UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 1:16-cv-01460 (APM)**
	)	
U.S. FOOD AND DRUG ADMINISTRATION, et al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

This matter comes before the court once more on a challenge to aspects of the United States Food and Drug Administration's ("FDA") proposed regulation of pipe tobacco and cigar products, including the category of product known as premium cigars. On May 10, 2016, the FDA published a final rule "deeming" cigars, pipe tobacco, and certain other products (e.g., e-cigarettes) subject to the federal Family Smoking Prevention and Tobacco Control Act of 2009. The FDA's "Final Deeming Rule" subjects these newly deemed products to comparable statutory and regulatory requirements already imposed on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. In a previous opinion, this court addressed, among other things, the Deeming Rule's imposition of health warnings on cigar product packaging and advertising (a decision since reversed by the D.C. Circuit) and the imposition of a user fee on manufacturers and importers of cigar and pipe tobacco products. In this opinion, the court considers six challenges stemming from the FDA's implementation and imminent enforcement of the requirement that manufacturers of new tobacco products covered by the Act obtain premarket authorization from the FDA before

marketing their products.

For the reasons set forth below, the court grants in part and denies in part Plaintiffs' Motion for Partial Summary Judgment, denies as moot Plaintiffs' Motion for a Preliminary Injunction, and grants in part and denies in part Defendants' Cross-Motion for Partial Summary Judgment. In issuing the Final Deeming Rule, the FDA arbitrarily failed to address commenters' requests for a streamlined substantial equivalence process for premium cigars undergoing premarket review. Accordingly, the court remands the Final Deeming Rule for the limited purpose of considering that issue anew and enjoins enforcement of the premarket review requirements against premium cigars during that time. In all other respects, however, Defendants' actions were lawful, reasonable, and adequately explained.

II. BACKGROUND

A. Statutory Background

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("TCA") to "provide authority to the [FDA] to regulate tobacco products . . . by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products," among other purposes. Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781–82 (2009). The legislation immediately subjected "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" to a panoply of statutory and regulatory requirements, and also reserved future application of the TCA to "any other tobacco products that the Secretary [of Health and Human Services] by regulation *deems* to be subject to this chapter." 21 U.S.C. § 387a(b) (emphasis added).

A central feature of the TCA is its "'comprehensive restrictions on the sale, promotion, and distribution' of tobacco products." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 272 (D.C. Cir.

2019) (quoting § 2(6), 123 Stat. at 1777). The TCA therefore requires tobacco product manufacturers to obtain premarket authorization before introducing a "new tobacco product" into interstate commerce. 21 U.S.C. § 387j(a)(1)–(2). A "tobacco product" is "new" if it was not commercially marketed in the United States on or before February 15, 2007, or if it was modified after that date. *Id.* § 387j(a)(1)(A)–(B). By contrast, products already on the market on that date are "grandfathered" and not subject to premarket review. *Nicopure*, 944 F.3d at 271.

The TCA establishes three pathways for manufacturers of new tobacco products to seek premarket authorization. Under the substantial equivalence pathway that most cigar and pipe tobacco manufacturers are expected to use, a manufacturer can submit a report to the FDA showing that its product is "substantially equivalent" to either (a) a product that was marketed on or before February 15, 2007, or (b) a product that has already been found to be substantially equivalent to such a grandfathered product. 21 U.S.C. §§ 387e(j)(1), 387j(a)(2)(A). The report must show that the product either has the "same characteristics"—that is, "materials, ingredients, design, composition, heating source, [and] other features"—as the predicate product, or has "different characteristics" but "does not raise different questions of public health." *Id.* § 387j(a)(3)(A), (B). In addition to these statutory requirements, the report must conform to "such form and manner as the [FDA] shall prescribe." *Id.* § 387e(j)(1). In order for a product to qualify under the substantial equivalence pathway, the FDA must "issue[] an order" finding that the product is substantially equivalent to a qualifying product and is in compliance with Chapter IX of the TCA. *Id.* § 387j(a)(2)(A)(i).

Alternatively, if the FDA concludes that a new tobacco product has been modified in only a "minor" respect from a product that is already permissibly marketed under the TCA, the agency may "exempt" the modified product from "the requirements of this subsection relating to the

demonstration that a tobacco product is substantially equivalent" to another approved product. 21 U.S.C. §§ 387j(a)(2)(A)(ii), 387e(j)(3); *see also Nicopure*, 944 F.3d at 276 n.3. If neither the substantial equivalence nor the "minor modification" exemption pathways are available, the manufacturer must submit a premarket tobacco application ("PMTA"), which requires significantly more information and is therefore most costly and burdensome. *See* 21 U.S.C. § 387j(a), (b); *Nicopure*, 944 F.3d at 276 n.3.

Failure to obtain premarket authorization via an appropriate pathway can carry serious consequences. A tobacco product marketed without appropriate authorization is considered "adulterated" and "misbranded." 21 U.S.C. §§ 387b(6), 387c(a)(6). The FDA can initiate a civil action to enjoin illegal conduct or seize the adulterated and misbranded products, *id.* §§ 332, 334, or it may seek criminal penalties, *id.* § 333.

B. Regulatory Background

1. Proposed Deeming Rule

On April 25, 2014, the FDA issued a proposed rule that would "deem" cigars, pipe tobacco, and e-cigarettes to be subject to the TCA. *See* 79 Fed. Reg. 23,142 (Apr. 25, 2014) ("Proposed Deeming Rule"). In the Proposed Deeming Rule, the FDA proposed two options which "would provide two alternatives for the scope of the deeming provisions and, consequently, the application of the additional specific provisions." *Id.* at 23,143. Under Option 1, the FDA would deem nearly all products meeting the statutory definition of "tobacco product"—including cigars and pipe tobacco—to be subject to the TCA. *Id.* Under Option 2, the FDA would deem "only a subset of cigars" and "exclude from the scope of [the] proposed rule certain cigars that we refer to as 'premium cigars.'" *Id.* To effectuate this carve-out, Option 2 proposed a definition of "premium cigar" as:

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

Id. at 23,150. In explaining why it had proposed an option that might treat premium cigars differently, the FDA stated that "it has been suggested that different kinds of cigars may have the potential for varying effects on public health, based on possible differences in their effects on dual use [with other tobacco products], youth initiation and frequency of use by youth and young adults." *Id.* at 23,143. "Accordingly," the agency said, it "is seeking comment on these options to determine whether all cigars should be subject to deeming and what provisions of the proposed ruled may be appropriate or not appropriate for different kinds of cigars." *Id.*

In addition, regarding premarket review, the FDA sought comment on "what FDA actions or regulatory approaches, if any, should be taken for proposed deemed tobacco products that are 'new tobacco products,'" and whether the agency should "consider a different compliance policy for proposed deemed tobacco products that cannot, as a practical matter, use the [substantial equivalence] pathway." *Id.* at 23,174–76.

2. Final Deeming Rule

The FDA selected Option 1 and promulgated the final Deeming Rule on May 10, 2016, thus deeming all categories of cigars, including "premium cigars," to be subject to the TCA. *See* 81 Fed. Reg. 28,974, 29,020 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143) ("Final Deeming Rule"). The agency "concluded that deeming all cigars, rather than a subset, more completely protects the public health." *Id.*

In the preamble to the Rule, the FDA announced "staggered compliance periods" during which the agency would defer enforcement of the TCA's premarket review requirement for newly deemed tobacco products that were already on the market on the Rule's effective date. *Id.* at 29,011. For products that would require premarket authorization via substantial equivalence reports, the preamble explained that the FDA did not intend to enforce the premarket review requirement for 18 months while manufacturers submitted substantial equivalence reports, and for up to an additional 12 months while the FDA reviewed those reports. *Id.* at 29,010–29,012. The FDA noted that "[t]o help provide clarity regarding submission requirements for marketing applications, FDA has issued several guidance documents, and is finalizing other guidance documents, regarding the evidence needed for [substantial equivalence] reports," and that it would "issue additional guidance" if it determined that "additional guidance is necessary to help manufacturers prepare marketing applications." *Id.* at 29,012.

3. Subsequent Regulatory and Judicial Developments

Just over a year after the FDA finalized the Deeming Rule, and six months following the start of a new administration, the FDA issued a press release describing "a new comprehensive plan for tobacco and nicotine regulation." *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death*, FOOD & DRUG ADMIN. (July 27, 2017) ("July 27 Press Release").[1] The FDA announced three policy changes that are relevant here. First, the agency stated that it "plan[ned] to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers," and, to that end, it would "issue regulations outlining what information the agency expects to be included in . . . reports to demonstrate Substantial Equivalence." Close to two years later, in April 2019, the FDA issued a

[1] Available at https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

proposed rule seeking comments on what should be included in substantial equivalence reports. *See* 84 Fed. Reg. 12,740 (April 2, 2019). That rule is not yet finalized. *See* Tr. of 7/22/2020 Oral Arg. Hr'g [hereinafter Hr'g Tr.], at 6.

Second, the FDA announced that it "plan[ned] to issue guidance" that would "extend timelines to submit tobacco product review applications for newly regulated tobacco products that were on the market as of Aug. 8, 2016." July 27 Press Release. That guidance came quickly but ultimately was doomed. In an August 2017 guidance document, the FDA declared that it would defer enforcement of the premarket review provisions until August 2021 for cigars and pipe tobacco, and until August 2022 for noncombustible products (like many e-cigarettes). *See* Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, 82 Fed. Reg. 37459 (notice of availability) [hereinafter 2017 Guidance]; *see also* Defs.' Cross-Mot. for Partial Summ. J., ECF No. 180, Defs.' Mem. in Opp'n to Pls.' Mot. for a Prelim. Inj. & for Partial Summ. J. & in Supp. of Defs.' Cross-Mot. for Partial Summ. J., ECF No. 180-1 [hereinafter Defs.' Cross-Mot.], at 11–12. A coalition of public health groups and doctors challenged the 2017 Guidance in the District of Maryland, and in May 2019, the court vacated the compliance deadline extensions, concluding that they violated the TCA and were not exempt from the Administrative Procedure Act's notice and comment requirements. *Am. Acad. of Pediatrics v. FDA* ("*AAP*"), 379 F. Supp. 3d 461, 498 (D. Md. 2019). The *AAP* court thereafter ordered the FDA to require that premarket applications be filed by May 12, 2020. *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019). Due to the COVID-19 pandemic, the court extended the application deadline to where it remains today, September 9, 2020. *See* Joint Status Report, Ex. 1, ECF No. 199-1.

Third, the FDA announced in its July 27 Press Release that it intended to issue an advanced

notice of proposed rulemaking ("ANPRM") seeking additional information concerning how "premium" cigars might be defined and how the patterns of use may impact public health. July 27 Press Release. The FDA issued the ANPRM in March 2018, *see* 83 Fed. Reg. 12,901 (Mar. 26, 2018), and the comment period closed in July 2018, *see* Defs.' Cross-Mot. at 11.

To date, the agency has not yet issued a proposed rule regarding premium cigars, *see* Hr'g Tr. at 6; however, with only weeks to go before the September 9 substantial equivalence deadline, the FDA recently indicated its intent to issue premarket enforcement guidance specific to premium cigars. Citing the comparatively low risk of youth smoking initiation for premium cigars, the need for additional research on their public health effects, and the potentially "large influx of premarket applications" for the products, the FDA, on August 5, 2020, requested authorization from the *AAP* court to issue "a guidance" document describing "how manufacturers and importers of premium cigars may, on a case-by-case basis, request deferral of enforcement of the premarket authorization requirement for products meeting the definition of premium cigars set forth in the guidance." *See* Defs.' Notice of Filing of Request for Clarification of Scope of Remedy Order in *AAP v. FDA* with Respect to FDA's Forthcoming Enforcement Guidance on Premium Cigars, ECF No. 209, at PDF pp. 3–4 [hereinafter August 2020 Notice]. In its request, the FDA defines a premium cigar slightly differently than it did in the Proposed Deeming Rule. According to the updated definition, a premium cigar is:

> a cigar that: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units.

Id. at PDF p. 4 n.2. The agency proposes that, if it determines that a premium cigar manufacturer is entitled to a deferral, it will "defer enforcement until it has completed the premium cigar research effort and assessed the results." *Id.* at PDF p. 5. The *AAP* plaintiffs oppose the agency's proposed deferment of enforcement, and briefing on the FDA's request is ongoing. *Id.*; *see also* Tr. of 8/10/2020 Hr'g., ECF No. 213, at 10–11.

C. Procedural Background

The Cigar Association of America, the Premium Cigar Association (formerly known as the International Premium Cigar and Pipe Retailers Association), and Cigar Rights of America (collectively, "Plaintiffs") filed a fourteen-count complaint in July 2016, challenging the Final Deeming Rule and another rule, *see* Compl., ECF No. 1; *see also* Third Am. Compl., ECF No. 184 [hereinafter Third Am. Compl.], ¶ 1.[2] Plaintiffs have amended their complaint three times, *see* Third Am. Compl., and have sought resolution of their claims piecemeal, *see Cigar Ass'n of Am. v. FDA* ("*Cigar I*"), 315 F. Supp. 3d 143 (D.D.C. 2018) (addressing Plaintiffs' challenges to, among other things, the Final Deeming Rule's warning label requirements for cigar and pipe tobacco products and the User Fee Rule), *rev'd in part, appeal dismissed in part sub nom. Cigar Ass'n of Am. v. FDA*, No. 18-5195, 2020 WL 3738096 (D.C. Cir. July 7, 2020); Order, ECF No. 158 (resolving Count X of Plaintiffs' Amended Complaint).

Plaintiffs now seek summary judgment on the following six counts in their Third Amended Complaint, all of which are premised on the Administrative Procedure Act ("APA"), *see* Pls.' Mot. for Summ. J. or a Prelim. Inj., ECF No. 178, Mem. in Supp. of Pls.' Mot. for Summ. J. or a Prelim. Inj., ECF No. 178-1 [hereinafter Pls.' Mot.]:

[2] The other rule, also promulgated in May 2016, but not at issue here, is known as the "User Fee Rule." *See* 81 Fed. Reg. 28,707 (May 10, 2016); 21 C.F.R. § 1150.5.

- Count I: Challenge to the FDA's failure to adjust the TCA's February 15, 2007 grandfather date for cigar and pipe tobacco products, Third Am. Compl. ¶¶ 104–123; Pls.' Mot. at 27–33;

- Count XI: Challenge to the FDA's decision to enforce the TCA's premarket review requirements without first issuing guidance about the substantial equivalence process, Third Am. Compl. ¶¶ 179–190; Pls.' Mot. at 19–23;

- Count XII: Challenge to the FDA's enforcement of the substantial equivalence requirements against premium cigars during the pendency of new rulemaking about those products, Third Am. Compl. ¶¶ 191–199; Pls.' Mot. at 34–38;

- Count XIII: Challenge to the Final Deeming Rule's effective date as being premised on legal error regarding the FDA's discretion to set later compliance dates, Third Am. Compl. ¶¶ 200–213; Pls.' Mot. at 24–26;

- Count XIV: Challenge to the FDA's failure to establish a more streamlined substantial equivalence process for premium cigars, Third Am. Compl. ¶¶ 214–227; Pls.' Mot. at 38–43; and

- Count XV: Challenge to the FDA's cost-benefit analysis with respect to cigars and pipe tobacco, Third Am. Compl. ¶¶ 228–245; Pls.' Mot. at 43–46.

In addition, Plaintiffs seek a preliminary injunction enjoining the FDA's enforcement of the premarket review process against cigar and pipe tobacco products pending the resolution of Plaintiffs' claims. *See* Pls.' Mot. at 46–51. Defendants seek summary judgment in their favor on each count. *See generally* Defs.' Cross-Mot. The court heard argument on the parties' motions on July 22, 2020. *See* Minute Entry (July 22, 2020).

III. LEGAL STANDARD

When reviewing an agency action under the APA, "summary judgment is the mechanism for deciding whether as a matter of law an agency action is supported by the administrative record and is otherwise consistent with the APA standard of review." *Louisiana v. Salazar*, 170 F. Supp. 3d 75, 83 (D.D.C. 2016) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971)). The court must uphold an agency's decision unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The court's

task is determining whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (cleaned up). An agency action is "arbitrary and capricious" and will be set aside if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

IV. DISCUSSION

The court begins its analysis by considering Counts I, XIII, XI, and XV, which apply equally to all cigar and pipe tobacco products. The court then will consider the claims specific to premium cigars only.

A. Challenges Applicable to All Cigar and Pipe Tobacco Products

1. Count I – Challenge to the 2007 Grandfather Date

The TCA requires that, with limited exceptions, all "new tobacco product[s]" must undergo premarket review. *See* 21 U.S.C. § 387j(a)(2). A new tobacco product is defined as "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007," or "any modification . . . of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." *Id.* § 387j(a)(1). To grant a new tobacco product premarket authorization through the substantial equivalence pathway, the FDA must "issue[] an order" finding that the product is "substantially equivalent to a tobacco product commercially marketed . . . in the United States as of February 15, 2007." *Id.* §§ 387j(a)(2); 387e(j)(1)(A). The 2007 look-back date is known as the "predicate"

date, or the "grandfather" date. *See* Pls.' Mot. at 3; Defs.' Cross-Mot. at 16.

During the rulemaking process for the Deeming Rule, commenters expressed concerns that requiring manufacturers of new tobacco products to look back nearly a decade to identify substantially equivalent products would be burdensome for cigar and pipe tobacco manufacturers. *See* Pls.' Mot. at 27–29 (collecting comments). The FDA responded that it did "not believe that we have the authority to alter or amend this grandfathering date, which is set by statute," but it requested comments on whether there were "other legal interpretations of the substantial equivalence grandfather provision that FDA should consider." 79 Fed. Reg. at 23,174, 23,176. After considering comments, the FDA concluded in the Final Deeming Rule that it "lacks authority to change the grandfather date." 81 Fed. Reg. at 28,993.

Plaintiffs now challenge that determination. They contend that the FDA has the authority to adjust the grandfather date, and that it arbitrarily failed to do so for newly deemed cigar and pipe tobacco products. *See* Pls.' Mot. at 27–33. Plaintiffs do not dispute that the statute plainly fixes February 15, 2007 as the grandfather date, but they insist that four other statutory authorities empower the FDA to alter that date by regulation. *See* Pls.' Reply in Further Supp. of Pls.' Mot. & Opp'n to Defs.' Cross-Mot., ECF No. 185 [hereinafter Pls.' Reply] at 32–34. None of those provisions, however, grants the FDA authority to rewrite the statutorily-established date.[3]

First, Plaintiffs cite 21 U.S.C. § 387g(a)(3)(A), which allows the FDA to adopt "tobacco product standards in addition" to certain standards established by Congress, if the agency "finds that a tobacco product standard is appropriate for the protection of the public health." *See* Pls.' Mot. at 30 (citing 21 U.S.C. § 387g(a)(3)(A)). Plaintiffs suggest that the FDA could have used

[3] Plaintiffs contend that the FDA's interpretation is not entitled to *Chevron* deference. *See* Pls.' Mot. at 32. The court need not decide that question, however, as the statute unambiguously does not permit the agency to alter the grandfather date.

this authority "to craft a regulatory scheme that did not include the substantial equivalence process and its 2007 predicate date." *See* Pls.' Reply at 32. However, Section 387g speaks to the FDA's authority with respect to adopting "product standards," and "standard" in that context refers to a tobacco product's "level of quality," which does not naturally encompass the predicate date for substantial equivalence purposes. *See Standard*, CAMBRIDGE DICTIONARY (2020) ("a level of quality")[4]; *Standard*, MERRIAM-WEBSTER (2020) ("something set up and established by authority as a rule for the measure of quantity, weight, extent, value, or quality")[5]; *see also* 21 U.S.C. § 387g(a)(4) (citing as possible "product standards" rules concerning, among other things, nicotine yields; ingredients; testing and measurement of tobacco products; and restrictions on sales). Additionally, Section 387g only authorizes the FDA to impose *additional* requirements on top of those required by Congress; it does not empower the FDA to undo baseline requirements imposed elsewhere in the Act. The premarket review requirements, including the grandfather date, automatically apply once the FDA "deems" a tobacco product to be subject to regulation under Chapter IX of the TCA, *see* 21 U.S.C. §§ 387a(b), 387j(a), and Section 387g provides the FDA no authority to eliminate them.[6] As another court in this District concluded when confronted with a similar challenge to the FDA's failure to adjust the grandfather date, "the statute is clear," and the FDA has "no power to change it." *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 399 (D.D.C. 2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019).

[4] Available at https://dictionary.cambridge.org/us/dictionary/english/standard.

[5] Available at https://www.merriam-webster.com/dictionary/standard.

[6] Insofar as Plaintiffs are actually arguing that the FDA should have regulated cigars and pipe tobacco under Section 387g *in lieu* of deeming the products under Section 387a, *see* Pls.' Reply at 32–33, that argument is not before the court as Plaintiffs are not challenging the FDA's decision to deem the products. Even if the argument were properly presented, however, it would be unavailing. Both Sections 387a and Section 387g are part of Chapter IX of the TCA, and the entire chapter applies only once a product is "deem[ed] to be subject" to the Act. *See* 21 U.S.C. § 387a(b). Thus, the FDA may impose additional tobacco product standards under Section 387g *only* if it has first deemed the product pursuant to Section 387a.

Second, Plaintiffs invoke 21 U.S.C. § 387a(b), which provides that "[t]his subchapter"—i.e., Chapter IX of the TCA—"shall apply . . . to any other tobacco products that the [FDA] *by regulation* deems to be subject to this subchapter." 21 U.S.C. § 387a(b) (emphasis added); *see* Pls.' Mot. at 30–31. Plaintiffs suggest that the power to deem products "by regulation" includes the power to "calibrate the regulatory scheme to newly deemed products, including through the adjustment of the" grandfather date. Pls.' Reply at 33. Not so. As the FDA explains, that power "is an on/off switch that merely authorizes the FDA to subject tobacco products to the requirements of Chapter IX" of the TCA. *See* Defs.' Reply in Further Supp. of Defs.' Cross-Mot., ECF No. 188 [hereinafter Defs.' Reply], at 3. Once a product is "deemed" under Section 387a(b) the baseline premarket review requirements, including the grandfather date, automatically kick in and "may not [be] modif[ied]" by regulation. *Nicopure*, 944 F.3d at 281.

Third, Plaintiffs cite 21 U.S.C. § 387f(a), which provides that "any requirement established by or under section 387b, 387c, 387e, or 387i of this title applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under" the agency's other sources of rulemaking authority in the TCA. *See* Pls.' Mot. at 31. Critically, however, Section 387f(a) does not authorize changes to Section 387j, which includes the February 2007 grandfather date for substantial equivalence reports. *See* 21 U.S.C. §§ 387j(a)(1)(A), (a)(2)(A).

Fourth, Plaintiffs cite 21 U.S.C. § 387e(j)(3), which allows the FDA to exempt from the substantial equivalence requirements products that have been modified in only a "minor" respect from a product that is already permissibly marketed under the TCA. Once again, that provision contains no authority for the FDA to adjust the grandfather date for products that must undergo premarket review.

In sum, the FDA correctly concluded that it cannot alter the grandfather date, and so its

decision not to create a carve out for cigar and pipe tobacco products is "not subject to challenge under the APA." *Nicopure*, 944 F.3d at 282. While the court is sympathetic to Plaintiffs' policy concerns that the 2007 grandfather date is illogical and burdensome for their recently deemed products, the proper place to raise that issue is before Congress.

2. Count XIII – Challenge to the 2016 Effective Date

The FDA's Final Deeming Rule went into effect on August 8, 2016. 81 Fed. Reg. at 28,974, 29,003. To prioritize the FDA's resources and give manufacturers more time to comply, the preamble to the rule announced "staggered compliance periods" during which the FDA would defer enforcement of the TCA's premarket review requirement for most products until roughly 2019. *Id.* at 29,010, 29,014. In Count XIII of their Third Amended Complaint, Plaintiffs contend that the FDA premised the Final Deeming Rule's August 8, 2016 effective date on two faulty legal assumptions: (1) that "it could set later compliance dates for statutory provisions triggered by the deeming decision," and (2) "that it could adjust those compliance dates in the future without further notice-and-comment rulemaking." Pls.' Mot. at 24–25; *see also* Third Am. Compl. ¶¶ 200–13. Plaintiffs source these two alleged legal errors to the ruling in *AAP*, in which the court concluded that the FDA's 2017 Guidance postponing the Final Deeming Rule's compliance dates by multiple years contravened the TCA and was impermissibly issued without undergoing notice-and-comment rulemaking. *See* 379 F. Supp. 3d at 498. Plaintiffs posit that the same errors that the *AAP* court found infected the 2017 Guidance also infected the 2016 Final Deeming Rule, and because the Final Deeming Rule's effective date was premised on those faulty assumptions, the rule itself must be vacated. *See* Pls.' Mot. at 24–26; Pls.' Reply at 26. The FDA responds that Plaintiffs' claim is unreviewable and unavailing on the merits. *See* Defs.' Cross-Mot. at 27.

As a threshold matter, the court rejects the FDA's contentions that Plaintiffs' challenge is

unreviewable. The FDA argues that this challenge is moot because the compliance periods in the Final Deeming Rule elapsed in 2019, and that the compliance periods are not subject to challenge under the APA because they are "committed to agency discretion by law," and they are not final agency action. *See* Defs.' Cross-Mot. at 27–28. But the FDA attacks a straw man. Plaintiffs are challenging the Final Deeming's Rule's effective date, not the compliance periods, and so the reviewability of those compliance periods is not before the court. The agency also contends that Plaintiffs forfeited their challenge by failing to raise it during the notice-and-comment period. *Id.* at 27. However, the purported legal error Plaintiffs have identified was not apparent until the *AAP* court issued its ruling in 2019; Plaintiffs can hardly be faulted for failing to divine the issue three years prior. *See* CHARLES A. WRIGHT, ARTHUR R. MILLER & RICHARD MURPHY, 33 Fed. Prac. & Proc. § 8364 (2d ed. 2020) (explaining that the requirement of issue exhaustion may be excused "where 'issues by their very nature could not have been raised before the agency'" (quoting *Petroleum Commc'ns, Inc. v. FCC*, 22 F.3d 1164, 1170 (D.C. Cir. 1994))).

Nevertheless, the court agrees with the FDA that Plaintiffs' challenge fails on the merits. *See* Defs.' Cross-Mot. at 29–31. First, Plaintiffs incorrectly assert that the *AAP* court "held that the Family Smoking Prevention Act denies the agency the discretion to set later compliance dates for substantial equivalence reports and other premarket review applications, once an agency rule deeming products subject to the Act has taken effect." Pls.' Mot. at 24; *see also* Pls.' Reply at 29. That description overstates the *AAP* court's holding. The *AAP* court was only confronted with a challenge to the 2017 Guidance extending the compliance dates without notice and comment; it had no occasion to rule on the validity of the original compliance dates in the Final Deeming Rule. *See AAP*, 379 F. Supp. 3d at 468–69. Indeed, the parties in *AAP* "agree[d] that the FDA has some discretion to allow for a compliance period for new tobacco products," *id.* at 484, and the court

appeared to share that view, *see id.* at 471 (explaining that "[i]t is undisputed that the FDA has some discretion to . . . permit a compliance period for newly deemed products" (cleaned up)). While the *AAP* decision contains some language that supports the proposition advanced here by Plaintiffs that the FDA lacked the legal authority to establish compliance dates later than the Deeming Rule's effective date, *see, e.g.*, *id.* at 492 (holding that "[t]hrough the August 2017 Guidance, the FDA is abdicating its statutory duty to review new tobacco products in the prompt fashion dictated by Congress"), ultimately that specific issue was not before the *AAP* court. In fact, Plaintiffs themselves admitted as much in their appeal of the *AAP* decision, wherein they argued that the court "never suggested the TCA barred FDA from permitting [the] initial compliance periods" in the Final Deeming Rule. *See* Consol. Opening Br. of Appellants at 63, ECF No. 71, *In re Cigar Ass'n of Am.*, No. 19-2130 (4th Cir. Jan. 23, 2020).[7]

Moreover, another court in this District has expressly held that the FDA's "imposition of a compliance period" in the Final Deeming Rule "did not violate the APA," and that the "agency's decisions about whether to impose a compliance period at all" were not arbitrary. *Nicopure*, 266 F. Supp. 3d at 400. Though the *Nicopure* court was not directly presented with a statutory challenge to the FDA's authority to set later compliance periods, it did observe in dicta that "[t]here is certainly nothing in the statute . . . that would bar" the FDA from "establish[ing] a more manageable timeline" for premarket review. *Id.* at 398. Thus, the *Nicopure* court appears to endorse the FDA's authority to set later compliance periods in the Final Deeming Rule, and the *AAP* court arguably questions that authority, but neither case directly answers the question. This tension reinforces this court's conclusion that the holding in *AAP* should not be read as broadly as Plaintiffs insist. Thus, the central premise of Plaintiffs' challenge—that the FDA erroneously

[7] The Fourth Circuit never reached Plaintiffs' argument because it concluded that Judge Grimm had properly denied Plaintiffs' motion to intervene in that case. *See In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020).

believed it could set compliance dates later than the Final Deeming Rule's effective date—remains unresolved. Nor do Plaintiffs specifically challenge the validity of the compliance dates in this action; rather, they "are challenging the *August 2016 effective date* of the Rule, not the later compliance dates." *See* Pls.' Reply at 27. The court therefore lacks any basis to conclude that the FDA erroneously set the effective date of the Final Deeming Rule based on this purported error.

As for Plaintiffs' second asserted legal error, nothing in the Rule or its preamble suggests that the FDA set the Rule's effective date "on the assumption that the agency could monitor events and adjust [the compliance] dates later, without notice-and-comment rulemaking." Pls.' Mot. at 25. Nor does any portion of the Rule support Plaintiffs' supposition that had the FDA understood that future compliance extensions would require notice and comment, it would have selected a later effective date for the Rule and, by extension, later compliance dates. *See id.* at 26. To the contrary, the FDA insisted that "[b]y providing a date in which the continued compliance period ends, manufacturers will have an incentive to submit a complete application and respond substantively and expeditiously to questions raised during the review process instead of an incomplete or deficient application just to stay on the market indefinitely." 81 Fed. Reg. at 29,011. Further, the FDA expressed that "it would negatively impact public health if FDA were to significantly delay implementation of its premarket requirement authorities after issuance of this deeming rule." *Id.* at 28,997. Thus, it appears that the FDA fixed the Final Deeming Rule's premarket compliance periods with the understanding that they would be firm, and that additional extensions would be considered only on a "case-by-case basis," *id.* at 29,010—a classic and lawful exercise of agency enforcement discretion, *see AAP*, 379 F. Supp. 3d at 493. While it is true that there is some tension between the FDA's stated belief that "[a]gency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking,"

see 81 Fed. Reg. at 29,010, and the *AAP* court's eventual ruling that the compliance dates could not subsequently be adjusted without further notice-and-comment procedures, there is no indication that the agency fixed the premarket compliance dates or the effective date with any intent to freely adjust those dates in the future.

Plaintiffs point to the FDA's statement that it "would 'clarify the compliance periods for manufacturers of newly deemed tobacco products' with revised guidance following publication of the Final Deeming Rule," *see* Pls.' Mot. at 25 (quoting 81 Fed. Reg. at 29,005), but they take that statement out of context. Those compliance periods involved registration and listing requirements, which are governed by a separate statutory framework than premarket review. *See* 81 Fed. Reg. at 29,004–05, 29,006. Plaintiffs also highlight the FDA's assurance that it would "review and revise [its premarket compliance] policy as appropriate," and that if it were to change the compliance periods, it would "provide notice to affected entities." *See* Pls.' Mot. at 26 (quoting 81 Fed. Reg. 29,008). But an agency always may review and revise its earlier pronouncements, whether they be legislative rules or policy statements. That unremarkable statement is too slender a reed to support Plaintiffs' weighty inference that the agency "would necessarily have set a later effective date" had it known that it could not amend its compliance periods in the future without undergoing notice-and-comment rulemaking. *See id.*

In sum, the validity of the Final Deeming Rule's premarket compliance periods remains unresolved, and there is no basis to find that the FDA predicated its setting of the effective date on the assumption it could later extend the compliance periods without notice-and-comment rulemaking. Therefore, Plaintiffs have not shown that the setting of the effective date was "based on [a] faulty legal premise." *See Phillips Petroleum Co. v. FERC*, 792 F.2d 1165, 1171 (D.C. Cir. 1986).

3. *Count XI – Challenge to the FDA's Failure to Issue Substantial Equivalence Guidance*

As part its "new comprehensive plan for tobacco and nicotine regulation," the FDA announced in 2017 that it "plan[ned] to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers," and that it would "issue regulations outlining what information the agency expects to be included in . . . reports to demonstrate Substantial Equivalence." July 27 Press Release. In April 2019, the FDA issued a proposed rule seeking comments on what should be included in substantial equivalence reports. *See* 84 Fed. Reg. at 12,740. That rule is not yet finalized, however. *See* Hr'g Tr. at 6. And because the *AAP* court vacated the FDA's 2017 Guidance extending the compliance periods for manufacturers' premarket review, *see AAP*, 379 F. Supp. 3d at 498, cigar and pipe tobacco manufacturers now must submit their applications by September 9, 2020, without the benefit of the promised substantial equivalence regulations, *see Am. Acad. of Pediatrics*, 399 F. Supp. 3d at 487; Joint Status Report, Ex. 1, ECF No. 199-1.

Plaintiffs cry foul, arguing that "[t]he FDA's decision to enforce the substantial equivalence process against cigars and pipe tobacco, without finalizing necessary implementing rules, is arbitrary, capricious, and not in accordance with law." Pls.' Mot. at 19 (cleaned up). Plaintiffs advance two arguments. First, they assert that the agency was statutorily required to issue substantial equivalence regulations specific to cigars and pipe tobacco "before enforcing the substantial equivalence process against cigars and pipe tobacco." *See id.* at 22–23; Pls.' Reply at 15–17. This requirement, Plaintiffs argue, stems from the text of the TCA, which provides that manufacturers' substantial equivalence reports must be submitted "in such form and manner as the [FDA] *shall* prescribe." Pls.' Mot. at 22 (emphasis in original) (quoting 21 U.S.C. § 387e(j)(1)). Second, Plaintiffs urge that the FDA's decision to enforce the premarket review requirements

without issuing the promised (and, they say, required) regulations "undermines an essential justification for the Final Deeming Rule and renders its enforcement arbitrary and capricious." Pls.' Mot. at 20–22.

The court need not decide Plaintiffs' first challenge because, even if Plaintiffs are correct that the FDA must issue product-specific substantial equivalence regulations before requiring substantial equivalence reports, it does not follow that the FDA must have issued those regulations concurrently with the Final Deeming Rule. The Final Deeming Rule gave manufacturers of newly deemed tobacco products 18 months after the August 2016 effective date to submit their substantial equivalence reports, 81 Fed. Reg. at 29,010–12, and the FDA's authority to set later compliance periods is not challenged here. Consequently, at the time the FDA issued the Final Deeming Rule, the FDA had at least 18 months to issue the regulations Plaintiffs say were required. Thus, even accepting Plaintiffs theory that the FDA's present "demand for substantial equivalence reports without issuing a final rule specifying the form and content of such reports violates the [TCA]," Pls.' Mot. at 23, that is not a flaw that is traceable to the Final Deeming Rule and therefore would not justify the primary remedy Plaintiffs seek, which is to vacate the Final Deeming Rule.

Plaintiffs' second argument, that the FDA's failure to issue such "key rules and guidance . . . undermines an essential justification for the Final Deeming Rule and renders its enforcement arbitrary and capricious," Pls.' Mot. at 22, fares no better. First, a central premise of Plaintiff's argument—that the FDA "promised to issue guidance and implementing rules for applying the substantial equivalence process to cigars and pipe tobacco," in the Final Deeming Rule, *see* Pls.' Mot. at 9—is factually incorrect. The FDA did note that it was finalizing draft guidance to "help provide clarity regarding submission requirements for marketing applications," but none of this guidance was specific to cigars and pipe tobacco. *See* 81 Fed. Reg. at 29,001; *see also id.* at

29,078. As for additional guidance, the FDA never conceded any was necessary, explaining instead that "[i]f FDA determines that additional guidance is necessary . . . FDA will issue additional guidance and publish a notice of availability in the Federal Register." *Id.*; *see also id.* at 29,012.[8]

Second, Plaintiffs incorrectly assert that developments occurring after the FDA issued its Final Deeming Rule in 2016 retroactively render the Rule arbitrary and capricious. *See* Pl.'s Mot. at 21–22. The agency's promise in 2017 to issue "foundational rules" governing the substantial equivalence reporting, *see* July 27 Press Release, and the subsequent developments that have created obstacles to fulfilling that promise, including the *AAP* court's setting of a sooner-than-anticipated substantial equivalence deadline, were not before the FDA when it issued the Final Deeming Rule in 2016. These developments are therefore not part of the administrative record in this case, and they have no bearing on whether the Final Deeming Rule was arbitrary. *See CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) ("[I]n an Administrative Procedure Act case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." (cleaned up)). Plaintiffs cite *National Lime Ass'n v. EPA*, 627 F.2d 416 (D.C. Cir. 1980), in support of their argument that a reviewing court may evaluate an agency's "course of implementing [a] rule" when an agency relies on "flexibility built into the regulatory scheme to support the rationality of its standards," *see* Pls.' Mot. at 18 (cleaned up), but the court in that case never looked beyond the administrative record, and it expressly remanded the issue to

[8] Most of the Deeming Rule passages cited by Plaintiffs in support of their argument that the FDA acknowledged that cigar and pipe tobacco manufacturers would need more guidance before they could submit adequate reports, *see* Pls.' Mot. at 20, are not about the substantial equivalence process. *See* 81 Fed. Reg. at 28,980 (harmful or potentially harmful constituent reports under 21 U.S.C. § 387d(a)(3)); *id.* at 28,996 (same); *id.* at 29,004 (same); *id.* at 29,008 (same); *id.* at 29,026 (same); *id.* at 29,046 (same); *id.* at 29,051–52 (same); *id.* at 29,005 (annual registration and listing under 21 U.S.C. § 387e(b)–(d)). None of these passages suggests the FDA thought that cigar and pipe tobacco manufacturers would need more guidance to submit adequate substantial equivalence reports.

the agency "for amplification of the record," 627 F.2d at 449. There are, of course, "unusual circumstances" where a party may supplement the administrative record with information that was not before the agency at the time of its decision, *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008) (cleaned up), but Plaintiffs have identified none here.[9]

Plaintiffs were not left without a remedy; they just did not pursue it. The proper avenue for Plaintiffs to seek redress for these subsequent developments would be to petition the FDA to amend its Final Deeming Rule and appeal a denial, *see Alon Ref. Krotz Springs, Inc. v. Envtl. Prot. Agency*, 936 F.3d 628, 643 (D.C. Cir. 2019) (explaining that "arguments . . . that recent developments compel the amendment of an older regulation . . . are always cognizable through review of the denial of a petition to amend"), or bring a challenge under 5 U.S.C. § 706(1) to "compel agency action unlawfully withheld or unreasonably delayed," *see Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 57 (2004). But neither challenge is presented here. No denial of new rulemaking is before the court, and Plaintiffs have disclaimed any Section 706(1) challenge to "the fact that [the FDA does not] have the [substantial equivalence] rule out." Hr'g Tr. at 20; *see also* Pls.' Resp. to Defs.' Notice of Filing, ECF No. 211, at 2 (stressing that Plaintiffs' claims are "*against the Final Deeming Rule*" (emphasis in original)). Indeed, Section 706(1) of the APA appears nowhere in Plaintiffs' briefs or their Complaint. In sum, the only final agency action that Plaintiffs are challenging is the Final Deeming Rule, but the subsequent developments that Plaintiffs decry as unfair have no bearing on the reasonableness of that Rule.

At oral argument, Plaintiffs tried another tack, contending that the FDA failed to "run to

[9] Plaintiffs invoke *Portland Cement Ass'n v. EPA*, 665 F.3d 177 (D.C. Cir. 2011), in support of a related argument that "[t]he FDA must consider parallel rulemakings that could modify the rule that it seeks to enforce," Pls.' Mot. at 36, but that case involved "contemporaneous" rulemakings, 665 F.3d at 187. The FDA's 2017 Guidance and the ensuing developments postdate the Final Deeming Rule by a year and more—they are not contemporaneous. Nor do Plaintiffs argue that these developments "constitute final agency action reopening the" Final Deeming Rule. *See P&V Enters. v. U.S. Army Corps of Eng'rs*, 516 F.3d 1021, 1024 (D.C. Cir. 2008).

ground in the [F]inal Deeming Rule the question of whether it had sufficient instructions in place" regarding substantial equivalence reports for cigars and pipe tobacco products, Hr'g Tr. at 14–15, and that by "punt[ing]" on this question, the agency arbitrarily failed to consider an "important aspect of the problem," *id.* at 69; *see also id.* at 19–20. That argument is forfeited. Plaintiffs do not argue in their briefs or Complaint that the FDA should have "run to ground" whether there were sufficient instructions for all cigars and pipe tobacco manufacturers *at the time* it issued the Final Deeming Rule. Rather, they repeatedly characterize the problem as the FDA's failure to issue promised cigar- and pipe tobacco-specific substantial equivalence rules before the now-looming premarket enforcement deadlines, and they acknowledge that the agency could have issued these rules well after the Final Deeming Rule. *See, e.g.*, Pl.'s Mot. at 1–2 ("The problem is that the agency has not finalized key rules about what cigar and pipe tobacco substantial equivalence reports must contain.") (cleaned up); *id.* at 23 ("Having acknowledged the necessity of these foundational rules, the FDA could have included them in the Final Deeming Rule, six months after, or (at this point) three years after. By doing none of those and allowing cigars and pipe tobacco to crash into the [September] 2020 deadline, the agency is contradicting its own findings and acting arbitrarily and capriciously."); Third Am. Compl. ¶ 186 ("To the extent that the agency insists on the submission of [Substantial Equivalence] Reports simply on the basis of information currently available, the agency *will have* arbitrarily ignored multiple comments that additional guidance and implementing rules would be necessary *before* cigar and pipe tobacco manufacturers could be reasonably required to submit [such] Reports." (first emphasis added)).[10] "[A]rguments raised for the first time at oral argument" are usually forfeited, and Plaintiffs have

[10] Plaintiffs do argue in Count XIV that the FDA failed to consider in the Final Deeming Rule a streamlined substantial equivalence process for premium cigars. *See* Pls.' Mot. at 38–43. The court considers that narrower argument separately below.

identified no "exceptional circumstances" justifying a departure from that rule here. *See U.S. ex rel. Davis v. District of Columbia*, 793 F.3d 120, 127 (D.C. Cir. 2015).

The court is sympathetic to the bind Plaintiffs find themselves in. But because the court is presented with only a challenge to the Final Deeming Rule, and because that challenge is solely premised on the unfairness of subsequent developments which have no bearing on the reasonableness of the Rule, the court cannot provide relief. *See Banner Health v. Burwell*, 126 F. Supp. 3d 28, 81 (D.D.C. 2015) (The court "cannot invalidate a rulemaking" solely "because it subsequently becomes clear that [the] rulemaking was unwise."), *aff'd in part, rev'd in part on other grounds sub nom. Banner Health v. Price*, 867 F.3d 1323 (D.C. Cir. 2017).[11]

4. Count XV – Challenge to the FDA's Cost-Benefit Analysis

As part of the Final Deeming Rule, the FDA conducted a Regulatory Impact Analysis pursuant to Executive Orders 12866 and 13563, which require agencies to "assess all costs and benefits of available regulatory alternatives." 81 Fed. Reg. at 29,074. The FDA concluded that the final rule would annually cost between $66 and $77 million per year— about $2 per current user of tobacco products. *See* Final Regulatory Impacts Analysis, Joint App'x Vol. III, ECF No. 81-2 [hereinafter JA Vol. III], at AR023917, AR024027. The FDA thoroughly considered the qualitative benefits of the rule (including benefits stemming from premarket review), *id.* at AR023973–79, but it was unable to accurately quantify them "due to lack of information and substantial uncertainties associated with estimating" effects of the Final Deeming Rule, *id.* at AR023978. Therefore, the FDA conducted a "break-even" analysis—an economic tool that

[11] Because the court rules in the FDA's favor on the merits, it does not reach the agency's separate argument that Plaintiffs' challenges are unripe because they "would benefit from a more concrete factual setting," and "postponing review" would not "cause Plaintiffs any significant hardship." Defs.' Cross-Mot. at 21 (cleaned up). The "fitness and hardship factors" of the ripeness doctrine are "prudential," *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014) (cleaned up), and are "not, strictly speaking, jurisdictional," *Horne v. Dep't of Agric.*, 569 U.S. 513, 526 (2013).

considers how much the average beneficiary would have to be willing to pay for a rule for its benefits to equal its costs—and concluded that a cost of $2 annually per current tobacco user would be worth the rule's benefits. *Id.* at AR024026–27; *see also id.* at AR023921–22.

In Count XV, Plaintiffs argue that the FDA's cost-benefit analysis was arbitrary and capricious because it (1) failed to quantify the "benefits of applying the substantial equivalence requirements of the Final Deeming Rule to cigars and pipe tobacco," Pls.' Mot. at 44, and (2) neglected to separately consider whether the cost of regulating cigars and pipe tobacco, and premium cigars in particular, was justified by the benefits, *id.* at 44–45; *see also* Pls.' Reply at 37–38. The FDA responds that its cost-benefit analysis is unreviewable because it was taken pursuant to executive orders that provide no private right of action, the TCA does not require a cost-benefit analysis, and the FDA did not rely on its analysis to justify the Final Deeming Rule. *See* Defs.' Cross-Mot. at 37–41; Defs.' Reply at 20–21. Even if its analysis were reviewable, the FDA continues, it properly concluded that the benefits of the Final Deeming Rule justify the cost. Defs.' Cross-Mot. at 41–43.

First, the court rejects the FDA's contention that because it undertook the cost-benefit analysis pursuant to Executive Orders 12866 and 13563, its reasoning is unreviewable under the APA. *See* Defs.' Cross-Mot. at 37–39. It is true that those executive orders create no private right of action to enforce their terms, *see id.* at 38 (citing the relevant passages of both orders), but all that means is that a litigant cannot obtain judicial review based on alleged violations of the orders. Even when an agency's "regulatory impact analysis was conducted pursuant to Executive Orders," the analysis is reviewable under the APA whenever the "government relie[s] on" the analysis in its final rule. *See Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 54 n.11 (D.D.C. 2019) (citing *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012)). The cases the FDA cites are inapposite because they all involved arguments that the

agencies failed to comply with the executive orders themselves. *See* Defs.' Cross-Mot at 37–39 (citing *Meyer v. Bush*, 981 F.2d 1288, 1297 (D.C. Cir. 1993); *Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 8 (D.C. Cir. 1999) (deferring "dealing with petitioner's claims that the FAA did not adequately weigh the costs of this project against the benefits," but "definitively reject[ing] petitioner's assertion that any such process is governed by Executive Order No. 12,893"); *Fla. Bankers Ass'n*, 19 F. Supp. 3d 111, 118 n.1 (D.D.C. 2014); *All. for Natural Health v. Sebelius*, 775 F. Supp. 2d 114, 135 (D.D.C. 2011); *Trawler Diane Marie, Inc. v. Brown*, 918 F. Supp. 921, 932 (E.D.N.C. 1995); *Defs. of Wildlife v. Jackson*, 791 F. Supp. 2d 96, 120 (D.D.C. 2011)).

The same goes for the FDA's statutory argument. Whether or not the TCA requires the FDA to evaluate costs and benefits when deeming new tobacco products (the court need not decide this question), the agency did so, and its analysis is reviewable under the APA insofar as it relied on the cost-benefit analysis as part of its rulemaking. *See Nat'l Ass'n of Home Builders*, 682 F.3d at 1039–40 (explaining that although an agency may "not have a statutory duty to demonstrate that the benefits of the amended rule outweigh its costs," if the "agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable" (citations omitted)).

The question, then, is whether the FDA relied on its cost-benefit analysis in its Final Deeming Rule. An agency relies on a cost-benefit analysis when, for instance, it concludes that the analysis "support[s]" its final decision. *Id.* at 1040. The FDA insists its cost-benefit analysis did not support its final decision, noting that "it conducted a cost-benefit analysis because the Executive Orders required one," and "it did not claim [in the Final Deeming Rule] that its assessment that the benefits of the rule outweighed the costs was a reason why it was adopting the rule." Defs.' Reply at 20 (citing 81 Fed. Reg. at 28,975, 29,074). It certainly would be an odd

state of affairs for an agency to devote hundreds of pages and hours of time to preparing a cost-benefit analysis it then wholly ignores, but the court need not decide this non-jurisdictional reviewability question, because, as discussed below, the agency's cost-benefit analysis was reasonable. *See Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1207 (D.C. Cir. 2020) (declining to decide whether agency action was final "in light of [the court's] resolution of the merits"); *see also Nicopure*, 266 F. Supp. 3d at 400 (holding that "even if" the FDA's cost-benefit analysis were required and reviewable, "the cost-benefit analysis was adequate").

The principle "that a court is not to substitute its judgment for that of the agency" is "especially true when the agency is called upon to weigh the costs and benefits of alternative polices." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 303 (D.C. Cir. 2003) (cleaned up). "[I]n view of the complex nature of economic analysis typical in the regulation promulgation process," a court's review is deferential, and the plaintiff's "burden to show error is high." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 563 (D.C. Cir. 2002). The court will uphold an agency's decision against an arbitrary and capricious challenge so long as it is "reasonable and reasonably explained." *Nw. Corp. v. Fed. Energy Regulatory Comm'n*, 884 F.3d 1176, 1179 (D.C. Cir. 2018).

Here, Plaintiffs have identified nothing arbitrary or capricious about the FDA's cost-benefit analysis. First, the *Nicopure* district court already considered and rejected a similar argument that the FDA unreasonably "fail[ed] to quantify the benefits of the" Final Deeming Rule. 266 F. Supp. 3d at 406. As that court found, the agency "provided substantial detail on the benefits of the rule, and the reasons why quantification was not possible." *Id.* That was enough. *See Inv. Co. Inst. v. Commodity Futures Trading Comm'n*, 720 F.3d 370, 379 (D.C. Cir. 2013) ("[T]he law does not require agencies to measure the immeasurable."). Plaintiffs contend that the "purported benefits [the FDA] identified are susceptible to quantification, particularly given how long cigar and pipe

tobacco products have been on the market," Pls.' Reply at 38, but they do not identify any data that was before the agency at the time of the Final Deeming Rule that would have enabled it to quantify the benefits of regulating these newly deemed products, nor do they cite any judicially enforceable legal requirement that would have required the FDA to quantify the benefits instead of using a qualitative, break-even analysis. *See Nicopure*, 266 F. Supp. 3d at 406 (holding that "even if" the FDA had a statutory duty to measure the benefits of deeming, any such requirement "does not require that the benefits be quantified in any particular way when compared to the costs").

As to Plaintiffs' second argument that the FDA should have calculated the benefits of requiring premarket review specifically for cigars and pipe tobacco, *see* Pls.' Mot. at 44–45; Pls.' Reply at 37–38, Plaintiffs have not identified an enforceable legal requirement that the FDA undertake a "rigorous, quantitative economic analysis" specific to cigars and pipe tobacco, *see Inv. Co. Inst. Comm'n*, 720 F.3d at 379 (cleaned up). Nor have they identified anything about the benefits analysis that the FDA actually conducted that is arbitrary or unreasonable.[12] Instead, they simply assert that the agency "should have done some work, any work," to identify the unique costs and benefits of subjecting cigars, pipe tobacco, and premium cigars to premarket review because of the unique natures of these products. Pls.' Mot. at 44–46; Pls.' Reply at 38–40. However, "there is no legal support for the proposition that every product or industry affected by a rulemaking is entitled to a separate cost-benefit analysis." *Nicopure*, 266 F. Supp. 3d at 407.

In sum, to the extent the FDA "relied" on its cost-benefit analysis in the Final Deeming Rule and its analysis is subject to APA review, *see Council of Parent Attorneys & Advocates, Inc.*,

[12] In their reply brief, Plaintiffs list three assumptions that the FDA purportedly relied on that they say "are flatly contradicted by the record." *See* Pls.' Reply at 39–40. However, those three arguments are all premised on the assumption that the FDA was required to individually analyze the benefits for premium cigars, which the court rejects.

365 F. Supp. 3d at 54 n.11, the assessment was "reasonable and reasonably explained," *Nw. Corp.*, 884 F.3d at 1179. "While plaintiffs would surely have assessed the various costs and benefits in a different manner, the Court does not have the power to take up the agency's analysis *de novo*." *Nicopure*, 266 F. Supp. 3d at 407.

B. Challenges Applicable Only to Premium Cigars

Plaintiffs raise two additional challenges that are particular to premium cigars. In Count XII, they argue that [e]nforcing the substantial equivalence process against premium cigars, while the agency has a formal rulemaking open potentially to exempt premium cigars from any regulation, is arbitrary and capricious." Pls.' Mot. at 34. And in Count XIV, Plaintiffs contend that the FDA arbitrarily ignored commenters' requests to establish a separate, streamlined substantial equivalence process for premium cigars. *Id.* at 42. Because the court grants Plaintiffs' motion as to Count XIV and enjoins the FDA's enforcement of the premarket and substantial equivalence review requirements as to premium cigars, it does not reach Plaintiffs' arguments in Count XII.

1. The FDA's Request for Regulatory Alternatives for Premium Cigars

In the Proposed Deeming Rule, the FDA requested comments on whether it should deem all cigar and pipe tobacco products to be subject to the TCA under "Option 1," or whether it should exclude premium cigars "from the scope of [the] proposed rule" under "Option 2," 79 Fed. Reg. at 23,143, and "provide a separate regulatory regime" for those products, *id.* at 23,150. The FDA also stated that it was considering a hybrid approach, wherein it would "include elements of both options," *id.* at 23,150, and requested comment on whether "a different regulatory scheme for covered cigars . . . or other category of cigars would adequately address the dangers of tobacco use by adults," *id.* The agency additionally requested comment on "what FDA actions or regulatory

approaches, if any, should be taken for proposed deemed tobacco products that are 'new tobacco products,'" *id.* at 23,174, including whether the agency should "consider a different compliance policy for proposed deemed tobacco products that cannot, as a practical matter, use the [substantial equivalence] pathway," *id.* at 23,176.

Commenters heeded the FDA's call, urging the agency to develop a streamlined premarket review scheme for premium cigars. The Cigar Association of America, for instance, submitted a detailed proposal outlining "an alternative premarket approach under [21 U.S.C. § 387e(j)]" of the TCA, under which premium cigar manufacturers' substantial equivalence reports would "be limited to the following information: (i) a description of the product and its ingredients; (ii) specifics on how the new product differs from an existing product, i.e., change in blend, size, brand name, etc.; and (iii) a statement regarding the basis on which the manufacturer concluded the new product does not raise different questions of public health." *See* Cmt. of Cigar Ass'n of Am., JA Vol. III at AR129920. The Association proposed that if the FDA failed to reject such a report within 90 days, these reports would become an FDA substantial equivalence order as required under 21 U.S.C. § 387j(a)(2)(A)(i). *Id.* Other commenters submitted similar proposals. *See, e.g.*, Pls.' Mot., Ex. 4, Cmt. of Small Manufacturers Ass'n for the Reasonable Treatment of Tobacco, ECF No. 178-7, at 17–20 (proposing "targeted, up-front, category-specific guidance for tobacco product manufacturers on the requirements for premarket review"); *id.*, Ex. 5, Cmt. of Rocky Patel Premium Cigars, ECF No. 178-8, at 30 (recommending a substantial equivalence pathway for premium cigars based on 60-days advance notice to the agency).

2. The FDA's Failure to Respond to Commenters' Suggestions

In Count XIV, Plaintiffs argue that the FDA failed to meaningfully respond to these substantial comments. *See* Pls.' Mot. at 41–42. The court agrees. The closest the FDA came to

even touching on these comments is in the following passage of the Final Deeming Rule:

> At least one comment stated that FDA should eliminate the premarket and [substantial equivalence] application requirements for cigars and instead implement a system by which cigar manufacturers could introduce new products to the market after providing 90 days' notice to FDA of their intentions to do so.
>
> (Response) FDA disagrees. Sections [387e] and [387j] of the [TCA] establish specific requirements that apply to new tobacco products before they may be marketed.

81 Fed. Reg. 28,995; *see also* Defs.' Reply at 18 n.11 (citing this passage as the sole example of the FDA's consideration of commenters' requests that the agency consider "an easier substantial equivalence process for premium cigars").

This cursory response is not reasoned decision-making. For one, the FDA mischaracterizes commenters' suggestions. Though commenters did propose eliminating premarket review altogether, they also proposed options in which premium cigars would still be subject to the substantial review requirements, albeit in a streamlined form. *E.g.*, Cmt. of Cigar Ass'n of Am., JA Vol. III at AR129920 ("[I]f the agency will not exempt cigars from the premarket review requirement, [the commenter] proposes that the agency consider an alternative premarket approach under [the substantial equivalence provisions]" of the TCA.). Two, the FDA incorrectly implies that it has no authority to adjust the substantial equivalence requirements for premium cigars. While it may be true that the agency could not issue a rule converting a substantial equivalence application into a substantial equivalence "order" after 60 or 90 days of inaction, *see* 21 U.S.C. § 387j(a)(2)(A)(i), the agency has broad discretion to "prescribe" the "form and manner" that the substantial equivalence reports must take, *see id.* § 387e(j)(1). Commenters outlined various factors that "the substantial equivalence report [for premium cigars] should be limited to," *e.g.*, Cmt. of Cigar Ass'n of Am., JA Vol. III at AR129920, and the FDA's refusal to meaningfully

consider these options based on its incorrect and conclusory assertion that its hands were tied was arbitrary. "The requirement that agency action not be arbitrary or capricious includes a requirement that the agency . . . respond to relevant and significant public comments," *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (cleaned up), and an agency cannot meet this burden by "[n]odding to concerns raised by commenters only to dismiss them in a conclusory manner," *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020).[13]

The FDA's arguments to the contrary are not persuasive. First, the agency contends that because the substantial equivalence requirement is "an automatic statutory consequence of deeming," the FDA had no obligation to consider commenters' requests for streamlined procedures. *See* Defs.' Reply at 18. Not so. It is true that newly deemed products are automatically subject to premarket review, including substantial equivalence, but the FDA retains statutory discretion to "prescribe" the "form and manner" that the substantial equivalence reports must take. *See* 21 U.S.C. § 387e(j)(1). This discretion to set the form and manner of substantial equivalence reports distinguishes this case from *Nicopure*, in which the D.C. Circuit rejected an argument that the FDA failed to "tailor" the PMTA review process to e-cigarettes. *See* 944 F.3d at 281; *cf.* Defs.' Reply at 17–18 (arguing that the D.C. Circuit's decision in *Nicopure*

[13] Plaintiffs also argue that the FDA failed to address commenters' requests that the agency "exercise [its] exemption authority under [21 U.S.C § 387e(j)(3)] with regard to premium cigars," *see* Pls.' Mot. at 40, but no such request was before the agency. Though commenters generally requested an exemption from the premarket review requirements for premium cigars, *e.g.*, Cmt. of Cigar Ass'n of Am., JA Vol. III at AR129920–21, no commenter ever specifically requested an exemption based on 21 U.S.C. § 387e(j)(3). That was a critical oversight. A Section 387e(j)(3) exemption is available only for tobacco products that are "minor modification[s]" of products that can already be sold under the TCA, 21 U.S.C. § 387e(j)(3)(A)(i), but commenters' exemption requests focused on the fact that premium cigars "come in every size and shape, and with natural variation and the variability of premium cigar manufacturing practices," Cmt. of Cigar Ass'n of Am., JA Vol. III at AR129920–21. Further, the FDA's regulations on minor modification exemptions, which were in effect at the time the FDA issued the Proposed Deeming Rule, permit requests to be made "*only* by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product." 21 C.F.R. § 1107.1(b) (emphasis added). No commenter ever attempted to make such a showing or request that the FDA amend its regulations for premium cigars. Given the narrow, circumscribed statutory and regulatory requirements for a minor modification exemption, the FDA cannot be faulted for failing to construe commenters' requests for a general premarket exemption for premium cigars based on their natural variability as Section 387e(j)(3) minor modification exemption requests.

"foreclose[s]" Plaintiffs' claim). Unlike substantial equivalence reports, PMTA applications must comply with a much more extensive list of automatic statutory requirements, *compare* 21 U.S.C. 387j(a)(3), (4), *with id.* § 387j(b), and the TCA includes no analogous provision authorizing the FDA to establish their "form and manner."

Second, the FDA argues that it "need not 'solve every problem before it in the same proceeding,'" and that the comments were outside the scope of the proposed rule. Defs.' Cross-Mot. at 35–36 (quoting *Mobil Oil Exploration & Producing, S.E., Inc. v. United Distrib. Cos.*, 498 U.S. 211, 231 (1991)). But that argument overlooks how the agency actually framed its request for comments in the proposed Rule. The "agency asked for comments not only on whether to regulate premium cigars at all but whether the various types of regulation set forth in the Proposed Deeming Rule were appropriate for particular products." *Cigar Ass'n of Am. v. FDA* ("*Cigar II*"), 436 F. Supp. 3d 70, 89 (D.D.C. 2020). By inviting comments on whether it should develop "a different regulatory scheme for" premium cigars, 79 Fed. Reg. at 23,150, what "actions or regulatory approaches . . . should be taken for" newly deemed products, *id.* at 23,174, and whether the agency should "consider a different compliance policy for proposed deemed tobacco products that cannot, as a practical matter, use the [substantial equivalence] pathway," *id.* at 23,176, the FDA placed these issues on the table. It was therefore "incumbent upon the agency" to address relevant, substantial comments to this effect. *See Cigar II*, 436 F. Supp. 3d at 89.

Finally, the FDA argues that this issue is prudentially unripe for adjudication in light of the agency's recently filed, pending request before the *AAP* court to issue guidance that would, on a case-by-case basis, allow premium cigar manufacturers to receive enforcement deferrals from the premarket authorization requirements. *See* Tr. of 8/10/2020 Hr'g., ECF No. 213, at 5. The court disagrees. An agency cannot "stave off judicial review of a challenged rule simply by initiating a

new proposed rulemaking" or by proposing a guidance document. *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 388 (D.C. Cir. 2012). The prudential ripeness doctrine "exists to prevent the courts from wasting our resources by prematurely entangling ourselves in abstract disagreements." *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1431 (D.C. Cir. 1996). Forbearing judicial review of this purely legal issue at this late stage in the game, however, would waste judicial resources. Furthermore, there is no guarantee that the *AAP* court will accept the FDA's proposal—the plaintiffs in that case oppose the relief requested—in which case premium cigar manufacturers will be left scrambling to meet the September 9 premarket application deadline. Because the issue is fit for review and holding the matter in abeyance risks a hardship to Plaintiffs and their members, *see Garcia v. Acosta*, 393 F. Supp. 3d 93, 105 (D.D.C. 2019), the court rejects the FDA's eleventh-hour effort to avoid judicial review in this case.

C. The Remedy

Having concluded that the agency arbitrarily failed to consider a streamlined substantial equivalence process for premium cigars, the court must now consider the scope of the remedy. That question turns on the definition of premium cigars. As noted, the Proposed Deeming Rule suggested a definition of premium cigars, *see* 79 Fed. Reg. at 23,150, but the FDA did not settle on a definition in the Final Deeming Rule because it decided to regulate all cigars under Option 1, *see* 81 Fed. Reg. at 29,020. Plaintiffs Premium Cigar Association and Cigar Rights of America urge the court to define "premium cigars" as they are defined in the Proposed Deeming Rule, but to omit the $10 retail price element, Pls.' Mot. at 37 (citing 79 Fed. Reg. at 23,150). Plaintiff Cigar Association of America, on the other hand, opposes that definition, contending that "the appropriate remedy is to set aside the Final Deeming Rule as it applies to all cigars, so that FDA may decide in the first instance what qualifies as a 'premium cigar.'" *Id.* at 38 n.12.; *see also id.*

at 43 & n.15.

Contrary to the Cigar Association of America's contention, however, the FDA has already addressed what qualifies as a "premium cigar," at least for purposes of this case. In its August 2020 Notice, the FDA defined a premium cigar as:

> a cigar that: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units."

August 2020 Notice at PDF p. 3, n.2. This definition, which omits the $10 retail price component in the Proposed Deeming Rule, is similar to the definition that commenters urged the FDA to adopt during the rulemaking for the Final Deeming Rule. *See, e.g.*, Cmt. of Cigar Ass'n of Am., JA Vol. III at AR130346–48. Thus, the court need not "devise" a definition of premium cigars out of whole cloth. *Cf.* Pls.' Mot. at 38 n.12 (quoting *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1011–12 (D.C. Cir. 1999)).

Accordingly, the court remands the Final Deeming Rule for the limited purpose of considering whether a streamlined substantial equivalence process is appropriate for premium cigars. The court further finds that additional equitable relief is warranted and necessary to grant Plaintiffs a complete remedy. *See Ind. & Mich. Elec. Co. v. Fed. Power Comm'n*, 502 F.2d 336, 346 (D.C. Cir. 1974) ("A court sitting in review of an administrative agency . . . may adjust its relief to the exigencies of the case in accordance with the equitable principles governing judicial action."); 3 CHARLES H. KOCH, JR. & RICHARD MURPHY, ADMIN. L. & PRAC. § 8:31 (3d ed. 2020) ("[I]njunctive relief under the APA is controlled by principles of equity."); *see also Role Models*

Am., Inc. v. White, 317 F.3d 327, 333–34 (D.C. Cir. 2003) (directing the district court to enter a "permanent injunction . . . until the Government remedies the procedural errors" outlined in the court's opinion). The court therefore enjoins the FDA from enforcing the premarket review requirement against premium cigars, as that term is defined in the August 2020 Notice, until the agency's review is complete.[14] The FDA will retain discretion to specify the amount of time premium cigar manufacturers will have to file substantial equivalence reports after the agency completes its review.

The court is mindful that the relief afforded here is in tension with the relief afforded by the court in *AAP*, but ultimately this court sees no conflict because the *AAP* court did not have before it the specific issues presented here, nor does anything in its order foreclose another court from remedying errors made by the FDA in promulgating the Final Deeming Rule.

V. CONCLUSION AND ORDER

For the reasons set forth above, Plaintiffs' Motion for Partial Summary Judgment is granted in part and denied in part, Plaintiffs' Motion for Preliminary Injunction is denied as moot, and Defendants' Cross-Motion for Partial Summary Judgment is granted in part and denied in part, as follows:

1. The FDA's refusal to adjust the 2007 grandfather date for cigars and pipe tobacco products (Count I) was not arbitrary or capricious;

2. Plaintiffs have not shown that the 2016 Effective Date was premised on legal error (Count XIII);

3. The FDA's imminent enforcement of the substantial equivalence process against cigars and pipe tobacco without finalizing implementing rules (Count XI) does not render the Final Deeming Rule arbitrary, capricious, or contrary to law;

[14] The court rejects Plaintiffs' request to enjoin premarket enforcement against premium cigars until 12 months after the FDA publishes a decision resolving the ANPRM for premium cigars or issues a final rule regarding substantial equivalence reports. *See* Pls.' Mot. for Summ. J. or a Prelim. Inj., ECF No. 178, at 5. That relief goes too far, as the FDA may cure the error the court has identified without completing either rulemaking.

4. The FDA's cost-benefit analysis (Count XV) was reasonable and reasonably explained to the extent it is reviewable; and

5. The FDA arbitrarily failed to address commenters' suggestions that the FDA create a streamlined substantial equivalence process for premium cigars (Count XIV).

The court therefore remands the Final Deeming Rule to the FDA to consider developing a streamlined substantial equivalence process for premium cigars. The court further enjoins the FDA from enforcing the premarket review requirements against premium cigars, as those products are defined in the August 2020 Notice, until the agency has completed its review. No later than August 31, 2020, the parties shall submit a Joint Status Report proposing a schedule for further proceedings in this matter, if necessary.

Dated: August 19, 2020

Amit P. Mehta
United States District Judge