a tobacco company wishes to increase the volume of tobacco product inside a tin from one to three ounces. That increase in product quantity constitutes a change in the product's "design"—there are more of the product's constituent parts, including "the content . . . of nicotine" and "any other additive or ingredients." The same is true, to take Plaintiffs' example, of a cigarette pack that increases from 20 to 24 cigarettes. The tobacco product in that case is not the individual cigarette, but the sum of the component parts of all cigarettes contained within that package. Thus, when more cigarettes are added, there is an increase, or change, in the amount of nicotine and other additive or ingredients and thus a change in the product's "design" and "content." Put simply: an increase or decrease in quantity necessarily entails a change in the amount of the constituent ingredients and additives within a tobacco product, including nicotine. It is a modification of the tobacco product. Accordingly, the court has little trouble concluding that a change in quantity creates a new tobacco product that triggers

[4] "Design," Merriam-Webster Dictionary, http://www.merriam-webster.com/dictionary/design (last visited Aug. 16, 2016).
[5] "Content," Merriam-Webster Dictionary, http://www.merriam-webster.com/dictionary/content (last visited Aug. 16, 2016).

premarket or substantial equivalence review. And, because Congress has delegated to the FDA the authority to determine the "form and manner" in which substantial equivalence reports shall be submitted as part of this review, TCA § 905(j)(1), the FDA's Product Quantity Change SE Report also falls within the bounds of the statute.

b. The context and structure of the TCA

Although the court need look no further than the text to conclude that the FDA is correct in its determination that quantity changes create new tobacco products, the court finds that the structure and context of the TCA also support such a reading. *See Robinson*, 519 U.S. at 341. First, Congress indicated that a major reason for enacting the TCA was to reduce tobacco use in children and adolescents. TCA §§ 2(1), (4)-(6), (14)-(18), (20)-(28), (31)-(32). And, according to unchallenged information in the Second SE Guidance, the quantity or size of a tobacco product can affect the initiation and cessation behaviors of youth. The Guidance states:

> Smaller product quantities may allow for increased product uptake due to lower barriers to trying the product, are associated with lower product harm perceptions, and reduce product costs or increase product availability, all of which may affect use intentions and behavior, including initiation among youth. Large product quantities can potentially reduce cessation behaviors and increase tobacco product use among current users. Additionally, changes in product quantity may make the product appear novel to consumers, increasing appeal and lowering harm perceptions, both of which may lead to increased product use and initiation.

J.A. at 020. Because of the significant effect that changes in product quantity size can have on the behavior of youth, it is reasonable to believe that Congress contemplated that changes in product quantity would create new tobacco products and thus trigger either a premarket application or a substantial equivalence report.

Second, the court finds unpersuasive Plaintiffs' contention that permitting product quantity changes to create new tobacco products is inconsistent with the TCA's requirement that smokeless tobacco samples be distributed in smaller quantities. Pls.' Mot. at 45 (citing TCA § 102). Plaintiffs

appear to argue that because Congress did not require tobacco manufacturers to seek premarket review of these smaller sized samples, it therefore did not intend *any* change in product size to be subject to premarket review. *See* Pls.' Mot. at 45. The court disagrees. Instead, the limitations placed by Congress on sample size and place of sale—samples can be sold only in small sizes at "qualified adult-only facility[ies]," TCA § 102(d)(2)(A), (C)-(D)—lends support to the idea that Congress was cognizant of the impact of product size on behavior.

Accordingly, the court finds that the text, structure, and purpose of the TCA demonstrate that a change in product quantity creates a new tobacco product subject to review.[6]

2. Procedural Requirements

Next, Plaintiffs argue that the Second SE Guidance is a legislative rule which should have been promulgated through notice-and-comment rulemaking. Pls.' Mot. at 45. The FDA's failure to use such a procedure, they claim, violated the APA. *Id.*

The APA obligates agencies to make legislative rules through formal notice and comment, which requires them to publish proposed rules in the Federal Register and accept public comment on those rules for a set period of time. 5 U.S.C. § 553; *see also Appalachian Power*, 28 F.3d at 1021. In contrast, "the APA does not require such notice and comment for interpretative rules, general statements of policy, and rules of organization, procedure, or practice." *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 250 (D.C. Cir. 2014). "It is well-established," however, "that an agency may not escape the notice and comment requirements . . . by labeling a major substantive legal addition to a rule a mere interpretation." *Appalachian Power*, 208 F.3d at 1024.

[6] At oral argument, Plaintiffs indicated that the same First Amendment arguments that they made in relation to the label changes proposed by the FDA also are intended to address the product quantity changes, at least in part. Dr. Tr. at 31:24-3:9. Nowhere in their Complaint or their pleadings, however, do Plaintiffs argue that FDA's product-quantity interpretation violates the First Amendment. Accordingly, the court does not view Plaintiff's challenge to the FDA's product-quantity interpretation as a First Amendment claim.

Whether an agency action is a "substantive rule" or an "interpretive rule" is an area of law that is "quite difficult and confused." *Nat'l Min. Ass'n*, 758 F.3d at 251. The Supreme Court agrees. *Perez v. Mortg. Brokers Ass'n*, 135 S. Ct. 1199, 1203-04 (2015) (noting that the term "'interpretive rule[ ]' is not further defined by the APA, and its precise meaning is the source of much scholarly and judicial debate").

Yet recent clarification by the Supreme Court helps to shed some light on the issue. In *Perez v. Mortgage Brokers Ass'n*, the Supreme Court stated that "it suffices to say that the critical feature of interpretive rules is that they are 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" 135 S. Ct. at 1204 (citation omitted). And in *Shalala v. Guernsey Memorial Hospital*, the Court highlighted the "prototypical example of an interpretive rule issued by an agency [as one] [that] advise[s] the public of its construction of the statutes and rules it administers.'" 514 U.S. 87, 99 (1995).

Applying this Supreme Court precedent, the court concludes that the Guidance is not a legislative rule. The Guidance was issued to inform the public of the FDA's interpretation of the TCA, which is a statute it administers. As discussed above, the product-quantity portions of the Guidance are consistent with the text and structure of the statute. All the agency has done in the Guidance is supply "crisper and more detailed lines than the authority being interpreted." *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). Therefore, no notice-and-comment was required, and the Guidance was issued appropriately.[7]

[7] Plaintiffs also argued that the FDA's interpretation was arbitrary and capricious because it did not consider reasonable alternatives. Pls.' Mot. at 45. But that argument fails as the court already has ruled that Congress clearly intended that a quantity change to an existing product, unless exempted, would trigger substantial equivalence review.

D. Remedy

Having concluded that one part of the Second SE Guidance—the labeling-change interpretation—conflicts with the TCA, but the other part—the quantity-change interpretation—does not, a question arises as to the proper remedy. "Whether an administrative agency's order or regulation is severable, permitting a court to affirm it in part and reverse it in part, depends on the issuing agency's intent." *North Carolina v. FERC*, 730 F.2d 790, 795-96 (D.C. Cir. 1984). "Severance and affirmation of a portion of an administrative regulation is improper if there is 'substantial doubt' that the agency would have adopted the severed portion on its own." *Davis Cty. Solid Waste Mgmt. v. US EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997) (citations omitted). Here, the court harbors no doubt that the FDA would have adopted the product-quantity interpretation set forth in the Guidance separate and apart from the labeling-change interpretation. The court therefore vacates that portion of the Second SE Guidance relating to a labeling change, but affirms that portion relating to a product-quantity change.

V. CONCLUSION

For the reasons discussed above, Defendants' Motion to Dismiss is denied. Defendants' Motion for Summary Judgment and Plaintiffs' Motion for Summary Judgment are granted in part and denied in part. This matter is remanded to the agency for further proceedings, as needed.

A separate Order accompanies this Memorandum Opinion.

Dated: August 16, 2016

Amit P. Mehta
United States District Judge