UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SWISHER INTERNATIONAL, INC., Plaintiff, v. **UNITED STATES FOOD AND DRUG ADMINISTRATION** *et al.*, Defendants.	Case No. 22-cv-954 (CRC)

MEMORANDUM OPINION

Swisher International Inc. ("Swisher"), a tobacco company known for its "Swisher Sweets" line of cigars, challenges the promulgation and implementation of the Food and Drug Administration's ("FDA") 2016 "Deeming Rule." The rule subjected tobacco products, including Swisher's cigars, to regulation under the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA") and, as part of that regulation, required companies to submit pre-market applications to sell their products. Primary among Swisher's challenges is its allegation that the FDA has unreasonably delayed in reviewing the company's applications.

This suit originated in federal court in Florida but, after an appeal to the Eleventh Circuit, was transferred to the District of Columbia. This Court has already resolved one round of disputes, denying Swisher's motion to complete or supplement the administrative record and for extra-record discovery. Now before the Court are a tangle of motions: Swisher's motion for summary judgment, the FDA's motion to amend its answer, and the FDA's motion for summary judgment and partial motion to dismiss. Swisher has moved for summary judgment on five of the eight counts in its amended complaint. For its part, the FDA seeks to add the affirmative defense of claim preclusion to its answer, moves to dismiss one of Swisher count's for lack of

standing, and moves for summary judgment on its claim-preclusion defense and every count in Swisher's complaint.

The Court sides with the agency on all fronts. Five of Swisher's eight counts are precluded and lack merit. Two of Swisher's non-precluded counts also fail on the merits. And Swisher lacks standing to bring its third non-precluded count. Accordingly, the Court will deny Swisher's motion for summary judgment, grant the FDA's motion for leave to amend, grant the FDA's motion for summary judgment on Counts One to Seven, and grant the FDA's motion to dismiss Count Eight.[1]

I. Background

A. Tobacco Control Act and Deeming Rule

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA") to create a comprehensive scheme for regulating tobacco products. Pub. L. No. 111-31, § 2(6), 123 Stat. 1776, 1777. The TCA initially covered four enumerated categories of "tobacco products"—"all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—but it also contained what is known as the Deeming Provision. 21 U.S.C. § 387a(b). In that provision, Congress specified that, in addition to the enumerated products, the FDA could regulate "any other tobacco products that the Secretary [of Health and Human Services] by regulation deems to be subject" to the TCA. Id.

In 2016, the FDA exercised its authority under the Deeming Provision by promulgating a rule (known as the Deeming Rule) to sweep all tobacco products, including cigars, into the

[1] Because the parties filed their briefs and the second volume of the joint appendix under seal, the Court will keep this ruling under seal temporarily. The parties may request any redactions within seven days. Otherwise, the opinion will be filed at that time on the public docket.

TCA's ambit. Deeming Tobacco Products to be Subject to the Federal Food Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 29,102 (May 10, 2016). As relevant here, the Deeming Rule made cigars subject to the TCA's requirement that manufacturers obtain FDA approval before they market and sell any "new tobacco product," which the TCA defines as any product "that was not commercially marketed in the United States as of February 15, 2007." 21 U.S.C. §§ 387b(6), 387j(a)(1).

The TCA created three pathways for premarket approval. 21 U.S.C. § 387j(a)(2). First, for truly new products, like e-cigarettes and vapes, manufacturers must submit a "premarket tobacco application" ("PMTA") that demonstrates that "permitting [the] tobacco product to be marketed would be appropriate for the protection of public health." Id. § 387j(a)(2)(A), (c)(2)(A). On the second route, which Swisher took, manufacturers gain approval by submitting substantial equivalence ("SE") reports that demonstrate a tobacco product is "substantially equivalent" to a product that was on the market as of February 15, 2007. Id. § 387j(a)(2)(A)(i), (3)(A). And, third, for products that are modified only by adding, deleting, or changing the quantity of a tobacco additive, manufacturers can seek exemptions from the substantial equivalence requirement. Id. §§ 387j(a)(2)(A)(ii), 387e(j)(3).

If products are marketed without receiving authorization, they may be considered "adulterated" and seized, and the manufacturers, distributors, and retailers may be subject to civil and criminal enforcement. 21 U.S.C. §§ 331 (prohibited acts), 332 (court jurisdiction to issue injunction), 333(a) (criminal penalties), 334 (seizure), 387b(6) ("A tobacco product shall be deemed to be adulterated if . . . it is required. . . to have premarket review and does not have an order in effect . . . [or] it is in violation of an order under section 387j(c)(1)(A)[.]").

Though the Deeming Rule went into effect 90 days after its publication, the FDA delayed much of its force by establishing "compliance periods" for manufacturers to prepare and submit premarket applications. 81 Fed. Reg. at 28,976, 28,978. Manufacturers had twelve months to submit SE exemption requests, eighteen months to submit SE reports, and twenty-four months to submit PMTAs. Id. at 28,978. The agency staggered the "initial compliance periods based on the expected complexity of the applications to be submitted." Id. at 28,977. In the Deeming Rule, the FDA also announced that if manufacturers submitted applications by the close of the appropriate compliance windows, the agency would not enforce the premarket review requirement for an additional twelve months following the close of the initial compliance period (*i.e.*, twenty-four months for SE exemption requests, thirty months for SE reports, and thirty-six months for PMTAs). Id. at 28,978.

B. Postponement of Compliance Periods and *AAP* Litigation

In May 2017, the FDA extended the compliance periods by three months—both the deadlines for manufacturers to submit applications and the enforcement moratoriums. Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, 82 Fed. Reg. 22,338, 22,339 (May 15, 2017). Then, in August 2017, the FDA pushed the compliance periods back again. For combustible products (like cigars), manufacturers would have until August 2021 to submit applications (under any of the three pathways), and for non-combustible products (like e-cigarettes), manufacturers would have until August 2022. Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised) (August 2017), *available at* [ECF No. 48-1] Notice by Plaintiffs at 712, Am. Acad. of Pediatrics v. FDA ("AAP"), No. 8:18-cv-883-DLB (D. Md. filed Mar. 27, 2018). The agency further provided that it would extend its own enforcement

moratoriums for any product on the market on August 8, 2016 and for which an application had been submitted, "until the agency render[ed] a decision on an application . . . or the application [wa]s withdrawn." Id. at 716.

After the FDA released this guidance, a coalition of doctors and medical associations sued the FDA in the District of Maryland. Among other grounds, they alleged that the August 2017 guidance extending the compliance deadlines exceeded the FDA's statutory authority under the TCA and should have gone through notice and comment. AAP, 379 F. Supp. 3d 461, 490–91 (D. Md. 2019). The court agreed with the plaintiffs and vacated the August 2017 guidance. Id. at 494, 497–98. Following separate briefing, the court ordered that premarket applications be submitted by September 2020 and that the FDA's enforcement moratorium end a year later. Order, AAP (Apr. 22, 2020) [ECF 182].

C. Receipt of Applications and the FDA's Review

After the decision in AAP, the agency received a deluge of applications. By the September 2020 submission deadline set by the court, the FDA received over 7,000 SE reports and eight million PMTAs. JA (Vol. 1) at 1170, 1173. As of March 2024, that number had grown to nearly 9,000 SE reports and over nine million PMTAs.

Among the thousands of SE reports, Swisher submitted 171. Pl.'s Mot. Summ. J. at 14. The FDA assigned 267 unique Submission Tracking Numbers ("STNs") to these reports, which correspond to different cigar types and packaging sizes. Id. The agency adopted a randomized ordering system for reviewing the SE reports, which is summarized as follows in a September 2021 article authored by Mitch Zeller, the former Director of the FDA's Center for Tobacco Products:

> [SE Report] review order was determined using randomization by manufacturer. Using a basic random number generator, FDA assigned a number to the

> manufacturers that submitted at least one application to determine the order for entering acceptance review and subsequent review phases (e.g. notification, substantive review). At the substantive review, if the manufacturer submitted a number of products that exceeded the capacity of the scientific review team, FDA assigned a second randomly-generated number to each product in each submission to determine the order of the products. The products that are not assigned to the review team will remain in queue until all of the manufacturers with timely, accepted applications have had some products enter the substantive review phase once; this ensures that every manufacturer has an opportunity for some products to enter substantive review. The randomly-generated numbers stay with the application for the individual product and continue to determine its place in the queues throughout the review process.

JA (Vol. 1) at 1095.[2]

So far, only forty of Swisher's STNs have moved into substantive review: one batch of twenty in June 2022 and a second batch in October 2023. Def.'s Mot. Summ. J. at 53. [redacted]

D. Swisher's Suit

Swisher originally filed this suit in Middle District of Florida and simultaneously sought a preliminary injunction prohibiting the FDA from enforcing the TCA against Swisher's cigars and requiring the agency to expedite review of its SE reports. After the FDA assured Swisher that no enforcement actions against it were on the horizon and that it would notify the company

[2] Tracking 21 U.S.C. § 387j(a)(3)'s framework, the FDA sub-divided the SE report pathway into two review queues. The first is for SE reports, like Swisher's, that seek to show that new products, despite having "different characteristics" from their predicates, do not raise "different questions of public health." 21 U.S.C. § 387j(a)(3)(ii); Declaration of Matthew Farrelly ("Farrelly Decl.") [ECF No. 139-2] ¶ 7. The second is for SE reports claiming that new products have the "same characteristics" as their predicates—*i.e.*, that the new product is simply being sold in a different quantity. 21 U.S.C. § 387j(a)(3)(i); Farrelly Decl. ¶ 8. The reports in this second queue "do not require the same multi-discipline review as different characteristic SE reports" and have their own dedicated staff. Farrelly Decl. ¶ 8.

if that changed, the court denied Swisher's preliminary injunction motion and, following affirmance by the Eleventh Circuit, transferred the case to the district. See Swisher Int'l, Inc. v. FDA ("Swisher II"), 2022 WL 320889, at *3, 6 (11th Cir. Feb. 3, 2022); Transfer Order, ECF No. 64. Swisher then amended its complaint to remove the preliminary injunction request. It subsequently moved to complete or supplement the administrative record that the agency had certified and sought limited discovery. Swisher Int'l, Inc. v. FDA ("Swisher III"), No. 22-CV-954 (CRC), 2023 WL 6460028, at *3 (D.D.C. Oct. 4, 2023). The Court denied Swisher's motion. Id. at *7, 9.

That brings us to the present motions. Swisher moved for summary judgment on five of the eight counts in its amended complaint. Those counts allege that the Deeming Provision violates the non-delegation doctrine (Count One), the Deeming Rule exceeds the FDA's statutory authority (Count Four), the Deeming Rule is otherwise unlawful under the APA (Count Five), the FDA's failure to act on Swisher's SE reports is unlawful (Count Six), and the FDA's threatened enforcement against Swisher's cigars is unlawful (Count Eight). The FDA cross-moved for summary judgment on all the counts in the complaint, the remainder of which allege that the Deeming Provision violates the Appointments Clause (Count Two), the FDA's attempts to ratify the Deeming Rule are unlawful (Count Three), and the FDA's purported de facto ban on Swisher's cigars is unlawful (Count Seven). The agency also moved to dismiss Count Eight for lack of standing and moved to amend its answer to include the affirmative defense of claim preclusion. In this latter motion, the FDA asserts that all but Count Six of the amended complaint are precluded by a lawsuit brought by the cigar trade association of which Swisher is a prominent member. All three motions are briefed and ripe for review. The Court heard argument on the motions on July 17, 2024.

II. Legal Standards

A. Amendment of a Pleading

Federal Rule of Civil Procedure 15(a)(2) allows a plaintiff to file an amended complaint more than twenty-one days after an answer has been served only with the opposing party's consent or with leave of court. Fed. R. Civ. P. 15(a)(2). Leave to amend is to be "freely given when justice so requires," id., but may be denied for a number of reasons, including "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment[.]" Foman v. Davis, 371 U.S. 178, 182 (1962). "The party opposing amendment bears the burden of showing why leave file an amended pleading should not be granted." Schubarth v. Federal Republic of Germany, No. 14-cv-2140-CRC, 2021 WL 7889662, at *4 (D.D.C. Jan. 25, 2021) (Cooper, J.) (quotation marks omitted).

B. Dismissal

A "challenge to standing is properly raised" under Federal Rule of Procedure 12(b)(1). Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of Am. v. U.S. Dep't of Agric., 573 F. Supp. 3d 324, 332 (D.D.C. 2021). To establish standing, the party invoking federal jurisdiction must establish (1) an "injury in fact" (2) that is "fairly . . . trace[able] to the challenged action of the defendant" and (3) can be "redressed by a favorable decision." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992) (cleaned up); see also id. at 561 ("The party invoking federal jurisdiction bears the burden of establishing these elements."). And, because these elements "are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which

the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." Id. At the summary judgment stage, this burden of proof requires the plaintiff to "set forth by affidavit or other evidence specific facts" that establish standing. Swanson Grp. Mfg. LLC v. Jewell, 790 F.3d 235, 240 (D.C. Cir. 2015) (cleaned up).

C. Summary Judgment

Summary judgment is appropriate when the evidence demonstrates 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); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A fact is material if it can affect the outcome of litigation, and a dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986).

Summary judgment is the proper stage for determining whether, as a matter of law, an agency action is supported by the administrative record and is consistent with the APA. The APA provides that "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law[.]" 5 U.S.C. § 706(2)(A). Arbitrary and capricious review is "narrow." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The Court is not to "substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Rather, the Court must determine 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." Id. The Court's review is limited to the administrative record, Camp v. Pitts, 411 U.S.

138, 142 (1973), and the party challenging an agency's action bears the burden of proof, City of Olmsted Falls v. FAA, 292 F.3d 261, 271 (D.C. Cir. 2002).

III. Analysis

On the menu are the parties' dueling motions for summary judgment and the FDA's motion to amend and partial motion to dismiss. The Court finds that the agency may amend its answer to assert a claim preclusion defense and that the defense bars many of Swisher's claims. However, to inform any further appellate review should the D.C. Circuit disagree with the Court's resolution of the claim preclusion issue, the Court will nonetheless reach, and reject on the merits, each of Swisher's claims, save for the one that Swisher lacks standing to raise.

A. Amendment and Claim Preclusion

The FDA seeks to add the affirmative defense of claim preclusion to its answer and moves for summary judgment on that defense. It contends that the bulk of Swisher's claims are precluded by a suit that the Cigar Association of America ("CAA") and two other cigar trade associations have been litigating for almost eight years. In 2016, CAA, which is "the leading national trade association for the entire cigar industry" and counts Swisher in its senior ranks, and the other associations challenged the Deeming Rule under both the APA and First Amendment. See generally Fourth Am. Compl., Cigar Ass'n of Am. v. FDA ("CAA"), No. 16-cv-1460-APM (D.D.C.); Defs.' Mot. Amend at 2. That case has elicited several opinions from both the district and circuit courts, and two of the district court opinions are now on appeal. See generally Docket, CAA; Cigar Ass'n of Am. v. FDA, 964 F.3d 56 (D.C. Cir. 2020); Cigar Ass'n of Am. v. FDA, 5 F.4th 68 (D.C. Cir. 2021). The CAA plaintiffs have also amended their complaint four times, with one amendment challenging the District of Maryland's decision to invalidate the August 2017 guidance document. See First Am. Compl. ¶¶ 161–70, CAA. Citing

this morass of litigation, the FDA asserts that Swisher is barred from relitigating claims "that were or could have been litigated" in CAA. Defs.' Mot. Amend at 13 (quoting Alaska Forest Ass'n v. Vilsack, 883 F. Supp. 2d 136, 141–42 (D.D.C. 2012)).

Swisher opposes amendment on three grounds: (1) the FDA "offers no good reason for the delay," (2) the agency's "proposed amendment would prejudice Swisher by impairing its ability to respond," and (3) "amendment would be futile." Pl.'s Opp'n to Mot. Amend. at 1–2 (quotation marks omitted). Finding that none of Swisher's grounds for opposition carries the day, the Court will permit the FDA to amend its answer. The Court also finds that the FDA is entitled to summary judgment on its claim preclusion defense and will address that issue as part of its discussion of futility.

1. Undue Delay

Under the umbrella of undue delay, Swisher offers several reasons for why the Court should deny the FDA leave to amend. Some of the theories blend with Swisher's prejudice arguments, however, so the Court will address them there. Swisher's remaining delay arguments boil down to: (1) the FDA had "no good reason for the delay" and (2) its amendments add new factual allegations. Pl.'s Opp'n Mot. Amend at 9–10 (quotation marks omitted).

First, the reason for the FDA's delay. The short version is that the omission was "an inadvertent oversight not discovered until merits briefing" began. Defs.' Mot. Amend at 7. But the longer version is as follows: When opposing Swisher's motion for a preliminary injunction before the Middle District of Florida, the agency argued that "the affirmative defense of *res judicata* applied to most of Swisher's claims," and thus doomed the company's chance for demonstrating a likelihood of success on the merits. Defs.' Mot. Amend at 6 (citing Defs.' PI Opp'n at 10–16). The Florida court did not reach this argument, instead denying Swisher's

motion because it failed to show irreparable harm. Swisher Int'l, Inc. v. FDA, No. 3:21-cv-764-BJD-JBT, 2021 WL 4173841, at *3–5 (M.D. Fla. Sept. 7, 2021). The court also granted the agency's motion to transfer the case to the District of Columbia under the first-to-file rule and 28 U.S.C. § 1404, citing CAA. Id. at *6–9. Once the case landed in this district, Swisher amended its complaint and the FDA "inadvertent[ly]" did not include a claim preclusion defense in its answer. Defs.' Mot. Amend at 7. Soon after, Swisher moved to complete the administrative record, thus putting any merits briefing on hold until the Court resolved that motion. It was then not until the Court denied supplementation and "merits briefing [] recently got underway" that the agency noticed the omission. Id.

Against this backdrop, Swisher asserts that "[s]upposedly 'inadvertent' litigation choices are no excuse for the FDA's" delay. Pl.'s Opp'n Mot. Amend at 11. But the standard for amendment is not as strict as Swisher suggests. As the Supreme Court has held, "[a]n answer may be amended to include an inadvertently omitted affirmative defense, and even after the time to amend 'of course' has passed, 'leave [to amend] shall be freely given when justice so requires.'" Kontrick v. Ryan, 540 U.S. 443, 459 (2004) (quoting Fed. R. Civ. P. 15(a)) (second alteration in original); see also Harris v. Sec'y, U.S, Dep't of Veterans Affs., 126 F.3d 339, 343 (D.C. Cir. 1997) ("[T]he [Federal] Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." (cleaned up)).

This case is distinguishable from Mowrer v. Department of Transportation, 14 F.4th 723 (D.C. Cir. 2021), which Swisher cites. See Pl.'s Opp'n Mot. Amend at 11. There, plaintiffs sought to file a third amended complaint to re-add claims that they had previously raised in their opening complaint and then omitted from a consolidated complaint. Mowrer, 14 F.4th at 727–

28. Swisher suggests the agency's conduct here is no different because the FDA argued in its opposition to Swisher's preliminary injunction motion that claim preclusion barred its claims and later omitted that defense from its answer. See Pl.'s Opp'n Mot. Amend at 11. But the sequence of events sets the two cases apart. Unlike the plaintiffs in Mowrer, the FDA did not plead claim preclusion, omit that defense from a subsequent answer, and then try to add it back. Indeed, the operative answer is the only one the FDA has filed in this case, and, until the present motion, the FDA had never sought to amend it. So, while the agency may have made arguments about claim preclusion, it is not engaging in the game of yo-yo that the plaintiffs in Mowrer played.

Second, Swisher claims that the Court should deny leave to amend because the FDA's amendment would "add new factual allegations." Pl.'s Opp'n Mot. Amend at 10 (quoting Harrison v. Rubin, 174 F.3d 249, 253 (D.C. Cir. 1999)). In Harrison v. Rubin, the D.C. Circuit noted that it "recognized undue delay as a basis for denying a motion to amend . . . only where [parties] sought to add new factual allegations." 174 F.3d at 253. The FDA has added no new facts to the case through its proposed amendment. See Pl.'s Mot. Amend, Ex. A (Proposed Amended Answer). Instead, the only addition is a single line alleging that "Plaintiff's claims are precluded by the doctrine of *res judicata*"—in other words, a change to the FDA's legal theory. Id. at 30. But unless Swisher would be "prejudiced on the merits by a change in legal theory," the FDA "is not bound by the legal theory on which [it] originally relied." Harrison, 174 F.3d at 253 (quotation marks omitted). Thus, undue delay does not preclude amendment.

2. Undue Prejudice

That brings us to prejudice. Swisher contends it would be unduly prejudiced by the amendment because the FDA filed it after Swisher had moved for summary judgment and, as a result, Swisher missed an opportunity to gather evidence related to the defense.

As to timing, Swisher claims the D.C. Circuit has been "crystal clear": "[A] party must first raise its affirmative defenses in a responsive pleading before it can raise them in a dispositive motion." Pl.'s Opp'n Mot. Amend at 11–12 (quoting Harris, 126 F.3d at 345). But the FDA did that. It sought leave to amend *before* it moved for summary judgment. Thus, consistent with this Court's past practice, it does not view Harris as a barrier to amendment. See Mwimanzi v. Wilson, 590 F. Supp. 3d 231, 243, 245 (D.D.C. 2022) (Cooper, J.) (allowing plaintiff to bring and concurrently brief a motion to amend and a motion for summary judgment and granting both motions). Moreover, even when the order of filings is flipped (*i.e*, when parties move for summary judgment before moving to amend), courts in this district have still understood amendment to comply with Harris. As one judge noted, "[i]t is clearly the motion to amend that is crucial, not its timing." Butler v. White, 67 F. Supp. 3d 59, 67 (D.D.C. 2014); see also Nurriddin v. Goldin, 382 F. Supp. 2d 79, 91–92 (D.D.C. 2005), aff'd sub nom. Nurriddin v. Griffin, 222 F. App'x 5 (D.C. Cir. 2007) (per curiam).

Though the timing of the FDA's amendment does not run afoul of Harris, Swisher still contends that it would be prejudiced by losing the opportunity to conduct discovery. According to Swisher, the only discovery it seeks is from CAA, its own trade association. Tr. at 36; see also id. (noting that Swisher's only other fact-gathering would entail "consult[ing]" internally, "put[ting] a declaration together, and "find[ing] documents"); Pl.'s Opp'n Mot. Amend at 14. For three related reasons, the Court finds Swisher would not be unduly prejudiced by amendment.

First, much of the information Swisher has suggested CAA can supply is in the public record. In particular, Swisher claims that it would seek documents "show[ing] the make-up of the board" "going back to 2016" and including the present. Tr. at 38–39. Almost all of this is

public record. CAA, a tax-exempt organization, files annual Form 990s with the Internal Revenue Service ("IRS"), and these forms are available on the IRS's website and subject to judicial notice.[3] See also Arab v. Blinken, 600 F. Supp. 3d 59, 63 n.1 (D.D.C. 2022) ("The Court may take judicial notice of information posted on official public websites of government agencies." (citing Cannon v. District of Columbia, 717 F.3d 200, 205 n.2 (D.C. Cir. 2013))). These returns list the members of CAA's board of directors and reveal that from 2016, when CAA was filed, to at least 2021 a minimum of two Swisher executives served on CAA's twenty-plus-member Board each year. The FDA also presented evidence that at least two Swisher employees served on CAA's Board in 2022, which Swisher confirmed, see Pl.'s Opp'n Mot. Am. at 4 & n.2.[4]

Second, even if some of the information Swisher seeks cannot be found in public records, Swisher almost certainly has that information at its disposal. For example, if Swisher opposed

[3] https://apps.irs.gov/app/eos/details/ (EIN 13-5568722).

[4] In annual filings with Florida's Secretary of State, Swisher reports the names of its executives. When viewed alongside CAA's Form 990s, these filings reflect that a rotating cast of two Swisher executives served on CAA's Board from 2016 to 2021. Compare Swisher Int'l Inc., Fla. Sec. of State, 2016 Foreign Profit Corporation Annual Report (Apr. 19, 2016) (listing Peter Ghiloni and Christopher Casey as executives of Swisher); Swisher Int'l Inc., Fla. Sec. of State, 2017 Foreign Profit Corporation Annual Report (Apr. 11, 2017) (same); Swisher Int'l Inc., Fla. Sec. of State, 2018 Foreign Profit Corporation Annual Report (Jan. 19, 2018) (same); Swisher Int'l Inc., Fla. Sec. of State, 2019 Foreign Profit Corporation Annual Report (Apr. 15, 2019) (listing John Miller and Christopher Casey as executives of Swisher); Swisher Int'l Inc., Fla. Sec. of State, 2020 Foreign Profit Corporation Annual Report (Jan. 23, 2020) (same); Swisher Int'l Inc., Fla. Sec. of State, 2021 Foreign Profit Corporation Annual Report (Apr. 23, 2021) (same) with Cigar Ass'n of Am., Int. Rev. Serv., Form 990 for 2016 (listing Peter Ghiloni and Christopher Casey as members of the CAA Board of Directors); Cigar Ass'n of Am., Int. Rev. Serv., Form 990 for 2017 (same); Cigar Ass'n of Am., Int. Rev. Serv., Form 990 for 2018 (same); Cigar Ass'n of Am., Int. Rev. Serv., Form 990 for 2019 (listing John Miller and Christopher Casey as members of the CAA Board of Directors); Cigar Ass'n of Am., Int. Rev. Serv., Form 990 for 2020 (same); Cigar Ass'n of Am., Int. Rev. Serv., Form 990 for 2021 (same).

the filing of CAA in 2016 or objected to one of the four amended complaints filed since then, Swisher would not need third-party discovery to uncover that information. It could simply submit a declaration from one of its own employees to that effect. Indeed, Swisher has not suggested discovery would reveal such facts. Instead, it has given only generalized descriptions of the discovery it seeks—descriptions that "hardly meet[] the standard of showing what specific facts or evidence plaintiff has been deprived from uncovering." Butler, 67 F. Supp. 3d at 68.

Third, even if there were some information that was not in the public record or in Swisher's possession, CAA is Swisher's own trade organization and would be unlikely to resist overtures from Swisher to provide information absent formal discovery. Swisher claims that "without discovery [it] lacks any lawful basis to require third parties such as [CAA] to produce documents or provide written or oral testimony[.]" Pl.'s Opp'n Mot. Amend at 14. But Swisher has given no indication that it has requested that CAA produce documents or provide testimony, let alone that CAA has refused. In sum, Swisher's non-specific calls for discovery do not preclude amendment.

Finally, two other factors undercut Swisher's claim of prejudice. *First*, "res judicata belongs to courts as well as to litigants." Stanton v. D.C. Ct. of Appeals, 127 F.3d 72, 77 (D.C. Cir. 1997). Though the doctrine "exists in part to shield parties from duplicative and vexatious litigation, the interests that courts protect are also often their own—or, more precisely, those of society." Id. A "*party's* forfeiture of the right to assert" the defense therefore "does not destroy a *court's* ability to consider the issue sua sponte." Id. (emphasis in original). Regardless of whether the FDA amends its answer then, the Court may still consider whether CAA precludes relitigation of Swisher's claims. *Second*, there is no prejudice to Swisher for the simple reason

that—irrespective of claim preclusion—the Court finds dismissal of Swisher's claims warranted.[5]

3. Futility of Amendment

Because neither undue delay nor undue prejudice preclude amendment, the question comes down to futility. The circuits appear to disagree about whether the standard for futility requires that a proposed amendment be able to survive summary judgment (as opposed to a motion to dismiss) once a case has progressed to that stage of litigation. Compare Sound of Music Co. v. Minnesota Min. & Mfg. Co., 477 F.3d 910, 923 (7th Cir. 2007) ("If the amended claim would not survive a motion for summary judgment, the amendment is futile.") with Rose v. Hartford Underwriters Ins. Co., 203 F.3d 417, 421 (6th Cir. 2000) ("The test for futility, however, does not depend on whether the proposed amendment could potentially be dismissed on a motion for summary judgment; instead, a proposed amendment is futile only if it could not withstand a Rule 12(b)(6) motion to dismiss."). In an unpublished opinion, the D.C. Circuit held that a district court's denial of amendment was proper "because appellant's showing was insufficient to defeat the appellee's motion for summary judgment." West v. Potter, 171 F. App'x 849, 849 (D.C. Cir. 2005) (per curiam). The Court need not wade into this dispute, however, because it finds the FDA's amendment would not be futile under the standards for a motion to dismiss or summary judgment.

Under the doctrine of claim preclusion, "a final, valid judgment on the merits precludes any further litigation between the same parties on the same cause of action." Stanton, 127 F.3d

[5] The Court may consider the merits of Swisher's claims despite its conclusion that many of those claims are barred by claim preclusion because the defense, "while having a somewhat jurisdictional character, does not affect the subject matter jurisdiction of the district court." Smalls v. United States, 471 F.3d 186, 189 (D.C. Cir. 2006) (quotation marks omitted).

at 78. A subsequent lawsuit is "barred if there has been prior litigation (1) involving the same claims or cause of action, (2) between the same parties or their privies, and (3) there has been a final, valid judgment on the merits, (4) by a court of competent jurisdiction." Smalls, 471 F.3d at 192. The third element—a "final, valid judgment"—falls away where, as here, a party relies on the doctrine against claim-splitting. That doctrine precludes plaintiffs from "seek[ing] to maintain two actions on the same subject in the same court, against the same defendant at the same time." Clayton v. Dist. of Columbia, 36 F. Supp. 3d 91, 94 (D.D.C. 2014) (quotation marks omitted). While claim-splitting is an "aspect of *res judicata*, . . . a final judgment is not a necessary component of the claim-splitting analysis[.]" Id. at 95 n.2 (quoting Katz v. Gerardi, 655 F.3d 1212, 1218 (10th Cir. 2011)).

Swisher does not dispute that the CAA court is of competent jurisdiction but asserts that the FDA has failed to carry its burden as to the first two requirements for claim preclusion. Pl.'s Opp'n Mot. Amend at 16–25; see also Taylor v. Sturgell, 553 U.S. 880, 907 (2008) ("[A] party asserting preclusion must carry the burden of establishing all necessary elements." (quoting 18 C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure § 4405, at 83 (2d ed. 2002))).

a. Same Parties or their Privies

As for the requirement that the prior litigation involve the same parties or their privies, in Taylor v. Sturgell, the Supreme Court cited six exceptions to "the general rule that 'one is not bound by a judgment *in personam* in a litigation in which he is not . . . a party[.]'" 553 U.S. at 893 (quoting Hansberry v. Lee, 311 U.S. 32, 40 (1940)); see also id. at 893 n.6 (noting that the six exceptions provide a "framework," not a "definitive taxonomy").[6] Most relevant here is the

[6] As the FDA notes, in a trio of decisions predating Taylor, the D.C. Circuit held that judgments against trade association bound their members. See W. Coal Traffic League v. I.C.C., 735 F.2d 1408, 1411 (D.C. Cir. 1984) (R. B. Ginsburg, J.); Aluminum Co. of Am. v. I.C.C., 761

exception for adequate representation. "A party's representation of a nonparty is 'adequate' for preclusion purposes only if, at a minimum: (1) The interests of the nonparty and her representative are aligned; and (2) either the party understood herself to be acting in a representative capacity or the original court took care to protect the interests of the nonparty[.]" Id. at 900 (cleaned up). And in some cases, "adequate representation [also] requires (3) notice of the original suit to the persons alleged to have been represented[.]" Id. The Taylor court emphasized, however, that the adequate-representation exception is reserved for "limited circumstances," and listed as examples of such circumstances "properly conducted class actions" and "suits brought by trustees, guardians, and other fiduciaries." Id. at 894–95 (quoting Richards v. Jefferson Cnty., 517 U.S. 793, 798 (1996)).

Though it is a close question, CAA's representation of Swisher was adequate. *First*, CAA and Swisher's interests across the two suits are aligned. In the first suit, CAA, a 39-member trade association that includes Swisher, asserted associational standing as the basis for Article III jurisdiction. Fourth Am. Compl. ¶ 13, CAA ("[T]he Plaintiff Associations have standing to bring this suit because [] their members would otherwise have standing to sue[.]"). By claiming associational standing, CAA represented that its interests were aligned with those of its constituents. See Hunt v. Wash. State Apple Advertising Comm'n, 432 U.S. 333, 343 (1977) (holding that associations have standing only if "the interests it seeks to protect are germane to the organization's purpose"). Indeed, as the Supreme Court has observed, "the doctrine of

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F.2d 746, 751 (D.C. Cir. 1985) (Scalia, J.); Utah Power & Light Co. v. I.C.C., 764 F.2d 865, 871 (D.C. Cir. 1985); see also Reply Mot. Amend at 12. Though the Taylor court did not explicitly overrule those cases, it did note that lower courts, including the D.C. Circuit, had adopted "an expansive doctrine of virtual representation" that strayed beyond "the established exceptions" to the rule against nonparty preclusion. 553 U.S. at 896. To ensure its analysis does not similarly stray, the Court will adhere to Taylor's recognized exceptions.

associational standing recognizes that the primary reason people join an organization is often to create an effective vehicle for vindicating interests that they share with others." Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Brock, 477 U.S. 274, 290 (1986). A comparison of the operative complaints in the two suits confirms that CAA and Swisher have shared interests. Take the following parallel allegations:

CAA's Fourth Amended Complaint	**Swisher's Amended Complaint**
In its final regulatory analysis, "[t]he FDA either ignored or failed to adequately address Plaintiffs' comments and failed to supply a reasoned determination that the benefits of the regulation justify its costs." Fourth Am. Compl., CAA ¶ 156.	"The FDA [] failed to respond to the concerns of commenters . . . or adequately weigh the costs and benefits of the Deeming Rule." Am. Compl. ¶ 164.
The Deeming Rule's imposition of "the substantial equivalence process on cigars and pipe tobacco" was arbitrary and capricious. Fourth Am. Compl., CAA ¶¶ 283.	"The FDA [] failed to . . . consider obvious alternatives," Am. Compl. ¶ 164, including not deeming cigars, Pl.'s Mot. Summ. J. at 34.
The Deeming Rule is arbitrary and capricious because it is based on a "faulty legal premise" about whether the agency could extend, without notice and comment, the compliance periods during which it would not bring enforcement actions. Fourth Am. Compl., CAA ¶¶ 256–63.	"Swisher lacked fair notice that its products would be subject to an enforcement action before it received an answer from the FDA on its substantial-equivalence reports" in violation of the Due Process Clause, APA, TCA, and other laws. Am. Compl. ¶ 195.

Throughout its filings, Swisher also references and endorses points raised by CAA in the comment letter CAA submitted to the proposed Deeming Rule. See, e.g., Pl.'s Mot. Summ. J. at 4–5, 35, 39; Pl.'s Opp'n Mot. Summ. J. at 34; see also JA (Vol. 1) 182–217. Based on these factors, the Court finds the interests of Swisher and CAA aligned.

The FDA has also carried its burden as to Taylor's second element—that CAA "understood [it]self to be acting in a representative capacity." 553 U.S. at 900 (cleaned up). More than that, the FDA has demonstrated that CAA *was* acting in a representative capacity.

When an association is permitted to proceed on a theory of associational standing, the presumption is that it represents the interests of its members. See Brock, 477 U.S. at 290 ("The

very forces that cause individuals to band together in an association will thus provide some guarantee that the association will work to promote their interests."). Of course, the presumption that the association adequately represents its members can be rebutted. See id. ("We are not prepared to dismiss out of hand the [] concern that associations allowed to proceed under [a theory of associational standing] will not always be able to represent adequately the interests of all their injured members."). And when it is rebutted, "a judgment won against [the association] might not preclude subsequent claims by the association's members without offending due process principles." Id. But, as the Supreme Court implied in Brock, the presumption is that an association's judgment binds its members.

A fellow court in this district applied this framework in Alaska Forest Ass'n v. Vilsack, 883 F. Supp. 2d 136 (D.D.C. 2012). Finding that a constituent of a membership organization could not relitigate claims the organization had already pursued, the court noted that, "[i]n general, '[a] person who is not a party to an action but who is represented by a party is bound by and entitled to the benefits of a judgment as though he were a party.'" Id. at 142 (quoting Restatement (Second) of Judgments § 41 (1982)).[7] And though claim preclusion is an affirmative defense, the court put the onus on the plaintiff—the party resisting the application of the defense—to "meet [one] of the [] recognized exceptions to that [general] rule." Id. Because

[7] Alaska Forest Association ("AFA") was a member of Southeast Conference ("Southeast"), an Alaska Regional Development Organization whose members included municipalities, Native corporations, tribal councils, regional and local businesses, civic organizations, and individuals from the region. Compl. ¶ 8, Alaska Forest Ass'n, No. 8-cv-1598-JDB.

the plaintiff did not meet one of those exceptions, the court found the plaintiff had failed to rebut the presumption that the organization's representation was adequate. Id.[8]

This approach is also consistent with Taylor. There, the Supreme Court held that because claim preclusion is an affirmative defense, it is "incumbent on the defendant to . . . prove such a defense." Taylor, 553 U.S. at 907. But the Supreme Court did not disturb the general rule that, at summary judgment, "the moving party is entitled to the benefit of any relevant presumptions." United States v. Gen. Motors Corp., 518 F.2d 420, 441 (D.C. Cir. 1975); see also id. at 441–42 ("[I]f the established facts and relevant presumptions would have entitled [a party] to a directed verdict at trial, he is entitled to [] summary judgment under Rule 56.").

Applying that framework, the Court finds that CAA acted in a representative capacity on behalf of Swisher. The agency has offered evidence that CAA proceeded on a theory of associational standing and that Swisher is a member of CAA. Def.'s Mot. Summ. J. at 10. The public record further reveals that Swisher has played a longstanding leadership role in the association. See supra at 15 & n.4. These facts create a presumption that CAA represented Swisher, and Swisher has offered no evidence to rebut this presumption.[9]

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[8] AFA faced an uphill climb in seeking to rebut the presumption that it had been adequately represented by Southeast: AFA had submitted an affidavit in the precursor case supporting Southeast's standing argument and stating that Southeast's claims were in its interest. Alaska Forest Ass'n, 883 F. Supp. 2d at 142. Seizing on this fact, Swisher suggests that claim preclusion is not appropriate here because Swisher did not submit a similar affidavit in support of CAA's standing argument. Pl.'s Opp'n Mot. Amend at 21–22. But though the affidavit undercut any argument that AFA's interests had not been adequately represented, the presumption still stood in Alaska Forest Ass'n—with or without the affidavit—that Southeast's judgment bound its members. See 883 F. Supp. 2d at 142 (describing the affidavit in the context of explaining why none of the "recognized exceptions" to the rule of non-party judgment applied).

[9] Swisher insists it should not be required to consult its trade association or even gather facts internally to counter the FDA's claim-preclusion defense until the Court decides whether to permit amendment. See Tr. at 37 ("We're not required to have our client pay us to develop the record that assumes that [the FDA will] get the relief that [it is] asking [] for."). Though Swisher

But, as alluded to above, Taylor does not require that CAA actually represented Swisher. It merely requires that CAA "*understood* [it]self to be acting in a representative capacity." Taylor, 553 U.S. at 900 (cleaned up) (emphasis added). The complaint in CAA reflects it did. As early as the first complaint, the association stated that it "represent[s] cigar manufacturers" and that "neither the claims asserted nor the relief requested requires the participation of [its] individual members in the lawsuit." Compl. ¶¶ 9, 13, CAA. Accordingly, the agency is entitled to summary judgment as to this element of Taylor's tripartite test.

Finally, Taylor's third requirement for adequate representation—"notice of the original suit to the persons alleged to have been represented," which is only sometimes necessary—is also satisfied. 553 U.S. at 900 (cleaned up). Constructive notice suffices, see Midwest Disability Initiative v. JANS Enterprises, Inc., 929 F.3d 603, 608 (8th Cir. 2019); Yankton Sioux Tribe v. Dep't of Health & Hum. Servs., 533 F.3d 634, 641 (8th Cir. 2008), and Swisher surely had at least constructive notice of CAA's lawsuit. Again, from 2016, when CAA was initiated, until at least 2022, two Swisher executives served on the association's board of directors. Thus, the Court finds that CAA adequately represented Swisher's interests.

b. Same Claims or Cause of Action

That leaves the remaining element of claim preclusion—whether CAA and this case "involv[e] the same claims or cause of action." Smalls, 471 F.3d at 192. This inquiry "turns on whether [the two cases] share the same 'nucleus of facts.'" Drake v. FAA, 291 F.3d 59, 66 (D.C. Cir. 2002) (quoting Page v. United States, 729 F.2d 818, 820 (D.C. Cir. 1984)).

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may not want to invest resources in countering the defense, that is no reason to excuse its failure to offer evidence. Swisher had notice that the FDA was seeking to amend its answer and move for summary judgment on claim preclusion, see Pl.'s Opp'n to Mot. Ext. [ECF No. 110], and—as explained above—D.C. Circuit precedent allows a party to move for, and be granted, summary judgment on a claim that is also the subject of a motion to amend.

As alluded to above, both the plaintiffs in CAA and Swisher challenged the Deeming Rule on a range of theories under the Constitution and APA. Am. Compl. ¶¶ 132–96; Fourth Am. Compl., CAA ¶¶ 106–299. As support, their complaints rely on largely the same set of facts—namely, the history and provisions of the TCA; the history of the Deeming Rule, including the comments the agency received during the notice and comment period and its responses; and the numbers of applications the agency received or might expect to receive. Am. Compl. ¶¶ 22–28, 48–66, 89–93; Fourth Am. Compl., CAA ¶¶ 18–42, 74–76. And with limited exceptions, many of the facts Swisher relies on here were "in existence" at the time CAA filed suit. Cf. Drake, 291 F.3d at 66 ("*Res judicata* does not preclude claims based on facts not yet in existence at the time of the original action."). To be sure, some of the legal theories differ, but "it is the facts surrounding the transaction or occurrence which operate to constitute the cause of action, not the legal theory upon which a litigant relies." Page, 729 F.2d at 820 (cleaned up).

Accordingly, the Court finds that all of Swisher's claims except for Counts Six (the unreasonable-delay claim), Seven (the de-facto-ban claim), and Eight (the threat-of-enforcement claim) share a common nucleus of facts with CAA. The rest of Swisher's claims challenge either the Deeming Provision or are based on facts about the Deeming Rule that were either "known" or "reasonably discoverable" at the time CAA sued in 2016 or filed its fourth amended complaint in November 2020. Role Models Am., Inc. v. Penmar Dev. Corp., 394 F. Supp. 2d 121, 132 (D.D.C. 2005), aff'd, 216 F. App'x 5 (D.C. Cir. 2007) (per curiam); Ramey v. Potomac Elec. Power Co., 580 F. Supp. 2d 40, 44 (D.D.C. 2008) (applying claim preclusion because the relevant fact was known after plaintiff first filed suit but before he filed an amended complaint and over a year before a final order was issued). Indeed, most are based on the underlying facts of the Deeming Provision (Count One) or Deeming Rule (Counts Two, Four, and Five). Count

Three alleges that the FDA's attempts to ratify the Deeming Rule were independently unlawful, but the relevant ratifications occurred in 2016 and 2019—before CAA filed its latest amended complaint. Am. Compl. ¶¶ 146–51.[10]

The remaining counts do not involve the same nucleus of facts as CAA. The FDA acknowledges that is so for Count Six (the unreasonable-delay claim), see Defs.' Mot. Amend at 15, but Count Seven (the de-facto-ban claim) is based on the same set of facts as Count Six, see Am. Compl. ¶ 184 ("In practical effect, the FDA's failure to act is a de facto ban on Swisher's cigars.").

Count Eight also does not share a nucleus of facts with CAA. In this count, Swisher alleges that it "lacked fair notice that its product would be subject to an enforcement action before it received an answer from the FDA on its [SE] reports even if Swisher complied" with the agency's application deadlines. Am. Compl. ¶ 195. As a result, Swisher claims, the "FDA's threatened enforcement of the TCA against Swisher's cigars violates the Due Process Clause, the APA, the TCA, and other applicable law[.]" Id. ¶ 196; see also id. ¶ 197(e) (seeking injunctive relief prohibiting the FDA from enforcing the TCA against Swisher). The FDA maintains that Swisher is "attempt[ing] to obtain a second bite" at a claim for declaratory judgment that CAA

[10] As Swisher points out, the Court previously ruled that CAA and this case were not related under this district's local rules. Apr. 25, 2022 Minute Order; see LCvR 40.5(a)(3). Though the standards for related cases and claim preclusion are similar, they are not identical. See Univ. of Colorado Health at Mem'l Hosp. v. Burwell, 233 F. Supp. 3d 69, 81–82 (D.D.C. 2017). And in any event, as the Court explained in its minute order, it did not designate the two cases as related largely because of how CAA progressed. By the time the FDA sought to relate the cases, CAA had become "more narrowly focused on 'premium' cigars," Apr. 25, 2022 Minute Order, which Swisher's products are not. It was for this reason, and not because of the absence of common issues of fact, that the Court determined a "transfer would [] not benefit judicial economy." K.O. v. U.S. Immigr. & Customs Enf't, 468 F. Supp. 3d 350, 361 (D.D.C. 2020), aff'd sub nom. K.O. by & through E.O. v. Sessions, No. 20-5255, 2022 WL 3023645 (D.C. Cir. July 29, 2022).

raised. Defs.' Mot. Amend at 17. In July 2019, CAA moved to amend its complaint to include a count seeking a "declaration that the [FDA's August 2017] Guidance, including its extension of compliance deadlines . . . is valid and in effect for cigars and pipe tobacco or, in the alternative, for Plaintiffs and Plaintiffs' members." First Am. Compl., CAA [ECF No. 135-1] ¶ 170. Though success on Count Eight would—in effect—allow Swisher to obtain an extension of compliance deadlines (indeed, this is one way in which Swisher's and CAA's interests are aligned), Swisher relies on different facts than CAA did. For example, Swisher insists that the "FDA repeatedly assured manufacturers, implicitly and expressly"—and not just through the August 2017 guidance—that the agency "would not force newly deemed products off the shelves without providing manufacturers a meaningful opportunity to obtain premarket review." Am. Compl. ¶ 189; id. ¶ 190 ("The FDA also specifically promised Swisher and other cigar manufacturers that it would exercise its discretion to defer enforcement actions . . . ."). In Count Eight, Swisher also alleges that it "made substantial investments in its process for submitting [SE] reports," "timely submitted [its SE] reports" and "complied with all of the FDA's relevant instructions and deadlines"—facts that CAA did not rely on. Id. ¶¶ 191, 195.

In sum, the FDA has demonstrated that claim preclusion bars Counts One through Five of Swisher's complaint. But, as noted above, the Court will nonetheless address all of Swisher's counts.[11]

[11] Swisher also points to the Federal Trade Commission's brief in Ryan LLC v. FTC, No. 3:24-cv-986-E (N.D. Tex. Aug. 5, 2024), as proof that the government is trying to "have it both ways." See Def.'s Not. Supp. Auth. [ECF No. 144] at 2. That brief is not the "gotcha" that Swisher seems to think it is because this case is different from Ryan. In Ryan, the FTC argued that injunctive relief should not extend to all of the plaintiff trade association's unnamed members, who may not even know of the lawsuit. See id. at 69. Here, Swisher is not just any member of CAA; its executives served on CAA's board when CAA challenged the Deeming Rule. In any event, the government is free to take different positions in different cases against

B. Unreasonable Delay (Count Six)

The Court now turns to the merits of the parties' summary judgment motions and begins with Count Six, Swisher's principal claim in this case. Swisher alleges that the FDA has delayed too long in processing its applications for marketing approval. Agency delay claims are assessed under the factors outlined in Telecomms. Rsch. & Action Ctr. v. FCC ("TRAC"), 750 F.2d 70 (D.C. Cir. 1984). The six TRAC factors are:

> (1) the time agencies take to make decisions must be governed by a "rule of reason";
>
> (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;
>
> (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;
>
> (4) the effect of expediting delayed action on agency activities of a higher or competing priority;
>
> (5) the nature and extent of the interests prejudiced by delay;
>
> (6) there need not be any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

Id. at 80 (cleaned up). Though TRAC outlines six factors, the "two factors most important in this case," as in many cases, "are factor[s] one . . . [and] four." Da Costa v. Immigr. Inv. Program Off., 80 F.4th 330, 340 (D.C. Cir. 2023).

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different parties. See United States v. Mendoza, 464 U.S. 154, 162–63 (1984); Cotton v. Heyman, 63 F.3d 1115, 1119 n.2 (D.C. Cir. 1995).

1. Rule of Reason and Statutory Timeline (Factors 1 and 2)

The first two TRAC factors are "typically considered together" because of their overlap. Milligan v. Pompeo, 502 F. Supp. 3d 302, 317 (D.D.C. 2020). The Court will start with the second and return to the first.

Under the second factor, the statutory scheme does not establish a timetable for when the FDA must complete review of SE reports. The statute does set a 180-day period for review of PMTAs, 21 U.S.C. § 387j(c)(1)(A), but a similar deadline is conspicuously absent from sections governing the agency's review of SE reports. Swisher suggests that Congress must have intended for the 180-day timeframe to apply to SE reports as well, or at least that the timeframe serves as a "common sense marker of the outer boundary of reasonableness." Pl.'s Mot. Summ. J. at 22 (cleaned up). But these suggestions fly in the face of the "general[] presum[ption]" that "when Congress includes particular language in one section of a statute but omits it in another, Congress intended a difference in meaning." Maine Cmty. Health Options v. United States, 590 U.S. 296, 314 (2020) (cleaned up). Thus, there is no reason to treat the 180-day timeline for PMTAs as a "rule or ruler" for the FDA's review of SE reports. See Pl.'s Not. Supp. Auth. [ECF No. 132] at 2 (quoting Afghan & Iraqi Allies v. Blinken, 103 F.4th 807, 817 (D.C. Cir. 2024)); see also Ctr. for Sci. in the Pub. Int. v. FDA, 74 F. Supp. 3d 295, 301 (D.D.C. 2014) (rejecting the argument that a deadline requiring an initial response from the FDA "also provides a framework within which to gauge [the] FDA's delay in issuing a *final* response" (emphasis added)).

The other statutory and regulatory provisions Swisher references also do not supply "content" for the "rule of reason." TRAC, 750 F.2d at 80. One section of the TCA requires manufacturers to submit certain information to the FDA "90 days prior" to selling any product

not on the market prior to the date of the TCA's enactment. 21 U.S.C. § 387d(c)(1); see also 21 U.S.C. § 387e(j)(1) (imposing a 90-day reporting requirement on manufacturers for similar information). But this reporting requirement is independent from the premarket authorization pathways, and the volume and complexity of the requested information pales in comparison to that required in an SE report. Compare 21 U.S.C. § 387d(a) (listing the required contents of the 90-day report) with 21 C.F.R. § 1107.18 (listing the required contents of an SE report). 21 C.F.R. § 1107.42 is similarly unavailing. It states that the agency "intends to review the SE Report and either communicate with the applicant as described in § 1107.40 or take an action under § 1107.44 within 90 calendar days of FDA's receipt of the SE Report[.]" Id. § 1107.42(a). But this section does not set any deadline for the issuance of a final order, and the FDA did, in fact, satisfy its obligation. Consistent with § 1107.40, the FDA agreed to accept Swisher's reports within 90 days of receipt. See 21 C.F.R. § 1107.40(c) ("After receiving an SE Report under § 1107.18, FDA will either refuse to accept the SE Report for review or issue an acceptance for review letter."); see also Defs.' Mot. Summ. J. at 56. Accordingly, because Congress set "no statutory limit," "the agency is 'entitled to considerable deference' in setting administrative timelines." L'Association des Americains Accidentels v. Dep't of State, 633 F. Supp. 3d 74, 84 (D.D.C. 2022) (quoting Mexichem Spec. Resins, Inc. v. EPA, 787 F.3d 544, 555 (D.C. Cir. 2015)).

As for the first TRAC factor—whether the agency's delay is governed by "a rule of reason"—the relevant considerations can be slotted into two categories. *First*, courts consider whether the agency has "an identifiable rationale" for how to order its priorities and allocate scarce resources. Ctr. for Sci. in the Pub. Int., 74 F. Supp. 3d at 300. If so, courts typically find the agency timing to be governed by a rule of reason. Conversely, the opposite is true if the

delay results from agency choices that are arbitrary, unexplained, or discriminatory. See, e.g., Liu v. Mayorkas, No. 20-cv-654 (CRC), 2021 WL 2115209, at *3 (D.D.C. May 25, 2021) (Cooper, J.). *Second*, courts look to the length of the agency's delay. "In assessing whether an agency follows a rule of reason, [courts] evaluate the length of the delay in light of 'the complexity of the task at hand, the significance (and permanence) of the outcome, and the resources available to the agency.'" Da Costa, 80 F.4th at 340 (quoting Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1102 (D.C. Cir. 2003)). The Court will take up each criterion in turn.

a. Identifiable Rationale

The agency has articulated an "identifiable rationale" for processing SE reports. In his 2021 article, Mr. Zeller explained that the agency adopted a randomized approach to ensure that all manufacturers with timely, accepted applications could have at least some products enter the substantive review phase before September 9, 2021—the date the FDA's non-enforcement window closed. JA (Vol. 1) at 1095. In other words, the randomized process was designed to ensure fairness across manufacturers.

Swisher picks several bones with how the agency designed its review process. *First*, Swisher claims that the randomized queue for SE reports "stands in stark contrast to the reasoned approach the FDA adopted for PMTAs, where it prioritizes review of products with the most market share[.]" Pl.'s Mot. Summ. J. at 26. Conveniently, Swisher would find itself at the front of the line if the FDA adopted that approach for SE reports. Id. But the agency had a clear reason to modify the process for PMTAs. And the modification was slight in any case. As the FDA explained, "nearly all" of the PMTAs enter review queues through a randomized process. JA (Vol. 1) at 1095. But the agency decided to pull e-cigarettes, vapes, and other electronic

nicotine delivery systems ("ENDS") with "the largest overall market share" into a separate review stream because it determined "[t]he continued marketing of these products ha[d] the potential to have the greatest public health impact—either positively or negatively[.]" Id.; see also 81 Fed. Reg. at 29,028 ("FDA remains concerned about the rise in use of newly deemed products by youth and young adults, particularly the increase in use of ENDS.").

Second, Swisher views as unreasonable the agency's decision to separately review applications for the same cigars sold in different package sizes (*e.g.*, a two-pack vs. a five-pack). Pl.'s Mot. Summ. J. at 26. But "the quantity or size of a tobacco product can affect the initiation and cessation behaviors of youth." Philip Morris USA Inc. v. FDA, 202 F. Supp. 3d 31, 56 (D.D.C. 2016). Indeed, experimental studies have shown that "young adults show the strongest intentions to buy and smoke cigarillos that are in smaller pack sizes and sold at lower prices." Campaign for Tobacco-Free Kids Amicus Br. at 20 & n.30. Based on these facts, the FDA had a reasonable basis for differentiating among products based on their package size.

Third, Swisher maintains that the agency "is inexplicably planning to review many of Swisher's reports twice," a choice that "compound[s] an already unreasonable delay." Pl.'s Opp'n Mot. Summ. J. at 10. Swisher mischaracterizes the record. As the company correctly notes, the FDA created 267 STNs for the 171 SE reports Swisher submitted. Id. But the agency had a good reason to do this. When manufacturers listed multiple products in a single submission, the agency created unique STNs for each product. See JA (Vol. 2) at 1255. On one occasion, the FDA assigned distinct STNs to two products with different names but later determined that the products were duplicates. Id. at 1420. The agency can hardly be faulted for its original confusion.

Fourth, Swisher points to an independent report that it claims reveals "[t]he problem the FDA has created for itself and the industry." Pl.'s Mot. Summ. J. at 24. In 2022, the FDA Commissioner commissioned the Reagan-Udall Foundation to convene an expert panel to evaluate the Center for Tobacco Products ("CTP"), the division of the FDA conducting pre-market application review. JA (Vol. 1) at 1113. The panel did offer recommendations for improving CTP's review of PMTAs, see id. at 1127–29, but what Swisher fails to mention is that the panel found that "some [of CTP's] processes [were] perceived as working well" and specifically called out the "SE pathway[]" as one such success story. Id. at 1126. And, after soliciting comments from stakeholders, the panel noted that it "did not receive significant feedback concerning the SE [] pathway." Id. at 1127. Thus, for SE reports—the pathway Swisher is following—the Reagan-Udall report suggests the agency's implementation has proceeded with few hitches. And, as for the PMTA process, the FDA has committed to addressing the recommendations in the Reagan-Udall report. See id. at 1138 ("It may take some time to implement any recommended changes, but [the FDA is] committed to addressing them and communicating them to the public in a timely manner."). This commitment counsels against the Court interfering with that process. Cf. Am. Hosp. Ass'n v. Burwell, 812 F.3d 183, 192 (D.C. Cir. 2016) ("[T]he district court also correctly concluded that the Secretary's good faith efforts to reduce the delays within the constraints she faces—such as by implementing reforms that have doubled [] efficiency—push [against issuance of a writ of mandamus].").

Thus, each of Swisher's quibbles with the FDA's design of its review process come up short.

There is a final point to address, however, with respect to the FDA's design of its review process. In July 2024, the FDA informed the Court and Swisher that it had paused review of

Swisher's second batch of applications for several months in the spring of 2024. See Declaration of Brian King ("King Decl.") ¶¶ 6–8. Early that year, CTP decided to direct its resources away from reviewing premarket applications for cigars with characterizing flavors "in light of office capacity, CTP resources, and a pending FDA rulemaking" on flavored cigars. Farrelly Decl. ¶¶ 9–10.[12] If finalized as proposed, the rule would make the marketing of flavored cigars unlawful, obviating the need for the agency to review premarket applications for those products. Id. ¶ 10.

In early to mid-April, the agency "began to operationalize the reprioritization by only 'kicking off' bundles of tobacco-flavored products for review and identifying tobacco-flavored products within pending bundles under substantive scientific review." Farrelly Decl. ¶ 9. At that time, CTP was in the middle of reviewing Swisher's second batch of twenty applications, which was "a mixed 'bundle'" of both flavored and unflavored cigars. Id. ¶ 11. In May, the agency decided not to "[s]plit[] mixed bundles"—*i.e.*, pause flavored-products while continuing to review unflavored ones—for two reasons. One, the agency's review process was designed to "address[] [an] entire bundle of products in a single review." Id. Two, the FDA was concerned that splitting bundles might complicate the analysis in cases where manufacturers relied on studies that included both flavored and unflavored products. Id. Accordingly, the agency paused review of Swisher's second batch of SE reports and "other similar 'mixed bundles.'" Id.[13]

In July—soon after the agency published its spring Unified Agenda—CTP resumed reviewing applications for flavored cigars because the Unified Agenda changed the target

[12] The agency distinguishes cigars with characterizing flavors from tobacco-flavored products, which the Court also refers to as unflavored.

[13] The FDA clarified that its reprioritization did not delay Swisher's "third turn for review." Farrelly Decl. ¶ 14. "If Swisher's turn had come up while the reprioritization was in effect, CTP would have created a review bundle that included only tobacco-flavored products[.]" Id.

finalization date of the flavored-cigar rule from March 2024 to "to be determined." Farrelly Decl. ¶¶ 10, 12. [redacted]

Swisher complains that the FDA's belated disclosure of this pause "confirm[s] that the Court should grant summary judgment to Swisher" because it demonstrates that the FDA "will not get its act together[.]" Pl.'s Resp. to the FDA's Suppl. Filings at 7. Not so. First, a belatedly disclosed policy is not necessarily an unreasonable one. Second, the FDA's pause does not suggest an agency lost at sea. Instead, it demonstrates that the FDA is continuing to allocate its resources reasonably. Deprioritizing flavored-cigar applications avoided reviewing applications for products the FDA expected would soon be banned, and choosing not to split "mixed bundles" avoided disturbing its review procedures and complicating its analysis. The Court will not second-guess the FDA's decision to marshal its resources in this way. See In re Barr Lab'ys, Inc., 930 F.2d 72, 76 (D.C. Cir. 1991) ("The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.").

In the alternative, Swisher asks the Court to compel the FDA to complete the record and permit limited discovery. Pl.'s Resp. to the FDA's Suppl. Filings at 9–11. The Court previously denied Swisher's earlier motion to complete the record and take discovery. See Swisher III, 2023 WL 6460028. As the Court explained there, supplementation of the administrative record is inappropriate where the party seeking it cannot identify any records that are missing, and the record is sufficient to permit review of the agency's action. Id. at *3–4, *7. Swisher has not identified any reason why the current record is insufficient, or any records that might be missing. Nor has it given any reason to suspect that the FDA has acted in bad faith such that discovery is

necessary. See id. at *4, *9. For those reasons, the Court denies Swisher's renewed request to complete the administrative record and take discovery.

b. Length of the Delay

The Court also finds the agency's process is governed by a rule of reason despite the length of the delay. To be sure, the process is dragging on. Swisher has now waited almost four years for the agency to act on most of its reports. [redacted] But despite Swisher's almost four-year wait and the agency's slow progress, the agency's implementation still adheres to a rule of reason.

As for the length of the delay, Swisher suggests that a four-year delay is, in and of itself, unreasonable. It cites Midwest Gas Users Association v. FERC, 833 F.2d 341 (D.C. Cir. 1987), where the D.C. Circuit opined that "a reasonable time for an agency decision could encompass 'months, occasionally a year or two, but not several years or a decade.'" Id. at 359 (quoting MCI Telecomms. Corp. v. FCC, 627 F.2d 322, 340 (D.C. Cir. 1980)); see also Tr. at 12, 20–21.

More recent pronouncements from the circuit, however, dispense with the notion that four-year, or even longer, delays are *per se* unreasonable. In Mashpee Wampanoag Tribal Council, the Circuit reversed a district court judgment that found an agency's five-year delay unreasonable, finding that "whether the time the [agency] is taking to act upon the [applicant's] petition satisfies the rule of reason . . . cannot be decided in the abstract, by reference to some number of months or years beyond which agency inaction is presumed to be unlawful." 336

F.3d at 1100, 1102; see also id. at 1098 (noting that the General Accounting Office estimated the agency would take fifteen years to resolve all active petitions). More recently, in Da Costa, the D.C. Circuit rejected an almost identical argument to the one Swisher advances. 80 F.4th at 342. The plaintiffs there alleged that a four-and-a-half-year timeline for processing immigration petitions was "*per se* unreasonable." Id. The circuit disagreed. Though "[t]he processing time" was "long" and had even "increase[ed] over time," the Circuit concluded that "the length of the [plaintiffs'] wait alone [wa]s not sufficient to show that [the agency] [did] not follow a rule of reason." Id.

As for the agency's progress, while the FDA has issued a final decision on only 7.5 percent of Swisher's reports, it is important to put that number in context. In assessing the FDA's progress, the Court will focus on two data points. First, how many applications has the agency acted on so far—in other words, how much of its backlog has it cleared? Second, what is the agency's rate of progress—*i.e.*, how quickly is it clearing the backlog?

The answer to the first question is more promising. The FDA issues quarterly reports on its progress reviewing PMTAs and SE reports. As Table One reflects, as of March 31, 2024 (the date of the most recent data), the agency had acted on 33.32 percent of all SE reports submitted.

TABLE ONE: SE Reports[14]

	As of 3/31/2024
Applications Received	9,184
Withdrawn	528
Actual Applications Received	8,656
Refuse-to-Accept ("RTA") Orders	2,060
Substantial Equivalence ("SE") Orders	694
Not Substantially Equivalent ("NSE") Orders	130
Total Acted On	2,884
Action Rate	**33.32%**

The Court calculates the agency's "action rate" as follows: The numerator represents applications for which the FDA issued an SE, NSE, or RTA order, and the denominator is the number of applications received minus any withdrawn applications. The FDA issues RTA orders when an SE application has an obvious, non-substantive defect—*e.g.*, the submission does not comply with the FDA's format requirement, "does not pertain to a tobacco product," or "does not contain [required] contact information." 21 C.F.R. § 1105.10(a).

This is not the only possible way to calculate the agency's action rate. Swisher suggests that RTAs should not factor into the numerator but instead be subtracted from the denominator. Tr. at 6–7. In Swisher's view, the numerator should represent only orders for which "the agency [] actually [performed] its substantive review"—*i.e.*, SE and NSE orders. Id. Under this approach, the agency's action rate would drop to 12.49 percent as of March 31, 2024. But though RTA orders require less work for the agency than SE or NSE orders, the Court disagrees with Swisher's approach. For one, the decision whether to accept a pre-market application can at times be "complicated" and is therefore not "entirely ministerial." Tr. at 68. And, more to the

[14] JA (FDA Suppl.) at 1441–42.

point, Swisher has focused on the *process* the agency has designed for reviewing SE reports. See id. at 13 (characterizing the SE report pathway as "cumbersome"); id. at 28 ("This process is clearly not working[.]"). Though the acceptance review requires no substantive analysis, the agency should receive credit for designing a review process that weeds out clearly unmeritorious applications.

While the agency's action rate on SE reports was just 33.32 percent as of earlier this year, it has made more progress on processing PMTAs. As Table Two reflects, by March 31, 2024, the agency acted on roughly 93.57 percent of submitted PMTAs.

TABLE TWO: PMTAs[15]

	As of 3/31/2024
Applications Received	9,607,739
Withdrawn	2,399
Actual Applications Received	9,605,340
RTA Orders	2,564,631
Refuse-to-File ("RTF") Orders[16]	5,161,658
Marketing Granted Orders	33
Marketing Denial Orders	1,263,860
Total Acted On	8,990,182
Action Rate	**93.57%**

[15] FDA, Monthly Metrics March 2024 Final PMTA (Mar. 31, 2024), https://perma.cc/DR6U-LUDV. The FDA's reported numbers include over 17 million PMTAs filed by one company, all of which the FDA disposed of in 2023, likely through RTA orders. Id. Given that the FDA appears to have bulk-processed those 17 million applications, it seems likely that those 17 million PMTAs were rejected for ministerial reasons. To roughly account for the huge volume of these ministerial rejections, the Court has subtracted 17 million from the number of applications received and the number of RTA orders.

[16] Like SE reports, PMTA applications are screened for obvious, non-substantive defects as part of the agency's "acceptance review." 21 C.F.R. § 1114.27(a). The agency issues an RTA if the application fails that review, but—unlike SE reports—PMTA applications then undergo a second threshold review. As part of "filing review," the FDA assesses whether the "application contains sufficient information to permit a substantive review"—*e.g.*, the application includes "substantive information, including information from published literature or bridged from an investigation of another tobacco product" about the health risks of the product, the impact of the

Swisher urges the Court to ignore the FDA's review of PMTA applications in evaluating Swisher's unreasonable delay claim since, as Swisher sees it, "this case is about SE reports" and the FDA has not claimed "the reason [it] can't get through the SE report backlog is because it's working on the PMTA [backlog]." Tr. at 14. Not so. As the FDA has explained, a single division of the agency, CTP, "conducts substantive review of all premarket applications"—PMTA and SE alike. Defs.' Mot. Summ. J. at 54 n.18; Defs.' Suppl. Filing Regarding Current FDA Staffing 1–2. As a result, CTP has had to determine how to allocate resources between the two application types. See Defs.' Mot. Summ. J. 53 n.17 (noting that CTP has devoted more staff to the PMTA review stream because it determined that the "continued marketing" of ENDS products, which "effectively always take the form of PMTAs," "has the potential to have the greatest public health impact—either positively or negatively" (quoting JA (Vol. 1) at 1095)).[17] The picture is therefore incomplete without the agency's review of PMTAs in the frame. And when the FDA's action rate on PMTAs—93.57%—is considered, the agency's backlog is not as dire as Swisher would suggest.

The rate at which the agency is clearing its SE-report backlog is of more concern. By September 2023, the FDA had acted on 32.61 percent of SE reports. See Table Three. That number grew to just 33.32 percent by March 2024.

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product's labeling on nonusers, and the abuse liability of the product. Id. § 1114.27(b). If an application fails this review, the agency issues a Refuse-to-File ("RTF") letter.

[17] The agency has dedicated 250 employees (some full-time, some part-time) to review PMTA applications and 60 (some full-time, some part-time) to "different characteristics" SE reports. Defs.' Supp. Filing Regarding Current FDA Staffing 1–2; Farrelly Decl. ¶ 8; see also Tr. at 51 (noting that the agency is trying to "get more resources devoted to reviewing SE reports"). Additional staff are assigned to reviewing "same characteristic" SE reports. Farrelly Decl. ¶ 8.

TABLE THREE: Progress on SE Reports[18]

	As of 6/30/2023	As of 9/30/2023	As of 3/31/2024
Applications Received	9,073	9,087	9,184
Withdrawn	491	498	528
Actual Applications Received	8,582	8,589	8,656
Refuse-to-Accept ("RTA") Orders	2,045	2,045	2,060
Substantial Equivalence ("SE") Orders	628	644	694
Not Substantially Equivalent ("NSE") Orders	111	112	130
Total Acted On	2,784	2,801	2,884
Action Rate	**32.44%**	**32.61%**	**33.32%**

But this halting progress is not enough to find no rule of reason. *First*, the FDA has explained that it is reviewing applications—like Swisher's—that were submitted before the September 2020 deadline set by the AAP court before turning to any later-submitted applications. Farrelly Decl. ¶ 7. Thus, contrary to Swisher's claim, its "pool" of SE report applications is not growing. Tr. at 60. Instead, the FDA has effectively created two pools and is prioritizing the one with Swisher's applications.[19]

Second, there are reasons to believe the agency's review rate—both overall and for Swisher in particular—will improve over time. "There is a growing knowledge base" at the FDA that the agency expects "will increase efficiencies over time." Tr. at 51. And, as for Swisher in particular, because it submitted more applications than other manufacturers, it appears that Swisher can expect that over time the agency will be able to devote more resources to its

[18] JA (Vol. 1) at 1147–48, 1170–71; JA (FDA Suppl.) at 1441–42.

[19] The FDA continues to conduct acceptance review for reports submitted after September 2020. Farrelly Decl. ¶ 6. And because "same characteristics" reports have no backlog, that review queue's staff is continuing to substantively review reports of this type that were submitted after September 2020. Id. ¶ 8.

products. See id. at 49–50. Recall that the agency's review process was set up to ensure that each manufacturer had at least some products enter substantive review before the FDA turned to any manufacturers' additional products. As Mr. Zeller explained,

> At the substantive review, if the manufacturer submitted a number of products that exceeded the capacity of the scientific review team, FDA assigned a second randomly-generated number to each product in each submission to determine the order of the products. The products that are not assigned to the review team will remain in queue until all of the manufacturers with timely, accepted applications have had some products enter the substantive review phase once[.]

JA (Vol. 1) at 1095. Thus, as the agency finishes reviewing other manufacturers' first (and sometimes only) batches of twenty applications, agency resources will free up and Swisher's applications can be expected to enter substantive review at a greater frequency.

Last, but certainly not least, the Court finds the FDA's review is governed by a rule of reason because—despite the length of the delay—its task "involve[s] complex scientific and technical questions." Ctr. for Sci. in the Pub. Int., 74 F. Supp. 3d at 301; see also Mashpee Wampanoag Tribal Council, 336 F.3d at 1102 (Whether an agency adheres to a rule of reason "will depend in large part . . . upon the complexity of the task at hand.").

By statute, the substantial equivalence process requires the FDA to determine whether a tobacco product either "has the same characteristics as [a] predicate tobacco product" or has different characteristics but "does not raise different questions of public health." 21 U.S.C. § 387j(a)(3)(A). To enable the FDA to make that determination, the agency has clarified that SE reports should contain the following information about both the tobacco product and its predicate: their product design (*e.g.*, a cigar's mass, tobacco rod density, binder porosity or permeability, wrapper length, or wrapper weight), product composition (*e.g.*, chemical names for non-tobacco ingredients, and the type, curing method, and quantity of any tobacco ingredients), tobacco processing (*e.g.*, the fermentation process and composition of a tobacco starter culture

with genus and species names), heating sources, and shelf life and stability information. 21 C.F.R. § 1107.19.[20] In reaching a substantial equivalence determination, the FDA also reviews a product's Harmful and Potentially Harmful Constituents ("HPHCs"), which are the chemicals in tobacco products that can cause harm to the human body. Id. § 1107.19(d); see also 77 Fed. Reg. 20,034, 20,036–37 (listing HPHCs). If manufacturers elect to use the second SE route—*i.e.*, attempt to show that the new product is different but does not raise different questions of public health—the regulations contemplate that they will submit testing data regarding HPHCs, including information on any testing protocols, quantitative acceptance criteria, and data sets. 21 C.F.R. § 1107.19(d). Based on all this information, the agency must then determine whether a product and its predicate are substantially equivalent.

In short, this is no easy task. And "in light of the host of complex scientific and technical issues" involved, the Court will not second-guess the agency's timeline. In re United Mine Workers of Am. Int'l Union, 190 F.3d at 555 (quotation marks omitted); see also Ctr. for Sci. in the Pub. Int., 74 F. Supp. 3d at 301 ("Courts [] routinely defer to the judgment of agencies when assessing timelines that involve complex scientific and technical questions.").

Swisher retorts that the complexity of the process does not excuse the agency's delay and points to three cases in support. Pl.'s Opp'n Mot. Summ. J. at 7. But none applies. In Afghan & Iraqi Allies v. Pompeo, No. 18-cv-01388-TSC, 2019 WL 4575565 (D.D.C. Sept. 20, 2019), Congress set an explicit nine-month deadline for the State Department to issue decisions on special immigrant visas. Id. at *7. When the agency complained the complexity of the task

[20] These regulations do not apply to Swisher because it submitted its SE reports before the regulations went into effect in November 2021. See 86 Fed. Reg. 55,224, 55,224 (Oct. 5, 2021). But the regulations nevertheless indicate the breadth and depth of the analysis the FDA is conducting for applications submitted both before and after the effective date.

necessitated additional time, the court dismissed that argument "because Congress explicitly referenced that complexity in the 9-month provision." Id. There is no such timeline here.

Likewise, in In re Public Employees for Environmental Responsibilities, 957 F.3d 267 (D.C. Cir. 2020), Congress directed the Federal Aviation Authority and National Park Service to "make every effort" to issue regulations governing commercial sightseeing flights over national parks within two years of the first application for such a flight. Id. at 269. Nineteen years later, the D.C. Circuit found that neither the complexity of the task nor resource constraints justified the agency's delay, particularly when "the failure to meet the timeline . . . [was] primarily attributable to interagency conflict, not financial or personnel shortages." Id. at 274–75. That is a far cry from what is occurring at the FDA.

Finally, Swisher points to Cobell v. Norton, 240 F.3d 1081 (D.C. Cir. 2001). In that case, after at least six years, and arguably "decades," of the Interior Department failing to fulfill its fiduciary duties to Indian tribes, the D.C. Circuit found the agency's delay unreasonable because it "had yet to progress much beyond planting the 'seed' for discharging [its] obligations." Id. at 1095–96. Again, the FDA is in much better shape, having made decisions on thousands of SE reports and millions of PMTAs.

In sum, the Court finds that the agency's process is governed by a rule of reason.[21]

[21] In its ruling on Swisher's motion to supplement the administrative record, the Court commented that the picture of the FDA's progress in clearing the pre-market application backlog "was not pretty." Swisher III, 2023 WL 6460028, at *7. That conclusion was based on the information before the Court at the time. With the benefit of additional briefing and further consideration of the issue at the merits stage, the Court discerns if not a rosy, then at least a more nuanced picture. And as explained above, that picture does not belie the Court's finding that the FDA's pre-market review process has followed a rule of reason.

2. Effect of Reordering (Factor 4)

The fourth TRAC factor—"the effect of expediting delayed action on agency activities of a higher or competing priority," TRAC, 750 F.2d at 80—can also be dispositive. The D.C. Circuit has "refused to grant relief, even though all the other factors considered in TRAC favored it, where 'a judicial order putting [the petitioner] at the head of the queue [would] simply move[] all others back one space and produce[] no net gain.'" Mashpee Wampanoag Tribal Council, Inc., 336 F.3d at 1100 (quoting In re Barr Lab'ys, 930 F.2d at 75) (alterations in original).

Swisher's requested relief would do just that. Its amended complaint seeks "injunctive relief compelling the FDA to act on Swisher's pending substantial-equivalence reports in a timely manner." Am. Compl. ¶ 197(f). Swisher now claims that it merely seeks an order requiring the FDA to decide its reports within two years, which, Swisher claims, would not leapfrog it to the front of the queue. Pl.'s Mot. Summ. J. at 30; Pl.'s Opp'n Mot. Summ. J. at 14. But, even if this eleventh-hour change to its prayer to relief were permissible, see Harrison v. Off. of the Architect of the Capitol, 964 F. Supp. 2d 81, 95 n.4 (D.D.C. 2013) ("It is axiomatic that the Plaintiff cannot amend her Complaint by the briefs in support of or in opposition to a motion for summary judgment."), aff'd No. 14-5287, 2015 WL 5209639 (D.C. Cir. July 16, 2015) (per curiam), imposing Swisher's requested two-year deadline would still require the agency to move Swisher ahead of other manufacturers in the review queues. Perhaps Swisher would not leapfrog all the way to the front, but moving it up the line would still "mean additional delays for other applicants—many of whom undoubtedly face hardships of their own." Murway v. Blinken, No. 21-cv-1618-RJL, 2022 WL 493082, at *4 (D.D.C. Feb. 16, 2022) (cleaned up). Whether Swisher becomes first or fiftieth in line, "[r]elief that would simply reorder a queue of applicants seeking adjudication is generally viewed as inappropriate when no

net gain in such adjudications is achieved." Tate v. Pompeo, 513 F. Supp. 3d 132, 149 (D.D.C. 2021) (cleaned up).

Swisher insists that its requested relief would not necessarily require the agency to reprioritize its applications. Tr. at 28. It claims that a "judicial order [for the FDA] to act on [its] reports" might instead serve as "an incentive for the agency to fix [the review] process for everybody." Id. at 28–29. The D.C. Circuit rejected a similar argument in In re Barr Laboratories. There, Barr Laboratories sought a writ of mandamus to compel the FDA to act promptly on its pending generic drug applications. 930 F.3d at 73. Barr Laboratories, like Swisher now, argued that granting the writ would not force the agency to reorder its priorities and instead would incentivize the FDA to act "more efficiently" across the board. Id. at 76. The Circuit disagreed. "We have no reason to think," it held, "that a judicial decree advancing one applicant would cure FDA's incompetence, if it exists and even if it is severe. A court order could shift, but not lift, the burden that inefficiency inflicts on pharmaceutical suppliers and users." Id. Though "[t]he agency could alleviate its own inefficiencies, perhaps through generic rulemaking, or other simplifications of the review process," the circuit noted that "judges have neither the capacity nor the authority to require such measures." Id.

Next, Swisher claims that the presumption against reshuffling an agency's priorities does not apply where, as here, the agency uses an "arbitrary, *randomized* process" to review applications. Pl.'s Opp'n Mot. Summ. J. at 15. As the Court noted above, however, the FDA's randomized process is not arbitrary, but rather is a facially reasonable way to ensure that each manufacturer has at least some products enter substantive review in a timely manner. Even though the agency has not adopted a "first-come, first-served" process for reviewing applications, see id. (citing Campaign Legal Ctr. v. FEC, No. 20-cv-809-ABJ, 2021 WL

5178968, at *8 (D.D.C. Nov. 8, 2021)), it has made a reasoned decision about how to allocate its resources. And "delays stemming from resource-allocation decisions simply do not lend themselves to judicial reordering[s] [of] agency priorities." Milligan v. Pompeo, 502 F. Supp. 3d 302, 319 (D.D.C. 2020) (alterations in original) (cleaned up); see also In re Barr Lab'ys, Inc., 930 F.2d at 74 ("[R]espect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities.").

3. Remaining TRAC Factors

Though the remaining factors are less important, they do not compel relief either. See In re Barr Lab'ys, Inc., 930 F.2d at 75 ("[T]he impact of the FDA's sluggish pace on the public health is effectively irrelevant in light of our analysis of TRAC's fourth factor, the effect of relief on competing agency priorities."). Factors three and five often "apply similarly" and are therefore considered together. See, e.g., Da Costa, 80 F.4th at 344. Under factor three, "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." TRAC, 750 F.2d at 80. "Factor five is a broader version of the same idea: '[T]he court should also take into account the nature and extent of the interests prejudiced by delay.'" Da Costa, 80 F.4th at 344 (quoting TRAC, 750 F.2d at 80); see also In re Barr Lab'ys, Inc., 930 F.2d at 75 ("TRAC's third factor (which overlaps with the fifth, at least in this context) asks whether the case is primarily about 'human health and welfare' or 'economic regulation.'").

As in In re Barr Laboratories, where a drug manufacturer sought a writ of mandamus to compel the FDA "to act promptly" in either approving or disapproving its drug applications, Swisher's interest "is entirely commercial." 930 F.2d at 75. The company notes that the delay

has impeded its ability to allocate capital for new investments, modify the products for which it has submitted reports, or introduce new products that rely on earlier-submitted products as predicates—in effect, all economic harms. Pl.'s Mot. Summ. J. at 27–28; see also Tr. at 23.[22] Though these claimed harms may hurt Swisher's bottom line, they are not the kinds of hardships that "tilt the third and fifth factors" in favor of granting its requested relief. Punt v. U.S. Citizenship & Immigr. Servs., No. 22-cv-1218-RC, 2023 WL 157320, at *5 (D.D.C. Jan. 11, 2023); see also Da Costa, 80 F.4th at 345 ("The financial harms [Plaintiff] alleges, along with the uncertainty that results any time an individual must continue to wait to secure a benefit, are insufficient to tip TRAC factors three and five in his favor.").

Moreover, courts are hesitant to put much weight in considerations of "human health and welfare" when an agency's "*raison d'être*" is "public safety." Ctr. for Sci. in the Pub. Int., 74 F. Supp. 3d at 304. And that is the case for the FDA. Id. "Because everything [it] does involves health and welfare, . . . the fact that [Swisher's] petition also implicates these concerns is far less significant than it might otherwise be." Id.; see also Sierra Club v. Thomas, 828 F.2d 783, 798 (D.C. Cir. 1987) ("[A]lthough this court has required greater agency promptness as to actions involving interests relating to human health and welfare, . . . this factor alone can hardly be considered dispositive when, as in this case, virtually the entire docket of the agency involves issues of this type.").

Finally, agency impropriety. Though Swisher gripes about the Court's previous ruling regarding the scope of the administrative record and accuses the agency of manifesting "disdain for" Swisher's products, the company admits that it has no evidence of bad faith on the agency's

[22] At the motions hearing, Swisher also claimed that it was prejudiced by not being able to "enjoy a reasonable degree of regulatory certainty about the status of [its] products." Tr. at 24. But that is the case anytime a party sues its regulator, so this type of prejudice is of little import.

part. Pl.'s Mot. Summ. J. at 28; Pl.'s Opp'n Mot. Summ. J. at 16; see also Farrelly Decl. ¶ 9 (noting that the "reprioritization of [unflavored products] was not specific to Swisher or its products"). This factor therefore carries no weight.

In sum, then, TRAC factors one and four weigh in favor of denying Swisher relief, and none of the other factors tip the scales in Swisher's favor. The Court therefore grants summary judgment to the agency as to Count Six.

C. Threat of Enforcement (Count Eight)

Next, Swisher claims that the threat of an FDA enforcement action violates due process. Pl.'s Mot. Summ. J. at 30–34. Swisher lacks standing to raise this claim.

To establish standing under Article III, a plaintiff must assert "(1) an injury in fact, (2) a causal relationship between the injury and the challenged conduct, and (3) a likelihood that the injury will be redressed by a favorable decision." United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc., 517 U.S. 544, 551 (1996) (cleaned up). As for the first requirement, a plaintiff "does not have to await the consummation of threatened injury to obtain preventive relief." Pennsylvania v. West Virginia, 262 U.S. 553, 593 (1923). But "persons having no fears of state prosecution except those that are imaginary or speculative, are not to be accepted as appropriate plaintiffs[.]" Younger v. Harris, 401 U.S. 37, 42 (1971). "When plaintiffs 'do not claim that they have ever been threatened with prosecution, that a prosecution is likely, or even that a prosecution is remotely possible,' they do not allege a dispute susceptible to resolution by a federal court." Babbitt v. United Farm Workers Nat'l Union, 442 U.S. 289, 298–99 (1979) (quoting Younger, 401 U.S. at 42).

Swisher claims an FDA enforcement action is likely for two reasons: (1) the agency has "refused to rule out bringing [such an] action in the future," Pl.'s Mot. Summ. J. at 32; and (2)

the agency has issued warning letters and filed civil money penalty complaints against other tobacco companies, Pl.'s Opp'n Mot. Summ. J. at 19. To be sure, the Supreme Court has found both factors relevant to whether a plaintiff has an Article III injury. See, e.g., Susan B. Anthony List v. Driehaus, 573 U.S. 149, 165 (2014) ("The Government had charged 150 persons with violating the law and declined to disavow prosecution if the plaintiffs resumed their support of the designated organizations."); Holder v. Humanitarian L. Project, 561 U.S. 1, 16 (2010) ("The Government tells us that it has charged about 150 persons with violating [the statute at issue] . . . [and] has not argued to this Court that plaintiffs will not be prosecuted if they do what they say they wish to do."). But a closer look at both of Swisher's claims reveals that an enforcement action against Swisher remains "conjectural" or "hypothetical," not "real and immediate." City of Los Angeles v. Lyons, 461 U.S. 95, 102 (1983).

First, according to Swisher, the agency has "conspicuously refrained from offering an assurance of non-enforcement that extended beyond the day it was issued." Pl.'s Mot. Summ. J. at 32. While this may be true, let's remember how we got here. In an August 2017 guidance document, the FDA sought to assure the tobacco industry that it would not initiate enforcement actions while premarket applications were pending. See AAP, 379 F. Supp. 3d at 472. The District of Maryland invalidated this guidance, id. at 470, and set September 9, 2021 as the final date tobacco products with timely premarket applications could—as a blanket matter—"remain on the market without being subject to FDA enforcement," Swisher II, 2022 WL 320889, at *2 (cleaned up). The Maryland court acknowledged that the FDA could still exercise its discretion on a "case-by-case basis" to decline to enforce the TCA, but it invalidated the industry-wide disavowal in the August 2017 guidance. AAP, 379 F. Supp. 3d at 493. Against this backdrop, the FDA has continued to assure Swisher that it does not plan to initiate an enforcement action.

In August 2021, the agency wrote to Swisher that "[a]t present, [it] has no intention of initiating an enforcement action against any of Swisher's products" for which premarket applications had been submitted. Defs.' Opp'n to Prel. Inj. [ECF No. 27], Ex. 1 at 1. And in its motion for summary judgment, the agency repeated that, while "hypothetical[ly]" its intentions might change, it had "expressly committed *not* to initiate any enforcement proceedings regarding any of Swisher's products implicated by this suit[.]" Defs.' Mot. Summ. J. at 63. The FDA also repeated that it would first send Swisher a warning letter before initiating enforcement. Id.

To date, the FDA has not sent Swisher a warning letter, disavowed its earlier commitments, or initiated enforcement. So though the FDA has not unequivocally disavowed enforcement here, an enforcement action against Swisher remains unlikely. The Middle District of Florida court reached the same conclusion in denying Swisher's request for a preliminary injunction. See Swisher Int'l, Inc. v. FDA ("Swisher I"), No. 3:21-CV-764-BJD-JBT, 2021 WL 4173841, at *5 (M.D. Fla. Sept. 7, 2021) ("FDA's reticence to take enforcement action in light of the backlog of applications is clear."), aff'd, No. 21-13088, 2022 WL 320889 (11th Cir. Feb. 3, 2022). As the court noted, the agency "repeatedly extended the enforcement deadline; the current deadline exists merely as a possibility, and exists only because of AAP." Id. The Eleventh Circuit shared that view, holding that an FDA enforcement action once the deferment period ended was neither "'likely,' nor 'actual and imminent.'" See Swisher II, 2022 WL 320889, at *5 (cleaned up).

Moreover, the Eleventh Circuit found additional comfort in the fact that the agency had not instituted an enforcement action against Swisher since the court-imposed end of the deferment period in September 2021. See Swisher II, 2022 WL 320889, at *5 ("That no enforcement action against Swisher was intended or even contemplated by the FDA [after

September 2021] is further supported by the lack of enforcement to date."). That fact should provide even greater comfort to Swisher now when, almost three years past the deferment period, the agency has still "taken no steps to warn Swisher about its products or to institute an enforcement action." Id.; see also Defs.' Mot. Summ. J. at 18.

Second, Swisher claims the agency "boasted" that it issued hundreds of warning letters and "brag[ged] that it has filed '[civil money penalty] complaints' 'against 53 manufacturers'" for marketing and selling products without authorization. Pl.'s Opp'n Mot. Summ. J. at 19 (quoting FDA, Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products (Mar. 26, 2024)).[23] The Court would hardly characterize the FDA as "boasting" or "bragging." In any event, those pronouncements do not create a realistic specter of enforcement against Swisher. To date, the agency has initiated enforcement actions against only providers of e-liquid products who either did not file PMTAs or had their applications denied.[24] Id.; see Appendix A.[25] Swisher's position is readily distinguishable. As the company notes, it "timely" submitted its SE reports, Pl.'s Opp'n Mot. Amend at 6, [redacted]. Moreover, it should be no

[23] https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#4.

[24] E-liquids are components of electronic nicotine delivery systems ("ENDS")—a catch-all term for devices like "e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes." 81 Fed. Reg. at 28,976. ENDS "work by heating and aerosolizing a liquid mixture—called an 'e-liquid'—that includes various levels of nicotine and sometimes flavoring." Big Time Vapes, Inc. v. FDA, 963 F.3d 436, 439 n.11 (5th Cir. 2020).

[25] As Appendix A reflects, the companies subject to enforcement marketed e-liquid products despite one of the following: (1) the company did not submit a PMTA, (2) the FDA issued a refuse to accept letter for the products in the company's PMTA, see 21 C.F.R. §§ 1105.10(a), 1114.27(a); (3) the FDA issued a refuse to file letter for the products in the company's PMTA, see id. § 1114.27(b); or (4) the FDA issued a marketing denial order for the products in the PMTA, see id. § 1114.33.

surprise that the FDA has initiated enforcement against only e-liquid companies. The agency has repeatedly stated that it is "prioritizing enforcement against" the unauthorized sale of ENDS products. See JA (Vol. 1) at 1130. Thus, though "past enforcement against the same conduct is good evidence that the threat of enforcement is not chimerical," the FDA has not initiated enforcement against Swisher or any other similarly situated manufacturer that is simply waiting for its SE reports to be reviewed. Susan B. Anthony List, 573 U.S. at 164 (cleaned up).[26]

Accordingly, the Court grants the FDA's motion to dismiss Count Eight.

D. Arbitrary and Capricious (Count Five)

Next, Swisher alleges that the Deeming Rule is arbitrary and capricious. Agency action is arbitrary and capricious "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." Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). The agency is entitled to a "presumption of regularity," Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971), and courts must defer to the agency's expertise, see State Farm, 463 U.S. at 43, 53. But, though a court may not substitute its judgment for the agency's, the agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Id. at 43 (cleaned up); see also Pol'y & Rsch., LLC v. Dep't of Health & Hum. Servs., 313 F. Supp. 3d 62, 72 (D.D.C. 2018).

[26] Moreover, consistent with the FDA's commitment that it would give Swisher sixty-day notice of any planned enforcement action, the FDA sent warning letters to all but one of the e-liquid providers against whom it later filed enforcement actions. See Appendix A.

Swisher claims the Deeming Rule was arbitrary and capricious for three reasons: The agency unreasonably failed to (1) examine foreseeable consequences of the rule, (2) account for manufacturers' reliance interests, and (3) consider obvious alternatives. Before the Court turns to these arguments, it must address a threshold issue—whether Swisher has standing to challenge the Deeming Rule writ large or instead is limited to challenging the decision to deem cigars, as the FDA suggests.

Swisher may challenge the entirety of the rule. In Ascendium Education Solutions, Inc. v. Cardona, 78 F.4th 470 (D.C. Cir. 2023), the D.C. Circuit considered whether a loan guarantor had standing to challenge an agency rule that prohibited guarantors from assessing costs to borrowers who entered into agreements to either repay or rehabilitate their loans. Id. at 478. Even though the plaintiff had never charged costs to borrowers with "repayment" agreements and had no plans to do so, the Circuit determined that the guarantor had standing to challenge "the rule [as] unlawful in its entirety either because it was enacted without statutory authority or because it [wa]s arbitrary and capricious." Id. The same principle applies here. Though Swisher may be primarily a cigar manufacturer, it has standing to challenge the entirety of the rule as arbitrary and capricious. See Pl.'s Mot. Summ. J. at 4 (noting that cigar sales make up nearly 90 percent of Swisher's revenue).

Having determined the scope of Swisher's standing, the Court will now turn to its claims that the agency's action was arbitrary and capricious.

1. Foreseeable Consequences

First, Swisher claims that the FDA's decision to deem all tobacco products at once was premised on the faulty assumption that the agency could "complete premarket review for *millions* of newly deemed products *by 2019*." Pl.'s Mot. Summ. J. at 36 (emphasis in original). In 2011, following the TCA's passage, the agency received an influx of SE reports that it was

unable to clear until 2014. 81 Fed. Reg. at 29,002.[27] According to Swisher, it was therefore arbitrary for the agency to assume it could review "all of the PMTAs and [SE] reports for the newly deemed products in less time than it had already spent struggling to review the few thousand reports precipitated by the enactment of the TCA." Pl.'s Mot. Summ. J. at 36.

But Swisher has its facts wrong. Completing premarket review by 2019 was not a central premise of the Deeming Rule. Recall that the agency instituted compliance periods for newly deemed tobacco products. These periods gave tobacco manufacturers additional time to submit their premarket applications (12 months for SE exemption requests, 18 months for SE reports, and 24 months for PMTAs). 81 Fed. Reg. at 29,011. The agency then tacked on an additional 12 months to each compliance period, during which time the agency did "not intend to initiate enforcement for failure to have premarket authorization[.]" Id. According to Swisher, the setting of these compliance periods indicates that the agency assumed it could complete review by 2019 (*i.e.*, the year that both SE reports and PMTAs would become subject to enforcement). But, as the agency made clear in the final rule, it chose the compliance deadlines based on three factors—only one of which related to its review of applications. Namely, the agency set the various deadlines to "balance the public health concerns raised" in comments to the proposed rule, "allow the Agency to more efficiently manage the flow of incoming applications," and "encourage high-quality premarket submissions from applicants." Id. at 29,010. Indeed, as for the first consideration—"public health"—the agency received a range of recommendations, including that it afford no compliance period whatsoever to manufacturers of cigars or flavored

[27] Swisher suggests that the agency was still working to clear the backlog in 2016, when the Deeming Rule was issued, Pl.'s Mot. Summ. J. at 36, but the agency explained in the Deeming Rule that, by that point, it was "reviewing regular SE reports as they w[ere] received," 81 Fed. Reg. at 29,002.

tobacco products. See id. at 29,013 (cigars), id. 29,013–14 (flavored tobacco). In short, then, the FDA set the compliance periods based on a range of considerations, and they were not a forecast of when the FDA would finish premarket review.

The agency's other representations at the time the Deeming Rule was finalized confirm that it expected to be reviewing applications past the expiration of the compliance periods. It did promise to "act as expeditiously as possible with respect to all new applications," 81 Fed. Reg. at 29,011, and even suggested that the backlog for newly deemed products would be smaller than that for currently regulated products, Regulatory Impact Analysis ("RIA") at 43. But the agency never confirmed that it would complete review by the end of the compliance periods. Instead, the agency made clear that it would "actively monitor and enforce the premarket authorization requirements . . . even if [products listed in] a submission [were] still under review" by the agency. 81 Fed. Reg. at 29,080 (responding to a comment about PMTAs); see also id. at 29,002–03 (making a similar representation for all newly deemed products). It also explained that, at the expiration of the compliance windows, it may still choose to "defer enforcement" "on a case-by-case basis"—a representation that makes sense only if the FDA expected to still be reviewing applications at that time. Id. at 29,010. Because the Deeming Rule was not premised on the assumption that the FDA would finish premarket review by 2019, Swisher's first claim has no traction.

Even if the Deeming Rule were premised on the assumption that the agency could review applications by the end of the compliance period, the rule would still satisfy arbitrary-and-capricious review. *First*, contrary to Swisher's contention, the agency did not fail to "provide a 'reasoned response' to 'significant concerns' raised by commenters." Pl.'s Opp'n Mot. Summ. J. at 34 (quoting Bloomberg LP v. SEC, 45 F.4th 462, 472, 477 (D.C. Cir. 2022)). In response to

comments that the agency would become mired in premarket applications just like it had after the TCA's enactment, the FDA acknowledged its previous backlog and outlined the steps it was taking to accelerate its review, including "streamlining the SE report review process" and "[e]ncouraging teleconferences" between regulators and applicants. 81 Fed. Reg. at 29,002; see also RIA at 43 ("[W]e do not expect the review backlog for newly deemed products to be similar to that for currently regulated products, but rather to be reduced more quickly as FDA's Center for Tobacco Products and regulated industry gain experience."). Similarly, though commenters suggested that the FDA had "significantly underestimat[ed] the total number of premarket review submissions" it would receive, see e.g., JA (Vol. 1) 191–92, the FDA did not "brush[]" these concerns "aside," Pl.'s Opp'n Mot. Summ. J. at 34. Instead, in the RIA the agency painstakingly explained how it estimated the number of entities and products that would be affected by the rule (and therefore how many applications the agency would receive). See RIA at 24–30.

Second and relatedly, though the agency underestimated the number of applications it would receive, this miscalculation does not render the rule arbitrary and capricious. To be sure, the FDA's estimates were wrong. For ENDS products, they were very wrong. The FDA expected to receive 360 to 450 ENDS applications within two years of the rule's enactment, RIA at 84 tbl. 9, and ultimately received over eight million by September 2020, the end of the compliance period set by the court in AAP, JA (Vol. 1) at 1173. (That eight million includes some unknown number of applications from a company that submitted 17 million applications by September 2021, all of which the FDA disposed of in fiscal year 2023. Id.) The agency's estimates for cigar applications were much closer: It anticipated receiving 2,625 applications and actually received 3,066. RIA at 84 tbl. 9; JA (Vol. 1) at 1170.

But despite misjudging the number of applications, the agency's action was not arbitrary and capricious. The "'arbitrary and capricious' standard is particularly deferential in matters implicating predictive judgments[.]" Rural Cellular Ass'n v. FCC, 588 F.3d 1095, 1105 (D.C. Cir. 2009). "Such calculations fall squarely within the ambit of [the agency's] expertise." Newspaper Ass'n of Am. v. Postal Regul. Comm'n, 734 F.3d 1208, 1216 (D.C. Cir. 2013) (cleaned up). And therefore "when an agency's decision is primarily predictive, [a court's] role is limited" to ensuring that the agency "acknowledge[d] factual uncertainties and identif[ied] the considerations it found persuasive." Rural Cellular Ass'n, 588 F.3d at 1105.

The FDA satisfied this standard. *First*, it explained its predictions. For cigars, the FDA opted not to rely on a 2010 "cyclopedia" of cigars out of concern the publication was outdated. RIA at 28. FDA staff instead "coun[ted] products available for sale through two Internet retail sites carrying a wide variety of products." Id. FDA scientists then visited cigar-manufacturing sites to understand how cigars were made and assess how often products were modified. Id. at 83 (explaining that cigars are manufactured with "few, if any" modifications year-to-year, and thus many products would likely be grandfathered into the rule). *Second*, for ENDS products, the FDA acknowledged that its predictions were "uncertain" given the "state of flux" in that market but did identify the factors it found persuasive. Id. at 28. Namely, "[b]ased on [an] examination of 5 major retail websites and Nielsen scanner data, [the agency] [] estimate[ed] that there [we]re 5,000 to 10,000 e-liquid product-package combinations and the components to make 800 to 1,000 delivery systems product-package combinations." Id.; see also id at 26 ("[B]ased on logo counts from trade association websites and FDA listening sessions, we estimate that there are 168 to 204 manufacturers of ENDS products, other than retailers who mix their own e-liquids, selling goods in the US market. We also estimate that there are 14 importers of ENDS

products."). While these projections proved far from perfect, the agency's explanations satisfy the deferential standard for predictive judgments.

2. *Reliance Interests*

Second, Swisher asserts that the FDA failed to consider the reliance interests of tobacco manufacturers impacted by the Deeming Rule. Pl.'s Mot. Summ. J. at 37. "When an agency changes course, . . . it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." Dep't of Homeland Sec. v. Regents of the Univ. of California, 591 U.S. 1, 30 (2020) (cleaned up). Action is arbitrary and capricious unless the agency "assess[es] whether there were reliance interests, determine[s] whether they were significant, and weigh[s] any such interests against competing policy concerns." Id. at 33. But "Supreme Court precedent requiring the consideration of reliance interests before agencies shift policies . . . does not set a high bar." MediNatura, Inc. v. FDA, 496 F. Supp. 3d 416, 458 (D.D.C. 2020), aff'd, 998 F.3d 931 (D.C. Cir. 2021). Swisher outlines two categories of manufacturers whose interests the FDA allegedly ignored: (1) those affected by the agency's delayed processing times and (2) those whose products could not pass premarket review at all.

For the first group, Swisher pins its argument to its foreseeable-consequence claim, contending that the FDA failed to appreciate the impact of delays because it arbitrarily assumed that it could complete premarket review by 2019. Pl.'s Mot. Summ. J. at 37. But, as the Court already found, the agency did not make that assumption. It did mistakenly expect that its backlog would not grow as large as the one that accumulated for products initially deemed under the TCA, but, as noted above, that miscalculation was not arbitrary and capricious. The Court therefore declines to ding the agency for failing to appreciate reliance interests it reasonably did not anticipate.

For the second group, manufacturers whose applications would ultimately be denied, the FDA did take their reliance interests into account, albeit in somewhat piecemeal fashion. Consistent with Regents's three requirements, the agency first "assess[ed]" the relevant "reliance interests." 591 U.S. at 33. For example, it considered public comments that claimed the Deeming Rule's "application of the February 15, 2007 [] date"—the grandfather date set by the TCA—was "unfair to the manufacturers of the newly deemed tobacco products (particularly e-cigarettes) because they were not on notice of pending regulation" and their products would be "forced" from the market. 81 Fed. Reg. at 28,993. The agency then "determine[d]" that these reliance interests were not "significant," Regents, 591 U.S. at 33, because it believed products would either be "grandfathered" into the rule or could be the subject of premarket authorization requests. 81 Fed. Reg. at 28,993. The agency also noted that some manufacturers might fail to receive authorization for all their products, see RIA at 79 ("We [] assume that 90 percent of products seeking marketing authorization will obtain marketing authorization."), but deemed the reliance interests of these manufacturers not to be significant because they had been "on notice" for more than four years that the FDA planned to regulate all tobacco products, 81 Fed. Reg. at 28,993.[28] The FDA had announced its intention to deem all tobacco products in July 2011. See Dep't of Health and Human Servs. Regulatory Agenda, 76 Fed. Reg. 40,052, 40,061–62 (Jul. 7, 2011) (The FDA's "proposed rule would deem products meeting the statutory definition of 'tobacco product' . . . to be subject to the FDA's jurisdiction.").[29] Finally, the FDA "weigh[ed]"

[28] The agency noted that the "90 percent" estimate was an inexact "placeholder" but—consistent with the requirement for "predictive" judgments—explained that the "placeholder [wa]s comparable to the high end of observed medical product approval rates." RIA at 79 n.38; see also Rural Cellular Ass'n, 588 F.3d at 1105.

[29] Cigar manufacturers were on notice even earlier as in the spring of 2010 the FDA announced its plans to deem cigars subject to the TCA. See Office of Information and Regulatory Affairs, Office of Management and Budget, *Unified Regulatory Calendar, Cigars*

these reliance interests "against competing policy concerns." Regents, 590 U.S. at 33; see, e.g., RIA at 80 (explaining that "product exit would raise the overall quality level of the products in the market").

In sum, the agency's consideration of reliance interests was not arbitrary and capricious.

3. Obvious Alternatives

Finally, Swisher asserts that the Deeming Rule was arbitrary and capricious because the FDA failed to consider obvious alternatives. Agencies are required to "consider responsible alternatives to [their] chosen policy and to give [] reasoned explanation[s]" for rejecting those alternatives. Spirit Airlines, Inc. v. Dep't of Transp., 997 F.3d 1247, 1255 (D.C. Cir. 2021) (cleaned up). Swisher floats three possible alternatives it says the agency should have noodled.

First, Swisher suggests the agency should have allowed "products to remain on the market while premarket review was pending so long as manufacturers submitted timely reports." Pl.'s Mot. Summ. J. at 38. Under the TCA, Congress allowed products that were introduced after February 2007 but before the close of the TCA's twenty-one-month compliance window to remain on the market while their applications were pending. 21 U.S.C. § 387j(a)(2)(B)(ii). The agency considered adopting the same approach for newly deemed products. The Notice of Proposed Rulemaking ("NPRM") "contemplated" "indefinite compliance period[s]" that would immunize products from enforcement while the agency reviewed applications. See 81 Fed. Reg. at 29,010. The agency opted not to adopt this proposal however, choosing instead to set staggered deadlines after weighing the factors described above (public health, the flow of incoming applications, and the quality of premarket submissions). Id.; see also id. at 29,011

Subject to the Family Smoking Prevention and Tobacco Control Act, RIN No. 0910-AG38 (Spring 2010), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201004&RIN=0910-AG38.

(describing the public health considerations that factored into the agency's decision). In short then, the FDA considered this alternative and gave a "reasoned explanation" for rejecting it. Spirit Airlines, 997 F.3d at 1255 (cleaned up).[30]

Relatedly, Swisher claims the agency failed to consider whether cigars—as opposed to ENDS products—should have been accorded special compliance periods. The agency considered this option as well. It noted a range of comments "urg[ing] the FDA to stagger compliance dates for different product categories" and "delay compliance until FDA publishes a final guidance for each product category." 81 Fed. Reg. at 29,011. The agency rejected this approach, however, because "nicotine use in any form is of particular concern for youth and pregnant women." Id.; see also id. at 29,010 (describing a comment urging the FDA "not to implement a compliance period of any length for products sold in [] flavors other than tobacco"); id. at 29,014 (considering and rejecting a proposal to shorten compliance periods for flavored combusted products). This explanation too passes muster.

Second, Swisher contends that the FDA failed to "consider adopting a specialized process for premarket review of cigars" despite comments requesting "that the FDA adopt a distinct process that would take into account cigars' unique manufacturing processes and level of health risk relative to other tobacco products." Pl.'s Mot. Summ. J. at 38–40. The agency, however, was not required to respond to each proposal from the public comments. See Auto. Parts & Accessories Ass'n v. Boyd, 407 F.2d 330, 338 (D.C. Cir. 1968) ("We do not expect the agency

[30] Another court in this district found that the FDA acted reasonably with respect to a related issue: setting a two-year compliance window for PMTA applications. Nicopure Labs, LLC v. FDA, 266 F. Supp. 3d 360 (D.D.C. 2017), aff'd, 944 F.3d 267 (D.C. Cir. 2019). The court noted that "[w]hile other approaches may have been reasonable as well, the Court is not persuaded that the agency's decisions about whether to impose a compliance period at all, and how long a period would be necessary, are irrational given the range of viewpoints that had been presented during the notice and comment period." Id. at 400.

to discuss every item of fact or opinion included in the submissions made to it in informal rulemaking."); Simpson v. Young, 854 F.2d 1429, 1435 (D.C. Cir. 1988) ("The agency need only state the main reasons for its decision and indicate it has considered the most important objections[.]"). In any event, the FDA did address many of the specific comments Swisher points to. Take the following three comments, which Swisher cites in its motion for summary judgment. Pl.'s Mot. Summ. J. at 39.

- JA (Vol. 1) 183–95: In this comment, CAA described the differences between cigarettes and cigars and recommended a range of modifications to the proposed rule, including permitting "blending changes due to natural variation" in tobacco for the same cigar, not considering packaging and labeling as part of the tobacco product, and requiring premarket review only when a new "product family" is developed. Id. Though the FDA does not appear to have addressed the product-family comment, it did respond to the others. It noted that it did "not intend to enforce the premarket authorization requirements where manufacturers ma[d]e tobacco blending changes . . . due to variation in growing conditions" and discussed when (and why) packaging would be treated as part of the product. 81 Fed. Reg. at 28,996, 29,015–016.

- JA (Vol. 1) 220–22: Like CAA, the Small Business Cigar Association ("SBCA") submitted a comment highlighting the differences between cigars and cigarettes. Id. In the page ranges cited by Swisher, the SBCA did not offer concrete proposals, but the FDA did address (and reject) the suggestion that it not "overlay the existing regulatory framework for cigarettes onto" cigars because it found "cigars present a risk to public health, and, consequently, should be deemed." 81 Fed. Reg. at 29,027. The FDA also signaled its agreement with a comment stating that "failure to regulate all tobacco products would provide incentives for manufacturers to market new tobacco-based or tobacco-derived products that are unregulated and may induce people to switch to the unregulated products." Id. at 29,025.

- JA (Vol. 1) 263–66: The Small Manufacturers Association for the Reasonable Treatment of Tobacco ("SMARTT") recommended that, instead of requiring each manufacturer to submit a "full" PMTA to continue marketing, the FDA should adopt "a tobacco product category-specific premarket review structure." Id. at 263. In response to this comment and similar ones urging that the FDA to eliminate the "premarket and SE application requirements for cigars," the FDA explained that it understood the TCA as "establish[ing] specific requirements"—*i.e.*, the specific premarket pathways listed in the TCA—"that apply to new tobacco products before they may be marketed." 81 Fed. Reg. at 28,995. But the agency specifically noted that not every PMTA application would have to look

> the same. It said that the "requirements of a particular PMTA may [] vary based on the type and complexity of the product." Id.[31]

Though Swisher may disagree with some of the agency's conclusions, it is incorrect that the FDA failed to consider an alternative pathway for cigars.

Relatedly, the Court is not persuaded to expand CAA's ruling on premium cigars to cigars more broadly. In CAA, the court considered whether the FDA had adequately responded to comments suggesting the agency develop a streamlined premarket review scheme for premium cigars. Cigar Ass'n of Am. v. FDA, 480 F. Supp. 3d 256, 278 (D.D.C. 2020), aff'd, 5 F.4th 68 (D.C. Cir. 2021). The court found the agency had not done so, characterizing its response as "cursory" and "not reasoned decision-making." Id. But there is an important distinction between how the FDA treated premium and non-premium cigars. In the proposed

[31] Swisher suggests, in the alternative, that even if the FDA's response to comments "was not arbitrary-and-capricious," the agency's "erroneous belief" that it could not "adopt a process for substantial-equivalence reports that [took] individual products into account" is "itself an error that requires striking down the Deeming Rule[.]" Pl.'s Opp'n Mot. Summ. J. at 38; see id. ("Congress expressly provided that the FDA could determine the form and manner of substantial-equivalence reports." (quotation marks omitted)). Swisher both misrepresents the record and fails to acknowledge that the FDA has allowed the "form and manner" of both PMTAs and SE reports to vary. First, SMARTT, whose comment Swisher specifically cites, see Pl.'s Mot. Summ. J. at 39, suggested that the FDA create category-specific adjustments for *PMTAs* (not *SE reports*). See JA (Vol. 1) 263. And the FDA responded to this comment by stating that the "requirements of a particular PMTA may [] vary based on the type and complexity of the product." 81 Fed. Reg. at 28,995. (SMARTT also commented that the TCA's definition of substantial equivalence permitted the FDA to review newly deemed products with no predicates by comparing them to traditionally marketed tobacco products. JA (Vol. 1) at 266. But Swisher does not raise a challenge based on this comment.) Second, the FDA has issued regulations clarifying that the "form and manner" of PMTAs and SE reports are product-specific. See 21 C.F.R. § 1114.7(c) (specifying different PMTA requirements for cigarettes, roll-your-own tobacco, smokeless tobacco, ENDS, cigars, pipe tobacco, waterpipe tobacco, and heated tobacco); id. § 1107.19(a) (specifying different SE report requirements for cigarettes, smokeless tobacco, roll-your-own tobacco, cigars, pipes, waterpipes, ENDS, e-liquids, heated tobacco products, and more). In this way, the FDA "tailor[ed] th[e] [substantial-equivalance] pathway for cigars [based on] their unique characteristics." Pl.'s Second Not. Supp. Auth. [ECF No. 134] at 2.

Deeming Rule, the FDA had outlined, and requested comments on, two proposals for premium cigars: "Option 1," where the agency would deem all cigar and pipe tobacco products to be subject to the TCA, or "Option 2," where it would exclude premium cigars "from the scope of [the] proposed rule" and "provide a separate regulatory regime" for these cigars. Proposed Rule, 79 Fed. Reg. 23,142, 23,150 (Apr. 25, 2014). Because the agency had "invit[ed] comments" on creating a different regulatory scheme for premium cigars, the CAA court found it had "placed these issues on the table" and therefore had "to address relevant, substantial comments" on the topic. 480 F. Supp. 3d at 280. But the same was not true for non-premium cigars. The agency never proposed an alternate scheme for non-premium cigars and therefore did not place the issue on the table. Moreover, as described above, the FDA did respond to many of the cigar-specific comments it did receive.

Third, Swisher claims the FDA failed to "meaningfully consider limiting the scope of the Deeming Rule to specific products," for example "only vaping products, which were the primary new entrant to the industry." Pl.'s Mot. Summ. J. at 39. This claim too falls flat because, yet again, the FDA did consider limiting the scope of the rule. It rejected that approach because it determined doing so "would create regulatory loopholes [and] substantial delay (at the risk to public health)," and would "significantly impede FDA's ability to create a comprehensive regulatory scheme." 81 Fed. Reg. 28,982–83; see also id. at 28,984 ("[D]eeming all tobacco products will provide FDA with critical information regarding the health risks of the products. . . . Obtaining this information is particularly important given the addictiveness of nicotine and the toxicity associated with tobacco products."). Though Swisher claims the agency's reference to regulatory loopholes lacked explanation, Pl.'s Mot. Summ. J. at 39–40, it did not. In the NPRM, the agency noted its concern "that manufacturers may be labeling,

packaging, or otherwise representing tobacco products that are, in fact, cigarettes to be little cigars, cigarillos, or other products in order to evade the prohibition against characterizing flavors in cigarettes." 79 Fed. Reg. at 23,147; see MCI Telecomms., 675 F.2d at 414 n.38 (relying on NPRM to find agency action not arbitrary or capricious); Garcia v. Stewart, 531 F. Supp. 3d 194, 217 (D.D.C. 2021) (same). Likewise, the FDA cited research suggesting that the rise "in consumption of non-cigarette combustible products, particularly increases large cigar and pipe tobacco use, [was] associated with a decline in cigarette consumption," and noted that "industry documents indicate[d] that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop small cigars that cigarette smokers would smoke[.]" 79 Fed. Reg. at 23,147. Based on these findings, the agency concluded that "[w]ithout a common regulatory framework, tobacco firms can exploit differences in regulatory requirements to drive consumers to different product markets." Id. If this does not explain the FDA's concern about a regulatory loophole, it is not clear what would.

In sum, each of Swisher's arbitrary-and-capricious arguments misses the mark. The Court therefore grants summary judgment to the agency on Count Five.

E. Statutory Authority (Count Four) and Non-Delegation (Count One)

Swisher fares no better with respect to Counts One and Four. Count One alleges that the Deeming Provision violates the non-delegation doctrine while Count Four alleges that the Deeming Rule exceeds the FDA's statutory authority. Am. Compl. ¶¶ 132–37, 153–58. The Court will start there and return to Count One.

1. Statutory Authority

Swisher claims the Deeming Rule exceeded the FDA's statutory authority because the agency lacked authority to deem all tobacco products at once. In its view, the agency was

required to deem products on a class-by-class basis. It offers three supporting theories but none succeeds.

First, the statutory text. Swisher contends that the text of the TCA required the FDA to deem each class of products one-by-one. In the Deeming Provision, Congress established that "[t]his subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and *to any other products* that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a (emphasis added). Invoking the canon of *noscitur a sociis*, Swisher suggests that because "[s]tatutory words are often known by the company they keep," Congress intended for the FDA, "like Congress itself, [to] make category-by-category deeming decisions." Pl.'s Mot. Summ. J. at 42 (quoting Lagos v. United States, 138 S. Ct. 1684, 1688–89 (2018)). But this canon of construction is unnecessary when the words of the statute are clear. See Conn. Nat'l Bank v. Germain, 503 U.S. 249, 254 (1992) ("When the words of a statute are unambiguous, then, this first canon is also the last: judicial inquiry is complete." (cleaned up)). Congress permitted the FDA to deem "any other tobacco product[]" to be subject to the TCA. 21 U.S.C. § 387a(b). That language could hardly be clearer. Hardt v. Reliance Standard Life Ins. Co., 560 U.S. 242, 251 (2010) ("We must enforce plain and unambiguous statutory language according to its terms."). Nor would it make sense for the Deeming Provision to include limitations on *how* the FDA deemed products. The provision is listed in a subsection titled "Applicability," and, as the title suggests, the provision dictates the *kinds of products* the FDA can sweep into the TCA, not the *manner* by which the FDA effects that deeming. 21 U.S.C. § 387a(b).

Perhaps recognizing that the Deeming Provision does not require a category-by-category approach, Swisher goes fishing in the surrounding statutory text. And what does it catch? 21

U.S.C. § 387s, which provides that the Secretary shall not assess user fees "on a class of tobacco products unless *such class* of tobacco products is listed in section 387a(b) of this title or *is deemed by the Secretary* in a regulation under section 387a(b) of this title." 21 U.S.C. § 387s(b)(2)(B)(iii) (emphases added). Swisher's gloss on this provision goes as follows: "User fees can be assessed only on tobacco products that have been 'deemed,' either by Congress or the FDA—and Section 387s makes clear that Congress contemplated that such deeming decisions would operate on a 'class' by 'class' basis of tobacco products." Pl.'s Opp. Mot. Summ. J. at 41. But Swisher puts too much stock in § 387s. Section 387s governs how the FDA assesses user fees, not how it makes deeming decisions, so—at most—that provision requires the agency to render fee assessments on a class-by-class basis. Section 387s, however, does not purport to govern how the FDA makes deeming decisions. Nor would it make sense for Congress to bury such an important limiting principle in a separate section. See NACS v. Bd. of Governors of Fed. Rsrv. Sys., 746 F.3d 474, 494 (D.C. Cir. 2014) ("[W]e think it quite implausible that Congress engaged in a high-stakes game of hide-and-seek with the [agency], writing a provision that seems to require one thing but embedding a substantially different[,] . . . much more costly requirement in [another] section."). In short, Swisher seeks to impose a textual constraint not found in the text.

Second, the major questions doctrine. As the Supreme Court has held, 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). Citing this principle, Swisher asserts that "the power to deem *all* tobacco products to be subject to the TCA was a 'major' decision for which the FDA lacked

'clear congressional authorization.'" Pl.'s Mot. Summ. J. at 43 (emphasis in original) (quoting West Virginia v. EPA, 142 S. Ct. 2587, 2614 (2022)).

The history and text of the TCA, however, tell a different story. In FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000), which Swisher cites as a basis for this argument, the Supreme Court found that Congress had not delegated to the FDA the authority to regulate tobacco products in the Food, Drug, and Cosmetic Act ("FDCA"). Id. at 142–43. The TCA was Congress's answer to Brown & Williamson. See Nicopure Labs, LLC v. FDA, 944 F.3d 267, 272 (D.C. Cir. 2019). With the TCA, Congress intended for the FDA to address the public health risks of tobacco products "*comprehensively*, that is, in an 'all-encompassing or sweeping' fashion." Big Time Vapes, 963 F.3d at 445 (emphasis in original) (quoting Gundy v. United States, 588 U.S. 128, 141 (2019) (plurality)) (footnote omitted). And Congress made that purpose manifest in the text of the statute. See also id. at 445 n.25 (collecting provisions of the TCA that include the words "comprehensive" or "comprehensively"). The Deeming Provision, itself, "is written in starkly broad terms." Bostock v. Clayton Cnty., Georgia, 590 U.S. 644, 680 (2020).[32] Thus, while the power to regulate tobacco products is a significant delegation of authority, Congress was not shy about making that delegation explicit. See id. ("This elephant has never hidden in a mousehole; it has been standing before us all along.").

Seemingly acknowledging that the TCA gave the FDA authority to regulate tobacco products, Swisher claims instead that Congress "did not authorize" the FDA to declare all tobacco products subject to regulation "in a single order . . . with the clarity required by the major-questions doctrine." Pl.'s Opp'n Mot. Summ. J. at 42. As support, Swisher points to

[32] As the Court explains below, other provisions and features of the TCA impose limiting principles on this language.

NFIB v. Department of Labor, 595 U.S. 109 (2022), where the Supreme Court found Congress did not authorize the Occupational Safety and Health Administration ("OSHA") to issue a vaccine mandate to workers across the country. Id. at 117. The Supreme Court noted that OSHA could "regulate occupation-specific risks related to COVID-19"—for example, if "the virus poses a special danger because of the particular features of an employee's job or workplace" or if "researchers [] work with the COVID-19 virus." Id. at 119. But the "indiscriminate approach" of the nationwide vaccine mandate failed "to account for [the] crucial distinction [] between occupational risk and risk more generally.'" Id. (quoting 29 U.S.C. § 655(b)). Swisher suggests that the FDA finds itself in a similar position to OSHA because, like OSHA, the FDA cannot pass "expansive" regulations but has "statutory authority to issue narrower regulations on the same topic." Pl.'s Opp'n Mot. Summ. J. at 43. But what Swisher misses is that, unlike OSHA, the FDA *does* have the authority to regulate the activity at issue here—the marketing of *any* tobacco product. So, while the Supreme Court would presumably strike down OSHA regulations that, even though enacted piecemeal, amount to a nationwide vaccine mandate, the same would not be true (by Swisher's own admission) if the FDA took a class-by-class approach to tobacco products. In other words, NFIB deals with a grant of regulatory authority unlike the one at issue here.

Third, constitutional avoidance. Swisher suggests that to avoid non-delegation concerns with the TCA, the Deeming Provision must be interpreted to require class-by-class decisions. Pl.'s Mot. Summ. J. at 44. But "[t]he canon of constitutional avoidance comes into play only when, after the application of ordinary textual analysis, the statute is found to be susceptible of more than one construction." Jennings v. Rodriguez, 583 U.S. 281, 296 (2018) (cleaned up).

Where, as here, the statute is unambiguous, "the canon simply has no application." Id. (cleaned up).

Count Four therefore goes to the FDA as well.

2. Non-Delegation Doctrine and Limits on the FDA's Discretion

Finally, Swisher asserts that the Deeming Provision is unconstitutional because it affords the FDA "unfettered discretion to deem whatever products it chooses." Pl.'s Opp'n Summ. J. at 44. In Big Time Vapes, the Fifth Circuit considered a non-delegation challenge to the TCA raised by an ENDS manufacturer and an ENDS industry trade association. 963 F.3d at 437–38. The Fifth Circuit rejected that challenge wholesale, and this Court does the same.

A delegation is "constitutionally sufficient if Congress clearly delineates [1] the general policy, [2] the public agency which is to apply it, and [3] the boundaries of this delegated authority." Mistretta v. United States, 488 U.S. 361, 372–73 (1989) (quoting Am. Power & Light Co. v. SEC, 329 U.S. 90, 105 (1946)). The TCA easily checks all three boxes. First, "Congress undeniably delineated its general policy" in both the "purpose" and "fact-finding" sections of the TCA. Big Time Vapes, 963 F.3d at 444; see also id. (finding, contrary to the argument raised by the ENDS plaintiffs and now Swisher, that the TCA's various purposes are not "in [] tension with each other" and instead boil down to "(1) protecting public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products." (cleaned up)). Second, the TCA specifies the agency that makes deeming decisions: the Department of Health and Human Services ("HHS"), within which the FDA sits. Id. Third, Congress cabined the agency's discretion by "enacting a controlling definition of 'tobacco product,' which necessarily restricts the HHS Secretary's power to only products meeting that definition," and by "making many of the key regulatory decisions itself." Id. at 445–46. For example, the act requires manufacturers to submit data about their products and ingredients, file annual

registration statements, and submit premarket authorization applications. 21 U.S.C. §§ 387d(a), 387e(i)(1), 387j. The TCA also places an important outer boundary on the Secretary's authority: The Secretary cannot ban many forms of tobacco products or require "the reduction of nicotine yields of a tobacco product to zero." 21 U.S.C. § 387g(d)(3)(A). "As those substantive provisions show, Congress painted much of the regulatory canvas, leaving the finishing touches to the FDA. The [Supreme] Court has held, time after time, that that's enough to clear the Constitution's low hurdles." Big Time Vapes, 963 F.3d at 446.

As a final hedge, Swisher claims that if the "TCA's ten 'stated purposes' . . . provide 'clear guidance to guide' the FDA's deeming discretion," then the "Deeming Rule is unlawful because the FDA did not mention (let alone consider) the statutory purposes when enumerating the 'only pertinent limitations on the scope of the FDA's deeming authority.'" Pl.'s Opp'n Mot. Summ. J. at 46 (cleaned up); see also 81 Fed. Reg. at 28,983 ("The only pertinent limitations on the scope of FDA's deeming authority are the definition of ''tobacco product'' set forth in section 201(rr) of the FD&C Act and a provision regarding tobacco growers and similar entities and tobacco leaf[.]")

"[A]n agency's rule normally is arbitrary and capricious if it 'entirely failed to consider an important aspect of the problem' before it,'" Pub. Citizen v. Fed. Motor Carrier Safety Admin., 374 F.3d 1209, 1216 (D.C. Cir. 2004) (quoting State Farm, 463 U.S. at 43), and an agency defies a "statutory limitation on [its] authority" when it ignores a mandatory factor, United Mine Workers v. Dole, 870 F.2d 662, 673 (D.C. Cir. 1989). The FDA did not run afoul of either stricture. While the agency did not specifically acknowledge that the TCA's purposes cabined its discretion, it nonetheless considered those purposes in crafting the Deeming Rule. As the Fifth Circuit found, "the TCA's purpose sounds in (1) protecting public health and (2)

preventing young people from accessing (and becoming addicted to) tobacco products." Big Time Vapes, 963 F.3d at 444. The agency factored both considerations into its decision. See, e.g., 81 Fed. Reg. at 28,983 ("[R]egulation of the newly deemed products will be beneficial to public health."); id. at 28,984 ("The need for deeming is further confirmed by the continued dramatic rise in youth and young adult use of tobacco products such as e-cigarettes and waterpipe tobacco, and continued youth and young adult use of cigars (mainly cigarillos).").

Even if it was arbitrary and capricious for the agency not to specifically acknowledge the TCA's purposes, that error was harmless. "Courts reviewing agency action under section 706(2)(A)'s 'arbitrary and capricious' standard must take 'due account . . . of the rule of prejudicial error.'" Jicarilla Apache Nation v. U.S. Dep't of Interior, 613 F.3d 1112, 1121 (D.C. Cir. 2010) (quoting 5 U.S.C. § 706). "The harmless error rule applies to agency action because '[i]f the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration.'" Id. (quoting PDK Labs., Inc. v. U.S. DEA, 362 F.3d 786, 799 (D.C. Cir. 2004)). As described, the agency did factor the TCA's purposes into the Deeming Rule and therefore its "mistake," if it committed one, "did not affect the outcome." Id.

The Court thus finds the agency is entitled to summary judgment on Count One.

F. Remaining Counts

There are three remaining counts on which only the FDA seeks summary judgment: Counts Two (the Deeming Rule was issued by an unconstitutionally appointed official), Three (the FDA's attempts to ratify the Deeming Rule are independently unlawful under the APA), and Seven (the FDA's de facto ban on Swisher's cigars is unlawful). The agency is also entitled to summary judgment on these claims.

As Swisher acknowledges, the D.C. Circuit's opinion in Moose Jooce v. FDA, 981 F.3d 26 (D.C. Cir. 2020), forecloses Counts Two and Three. See Am. Compl. ¶ 145; Pls.' Mot. Summ. J. at 17 n.5. There, the circuit held that even if the original issuance of the Deeming Rule violated the Appointments Clause, former FDA Commissioner Scott Gottlieb's "effective[]" "ratification [of the rule] cured any Appointments Clause defect." Moose Jooce, 981 F.3d at 28–29; see also id. ("[T]his court has 'repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting the claim, resolves the claim on the merits by remedy[ing] [the] defect (if any) from the initial appointment.'" (quoting Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives, 920 F.3d 1, 13 (D.C. Cir. 2019))). Bound by this precedent, the Court grants summary judgment to the FDA as to Counts Two and Three.

As for Count Seven, Swisher has conceded that there is no genuine dispute as to the material facts. It acknowledges that "intervening factual developments indicat[e] that the FDA has not at this time imposed a de facto ban on mass-market cigars." Pl.'s Mot. Summ. J. at 17 n.5. And it does not dispute that it has continued to sell its cigars while its SE reports are pending. See Pl.'s Opp'n Mot. Summ. J. at 14 ("[T]he FDA was unable to force Swisher out of business."); Swisher II, 2022 WL 320889, at *5 ("[N]or has Swisher suggested that it has removed any of its products from stores or taken other mitigatory measures in anticipation of such agency action.").

The Court thus finds that the agency is entitled to summary judgment on Counts Two, Three, and Seven.

IV. Conclusion

For these reasons, the Court denies Swisher's motion for summary judgment, grants the FDA's motion for leave to amend, grants the FDA's motion for summary judgment as to Counts One to Seven, and grants the FDA's motion to dismiss as to Count Eight. A separate order accompanies this memorandum opinion.

CHRISTOPHER R. COOPER
United States District Judge

Date: August 30, 2024

APPENDIX A

Companies against which FDA has filed a civil money complaint as of August 30, 2024. See https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products.

Company	Warning Letter Issued	Product on Market Prior to Feb. 2007	Product Description	Status of Pre-Market Application
Gorilla Vapes LLC	Yes	No	E-Liquid	Submitted a PMTA for certain products and FDA issued Refuse to Accept determination
Vegas Vapor Emporium, LLC	Yes	No	E-Liquid	Did not submit a PMTA
Cali Steam LLC	Yes	No	E-Liquid	Submitted a PMTA for certain products and FDA issued a Refuse to File determination
Vape Game LLC	No	No	E-Liquid	Submitted a PMTA for certain products and FDA issued Refuse to Accept determination
Home Town Vapor LLC d/b/a Hometown Vapor	Yes	No	E-Liquid	Did not submit a PMTA
Vape NV LLC d/b/a Vape NV	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
Juice Roll Upz, Inc. d/b/a Juice Roll Upz	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order, Refuse to Accept Order, and an appeal denial of the Marketing Denial Order
8OHM1, LLC d/b/a Digital Smoke / Digital Smoke, LLC	Yes	No	E-Liquid	Did not submit a PMTA
Simply Vapour LLC d/b/a Simply Vapour	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Electric Freedom, Inc. d/b/a Crown7, d/b/a Crown Seven	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Robert Abbott d/b/a The Vaporium	Yes	No	E-Liquid	Did not submit a PMTA
Veronica Delaney d/b/a Vape Crusades	Yes	No	E-Liquid	Did not submit a PMTA

Northland Vapor Company, LLC d/b/a Northland Vapor Company	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Session Supply Co, LLC d/b/a Session Supply Company	Yes	No	E-Liquid	Did not submit a PMTA
Walker Trading Company Inc. d/b/a Vape Dojo	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
Dotmod, Inc. d/b/a Conweal	Yes	No	E-Liquid	Did not submit a PMTA
Cloud Hempistry LLC d/b/a Cloud Hempistry	Yes	No	E-Liquid	Did not submit a PMTA
FreedomsmokeUSA International, Inc. d/b/a Freedom Smoke USA	Yes	No	E-Liquid	Did not submit a PMTA
Tampa Vapor Inc. d/b/a Tampa Vapor	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Westside Vapor LLC d/b/a Vapor Station LLC	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Vertigo Vapor, Inc. d/b/a Baton Vapor	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Best Shop for Vapors LLC d/b/a Beachside Vapors / BSV Vape	Yes	No	E-Liquid	Did not submit a PMTA
Jayde's Vapor Lounge Inc. d/b/a Jayde's Vapor Lounge	Yes	No	E-Liquid	Did not submit a PMTA
Pink Spot Vapors, Inc. d/b/a Pink Spot Vapors	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Steam Puff Vapor LLC d/b/a The Vapery 2	Yes	No	E-Liquid	Did not submit a PMTA
Verdict Brands LLC d/b/a Verdict Vapors	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
E-Cig Central, LLC d/b/a E-Cig Central	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to File determination

Unlit Vapor Shoppe LLC	Yes	No	E-Liquid	Did not submit a PMTA
Vapor Boss LLC d/b/a Vapor Boss	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
TVC Management Corp d/b/a The Vapor Chef	Yes	No	E-Liquid	Did not submit a PMTA
White Horse Vapor Stores, LLC d/b/a White Horse Vapor	Yes	No	E-Liquid	Did not submit a PMTA
Vape Craft LLC d/b/a Vape Craft Inc. / Vape Craft / Vape Craft Incorporated	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
MJ Asset Holdings, LLC d/b/a Marco's Vapor	Yes	No	E-Liquid	Did not submit a PMTA
D and J Vapors LLC d/b/a D and J Vapors	Yes	No	E-Liquid	Did not submit a PMTA
PRV Enterprises LLC d/b/a Phoenix Rising Vapor	Yes	No	E-Liquid	Did not submit a PMTA
Vapor Dynasty LLC d/b/a Vapor Dynasty	Yes	No	E-Liquid	Did not submit a PMTA
Vapor Candy Inc. d/b/a The Vape Stop	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
E-Cig Vape Lounge LLP d/b/a E-Cig Vape Lounge	Yes	No	E-Liquid	Did not submit a PMTA
E-CIG USA INC d/b/a Hutchinson Tobacco and Cigars	Yes	No	E-Liquid	Did not submit a PMTA
Southbound Vapes LLC d/b/a Southbound Vapes	Yes	No	E-Liquid	Did not submit a PMTA
Vapor Plus OK LLC d/b/a Vapor Plus OK	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Juicemafia, Inc. d/b/a Ecig-Works	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order

Magical Creations by D LLC d/b/a Hookies and Bookies	Yes	No	E-Liquid	Did not submit a PMTA
YVL, LLC d/b/a Yogi's Vape Lounge	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
BLB7 LLC d/b/a The Vape Mall	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
Texas Tobacco Barn LLC d/b/a TXVapeBarn,	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Juicemafia, Inc. d/b/a Ecig-Works	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
DIY Vapor Supply LLC d/b/a DIY Vapor Supply	Yes	No	E-Liquid	Did not submit a PMTA
Go Vapor #2, LLC d/b/a Go Vapor	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to File determination
Bradley Jaramillo LLC d/b/a Trinity Vapor Lounge	Yes	No	E-Liquid	Did not submit a PMTA
Kokomo Pure Vapors, LLC d/b/a Kokomo Pure Vapors	Yes	No	E-Liquid	Did not submit a PMTA
Victory Vapor, Inc. d/b/a Victory Vapor	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
Big Chief Vapor Products LLC d/b/a Big Chief Vapor Products	Yes	No	E-Liquid	Did not submit a PMTA
Vape N Juice, Inc. d/b/a Vape-N-Juice	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
5th and Nine Vape Co. LLC d/b/a 5th and Nine Alternatives Co.	Yes	No	E-Liquid	Did not submit a PMTA

GO VAPOR, LLC d/b/a GV1	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to File determination
Sin City Vapor LLC d/b/a Sin City Vapor	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Lynda's Legacy, LLC d/b/a Chaney's Tobacco	Yes	No	E-Liquid	Did not submit a PMTA
Drive Thru Vapors, LLC	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Refuse to Accept determinations
Lynda's Legacy LLC d/b/a Chaney's Tobacco Station	Yes	No	E-Liquid	Did not submit a PMTA
RTP Vapors, LLC d/b/a RTP Vapor	Yes	No	E-Liquid	Did not submit a PMTA
Cloud 9 Systems, LLC d/b/a Cloud 9 Vapor	Yes	No	E-Liquid	Did not submit a PMTA
Singing Hawk LLC d/b/a Sin City Vapor III	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Sabor Vapors LLC	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Hothead Vapor, LLC	Yes	No	E-Liquid	Did not submit a PMTA
BAM Group, LLC d/b/a VapEscape	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
Great American Vapes LLC d/b/a Great American Vapes	Yes	No	E-Liquid	Submitted PMTAs for certain products and FDA issued Marketing Denial Order
The Vapor Corner, Inc. d/b/a Vapor Corner, Inc., The Vapor Corner, and Vapor Corner	Yes	No	E-Liquid	Did not submit a PMTA
13 Vapor Co., LLC d/b/a 13 Vapor	Yes	No	E-Liquid	Did not submit a PMTA