UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

OPINION AND ORDER

In this suit, cigar manufacturer Swisher International Inc. ("Swisher") mounts various challenges to the Food and Drug Administration's 2016 "Deeming Rule," which subjected the company's "Swisher Sweets" line of stogies to regulation under the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"). One of Swisher's claims is that the FDA has unreasonably delayed its review of the company's applications for premarket approval of its products. After the FDA produced and certified the administrative record relevant to Swisher's agency-delay claim, Swisher moved to supplement the record. It also sought discovery. Finding that Swisher has failed to satisfy established standards for completing the record and that the addition of extra-record materials is not likely to materially advance the Court's review of the merits of Swisher's claim, the Court will deny the motion.[1]

[1] The parties filed their briefs under seal. While the Court doubts any content from this opinion need be sealed, in an abundance of caution it will keep the 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.

I. Background

The Family Smoking Prevention and Tobacco Control Act of 2009 created a comprehensive scheme for regulating tobacco products. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2(6), 123 Stat. 1776, 1777. The Act covers four enumerated categories of "tobacco products"—"all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—as well as "any other tobacco product that the Secretary [of Health and Human Services] by regulation deems to be subject" to coverage. 21 U.S.C. § 387a(b). In 2016, the FDA exercised this regulatory authority by adopting the Deeming Rule, which applied the TCA's provisions to other tobacco products, including cigars. Mot. at 3; Opp'n at 3; see also 81 Fed. Reg. 28,974, 29,102 (May 10, 2016)). Under the TCA, manufacturers must obtain FDA approval before they market and sell any "new tobacco product." Mot. at 3 (citing 21 U.S.C. §§ 387b(6), 387j(a)(1)). According to Swisher, this requirement applies to nearly its entire portfolio of products. Id.

The Deeming Rule created three pathways for premarket approval. Mot. at 4 (citing 21 U.S.C. § 387j(a)(1)). On the first 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 in February 2007. Id. (citing 21 U.S.C. §§ 387j(a)(2)(A)(i); (3)(A)). Second, manufacturers can seek exemptions from the substantial equivalence finding. 21 U.S.C. §§ 387j(a)(2)(A)(ii), 387e(j)(3). And, third, for truly new products, like e-cigarettes and vapes, manufacturers are required to submit more onerous premarket tobacco applications ("PMTAs"). Mot. at 4–5 (citing 21 U.S.C. § 387j(c)(1)(A)). The Court will generally refer to all three types of applications as "premarket applications."

Many products on the market became non-compliant with the TCA when the Deeming Rule was issued. Opp'n at 5. As a result, the FDA established compliance periods with timelines for manufacturers to submit premarket applications. Id. The FDA gave manufacturers thirty months to submit SE Reports and paused enforcement for one year while it reviewed the reports. Mot. at 5–6; Opp'n at 5. According to Swisher, the FDA received concerns during the Deeming Rule's notice-and-comment period that its one-year timeline to review premarket applications prior to commencing enforcement would be insufficient given the backlog the FDA experienced during a similar process in 2011. Mot. at 5–6. In August 2017, the FDA extended the review timelines, but the U.S. District Court for the District of Maryland vacated the extensions, finding they should have been established through notice-and-comment rulemaking. Am. Acad. of Pediatrics v. FDA, 379 F. Supp. 3d 461, 497–98 (D. Md. 2019). That court subsequently ordered that premarket applications be submitted by September 2020 and that FDA enforcement not begin until a year later. Mot. at 6.

In advance of the September 2020 submission deadline, the FDA received some 7,000 SE Reports and five million PMTAs. Id. at 7; Opp'n at 6. The agency adopted a randomized ordering system for reviewing the SE Reports. Opp'n at 6. That process is summarized as follows in a September 2021 article authored by Mitch Zeller, the Director of 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.

A.R. at FDA-22954-000110.

Swisher submitted 171 SE Reports, which the FDA assigned 267 unique Submission Tracking Numbers ("STNs"), apparently corresponding to different cigars and packaging sizes. Mot. at 8; Opp'n at 6. On June 27, 2022, Swisher received notice that twenty of its STNs were under substantive review but says it has received no information on the remaining ninety-three percent. Mot. at 9. Although Swisher claims that the FDA warned manufacturers that they would risk enforcement if they marketed unapproved products after September 2021, id., nothing before the Court suggests that the FDA has taken or threatened any enforcement action against Swisher to date.

Swisher originally filed this suit in Middle District of Florida and simultaneously sought a preliminary injunction prohibiting the FDA from enforcing the TCA against all 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 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, 2022 WL 320889, at *2–3, 5–6 (11th Cir. Feb. 3, 2022); Transfer Order, ECF No. 64. Swisher then amended its complaint to remove the preliminary injunction request. In Count Six of the amended complaint, Swisher alleges that the FDA has unreasonably delayed its review of Swisher's SE Reports in violation of section 706(1) of the Administrative Procedure Act. Am. Compl. ¶¶ 167–181.

The FDA produced and certified the portion of the Administrative Record relevant to Swisher's unreasonable-delay claim in July 2022. As reported by the parties, the record includes:

(1) Swisher's SE Reports and acceptance letters from the FDA acknowledging their receipt;

(2) the September 2021 article by Mitch Zeller, which recounted the large volume of premarket applications received by the September 2020 deadline, set out the agency's approach to reviewing applications in each authorization pathway including the randomization process for SE Reports excerpted above, and described the progress of the agency's review efforts up to that point;

(3) a series of charts from the FDA's website showing the status of the agency's quantitative progress in reviewing the various types of premarket applications;

(4) descriptions of the FDA's progress in reviewing Swisher's SE Reports, including an internal FDA email authored by senior program manager Cristy Stark outlining the "kickoff" of the agency's review of a batch of reports (enumerated "Wave 24") containing the first 20 of Swisher's reports that had been placed under substantive review;

(5) correspondence between the FDA and Swisher regarding the FDA's request for additional information on some of Swisher's reports; and

(6) an internal FDA email reflecting the start of scientific review for some of Swisher's reports.

Mot. at 10–12; Opp'n at 7–9. In September 2022, after being alerted to the issue by Swisher, the FDA added four acceptance letters to the record that it explains were inadvertently omitted. Mot. at 13; Opp'n at 10.

Swisher's present motion to supplement the record followed. The motion seeks to add three broad categories of documents to the record: (1) the FDA's plans for reviewing the influx of premarket applications submitted before the September 2020 submission deadline; (2) the status of all of Swisher's SE Reports in the overall review queue; and (3) the agency's progress in clearing a backlog of SE Reports and PMTAs that are in line ahead of Swisher's reports.

II. Legal Standards

A. Completing or Supplementing the Record

In assessing challenges to agency delay under APA § 706(1), or agency action under APA § 706(2), "the court shall review the whole record or those parts of it cited by a party." 5 U.S.C. § 706. The "whole record" "consists of all documents and materials that the agency directly or indirectly considered, no more and no less." Oceana, Inc. v. Ross, 290 F. Supp. 3d 73, 77 (D.D.C. 2018) (cleaned up). Conversely, materials that were not considered by the agency fall outside the record, even if they exist and may be relevant to the plaintiffs' challenge. Maritel, Inc. v. Collins, 422 F. Supp. 2d 188, 196 (D.D.C. 2006). Nor are "predecisional" and "deliberative" documents part of the administrative record. Oceana, 290 F. Supp. 3d at 82–83.

An agency is "entitled to a strong presumption of regularity that it properly designated the administrative record." Id. at 77 (cleaned up). Because of this presumption, "[s]upplementation of the administrative record is the exception, not the rule." Pac. Shores Subdivision, Cal. Water Dist. v. U.S. Army Corps of Eng'rs, 448 F. Supp. 2d 1, 5 (D.D.C. 2006); see also Cape Hatteras Access Pres. All. v. U.S. Dep't of Interior, 667 F. Supp. 2d 111, 113 (D.D.C. 2009).

Still, a party may seek to add materials to the administrative record in two ways. First, a movant can seek to "complete" the record with inclusion of "evidence that should have been properly a part of the administrative record but was excluded by the agency." Nat. Res. Def. Council, Inc. v. Doremus, No. 20-cv-1150 (CRC), 2021 WL 2322349, at *2 (D.D.C. June 7, 2021) (cleaned up). A party taking this route must "put forth concrete evidence and identify reasonable, non-speculative grounds for her belief that the documents were considered by the agency and not included in the record." Id. (cleaned up). Additionally, the plaintiff must

"identify the materials allegedly omitted from the record with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are 'likely' to exist." Nat'l Parks Conservation Ass'n v. U.S. Dep't of Interior, No. 20-cv-3706 (RC), 2023 WL 1860960, at *5 (D.D.C. Feb. 9, 2023) (cleaned up).

Alternatively, movants can seek to "supplement" the record with "extra-judicial evidence that was not initially before the agency" but that they believe should nonetheless be included. Nat. Res. Def. Council, Inc., 2021 WL 2322349 at *2 (cleaned up). This method requires the moving party to "demonstrate unusual circumstances justifying a departure from the general rule against considering extra-record evidence." Id. (cleaned up). But supplementation of the record through this pathway is limited to three such "unusual circumstances": "(1) if the agency deliberately or negligently excluded documents that may have been adverse to its decision, (2) if background information is needed to determine whether the agency considered all the relevant factors, or (3) if the agency failed to explain administrative action so as to frustrate judicial review." Id. (cleaned up).

Plaintiffs also may seek discovery in APA record-review cases. But discovery is highly disfavored. It is available only upon a showing that the agency has engaged in "bad faith or improper behavior" in compiling the record, or in "the rare case in which the record is so bare as to frustrate effective judicial review." Cmty. for Creative Non-Violence v. Lujan, 908 F.2d 992, 997–98 (D.C. Cir. 1990); see also Theodore Roosevelt Conservation P'ship v. Salazar, 616 F.3d 497, 514–15 (D.C. Cir. 2010) (cleaned up).[2]

[2] Swisher suggests that these customary record-review principles do not apply in APA failure-to-act cases. See Mot. at 15–16. But that suggestion is inconsistent with the text of Section 706, which provides that challenges to both agency action and inaction are to be reviewed on "the whole record or those parts of it cited by a party." 5 U.S.C. §§ 706, 706(1); see also Dallas Safari Club v. Bernhardt, 518 F. Supp. 3d 535, 539 (D.D.C. 2021) ("Nothing in the

B. TRAC Factors

Agency delay claims like Swisher's 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). Whether agency delay is unreasonable will largely depend on "the complexity of the task at hand, the significance (and permanence) of the outcome, and the resources available to the agency." Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1102 (D.C. Cir. 2003).

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statutory text distinguishes the scope of record review based on whether the claim is directed at agency action or inaction. And nowhere does the text even hint at extra-record review occurring as a matter of course when agency action is alleged to be 'unlawfully withheld or delayed.'"). Swisher is correct that supplementation of the record may be required more often in agency delay cases because, where an agency has failed to act, the record may be too scant for the reviewing court to determine whether the delay is unreasonable. In those instances, however, the customary standards for record supplementation still apply.

III. Analysis

Swisher's motion seeks to add three categories of information to the administrative record: (1) records reflecting the FDA's plans for reviewing the influx of premarket applications it received in advance of the September 2020 deadline; (2) records showing the current status of all of Swisher's SE Reports and their place in the agency's queue; and (3) materials documenting the FDA's progress in clearing its overall backlog of premarket applications. For the reasons stated below, the Court will deny Swisher's motion.

In assessing Swisher's requests, it is important to keep in mind what the Court will be called upon to review at the merits stage of the case. As noted above, agency delay claims are assessed under the six TRAC factors. Three of these factors—whether Congress set a timetable for the decision under review (factor 2), whether the decision relates to economic regulation or human health (factor 3), and what prejudice has resulted from the delay (factor 5)—are not informed by materials within the agency's possession and thus have no relationship to the administrative record. The sixth factor—that agency impropriety is unnecessary for a finding of unreasonable delay—is simply an observational consideration rather than a factual inquiry and thus does not depend on the record either. The final two factors are informed by the information in the hands of the agency—whether the time the agency has taken to make the decision under review is governed by a "rule of reason" (factor 1) and what effect expedition of agency action would have on competing agency priorities (factor 4). Swisher does not argue that the FDA is withholding materials from the record that would bear on TRAC factor 4. Rather, it contends that the information it seeks goes to whether the agency has proceeded under a rule of reason in reviewing its SE Reports. See Mot. at 17. The Court therefore focuses on whether the current record is sufficient with respect to its anticipated merits review of the first TRAC factor.

The timing of agency action typically is governed by a rule of reason when the agency has "an identifiable rationale" for how to order its priorities and allocate scarce resources, as informed by any statutorily mandated timetables. Ctr. for Sci. in the Pub. Int. v. FDA, 74 F. Supp. 3d 295, 300 (D.D.C. 2014); see also Mashpee Wampanoag Tribal Council, Inc., 336 F.3d at 1102 ("[W]hether [the agency's timing] satisfies the 'rule of reason' . . . will depend in large part [] upon the complexity of the task at hand, the significance (and permanence) of the outcome, and the resources available to the agency."). Conversely, agency timing is not likely to be governed by a rule of reason if the delay results from agency choices that are arbitrary, unexplained, or discriminatory. See, e.g., Jingjing Liu v. Mayorkas, No. 20-cv-654 (CRC), 2021 WL 2115209, at *3 (D.D.C. May 25, 2021). On the merits, then, the Court will assess the rule-of-reason factor by first ascertaining whether the FDA adopted procedures to review Swisher's SE Reports (clearly it did) and then determining whether those procedures were reasonable under the circumstances and evenly applied by the agency.

Marrying the Court's anticipated review of the first TRAC factor with the APA record-review standards outlined above, the record in an agency-delay case like this one should consist of materials sufficient to describe any methods or procedures used by the agency that affect the timing of the relevant agency action (*i.e.*, the purported rule of reason). And if any such methods and procedures resulted from an evaluation of alternative approaches, the record should also contain any non-privileged, non-deliberative documents that agency decisionmakers considered in selecting the chosen path. The record also should be fulsome enough to enable the reviewing court to assess whether the agency has followed its proffered rule of reason in progressing towards the ultimate decision. See e.g., Ramirez v. Blinken, 594 F. Supp. 3d 76, 93 (D.D.C. 2022) (agency's failure to "adher[e] to the rule of reason [its] plan set out" was relevant to

unreasonable delay claim). Finally, the record should reflect the agency's progress towards reaching the decision the plaintiff seeks, so that the court can assess whether agency action has been, or will continue to be, unreasonably delayed. See, e.g., Ctr. for Sci. in the Pub. Int., 74 F. Supp. 3d at 302 (agency had not unreasonably delayed because it had "been at work reviewing the relevant scientific issues [and] ha[d] progressed in that work").

Swisher has not shown that the record here lacks specific required materials (to warrant completion) or will be too bare for the Court to assess the first TRAC factor at the merits stage of the case (to warrant supplementation). To start, there is no dispute that the FDA followed what it believes is a rule of reason in processing Swisher's SE Reports: the randomized review process described in Mr. Zeller's September 2021 article. In the article, Zeller describes how that process works and why the FDA selected it, as opposed to the market-share prioritization that it applied to other types of premarket applications it received. A.R. at FDA-22954-000110. Zeller's description of the review process appears sufficient to enable the Court, at summary judgment, to assess whether it in fact constitutes a rule of reason under TRAC factor one, as informed by any statutory timetables under TRAC factor two.[3]

Indeed, Swisher does not appear to contest this point. At the motion hearing, counsel for the company indicated that, while the randomization process might implicate the delay, it was not challenging the FDA's decision to adopt that method of review. Mot. Hearing Tr. ("Tr.") at

[3] Swisher contends that Congress contemplated that the FDA complete its review of SE Reports within ninety days. Mot. at 4. For support, Swisher cites two sources: (1) an FDA regulation, stating that the agency "intends to review" SE Reports within ninety days of receipt, 21 C.F.R. § 1107.42(a); and (2) a provision of the TCA applicable to the tobacco product manufacturers originally subject to the Act, see 21 U.S.C. § 387d(c)(1) (requiring manufacturers to submit information on their products "[a]t least 90 days prior" to introducing the products into interstate commerce). See also Tr. at 33–34. The Court takes no position at this stage on how these regulations bear on the first TRAC factor.

11–12. Nor did counsel suggest that supplementation of the record would reveal documents showing that the agency's decision to select the randomization process was unreasonable, arbitrary, or discriminatory. As a result, Swisher cannot be heard to argue that the agency failed to include in the record any documents considered by the agency in selecting the randomization process over other potential alternatives, including the market-share approach that Swisher would have preferred.

The current record also permits the Court to determine how Swisher's SE Reports have been handled by the agency and whether that treatment has hewed to the agency's proffered rule of reason. The FDA included the internal kick-off email preceding the FDA's review of SE Reports in Wave 24, which details the timetable the agency followed to review the first twenty of Swisher's products that received substantive review. A.R. at FDA-22954-000075–82. The agency has also acknowledged that only these twenty of Swisher's 267 products have been selected for substantive review to date. Mot. at 9; Opp'n at 9. As for the rest, the agency has declined to disclose Swisher's randomized number in the queue of manufacturers awaiting substantial equivalence decision.[4] The government further indicates that the FDA does not know when other Swisher products will be assigned to review teams, or when Swisher can expect rulings on its reports. Mot. at 9; Tr. at 43. The Court declines, at this stage at least, to question the agency's withholding of Swisher's place in line and its refusal to provide even an estimate of when the company can expect movement on its other products. But the agency will have to live with those choices, for if such uncertainty persists at summary judgment, Swisher will no doubt

[4] Government counsel reiterated the agency's refusal to provide this information, stating that "Swisher's number is not a public number." Tr. at 42.

argue that the indefinite limbo Swisher's reports appear to be in contributes to a finding of unreasonable delay.

The record further documents the FDA's progress in clearing the total backlog of all premarket applications it has received. The picture is not pretty. As of February 28, 2023, the FDA reported that it had received 7,421 SE Reports in the year preceding the September 2020 deadline. Of those, it had cleared only 328, or 4.4 percent. FDA, SE ACCEPTANCE PHASE METRICS (Feb. 28, 2023).[5] Considering all SE Reports the agency received as of February 28, 2023, including ones submitted after September 2020, the clearance rate increases to 12.3 percent. Id. Government counsel acknowledged at the hearing that these statistics had not substantially improved. Tr. at 5–6. Extrapolating from the current statistics, Swisher will no doubt calculate how many years its reports might languish without action, and argue on the merits that such delay is unreasonable, notwithstanding the FDA's asserted justifications.

The government also acknowledges that in agency-delay cases, the agency can update the record prior to merits consideration with any relevant material regarding its progress towards taking the action in question. Opp'n at 36. The FDA promises to do so here. Tr. at 20, 25, 28. At the hearing, government counsel also indicated that the agency was in the process of soliciting recommendations from an independent organization on how it might improve the review process. Id. at 43–44. The Court would expect the agency, prior to merits briefing, to provide both Swisher and the Court with a description of any revisions to the ongoing review process that might result from those recommendations.

[5] Calculated by dividing the total number of reports received for all categories of products by the sum of the number of reports approved, denied, and withdrawn.

Given all of the above, the Court is satisfied that Swisher has not identified any required documents that are lacking from the record so as to justify completion, or established that the present record, as updated with information on continuing developments, will be too bare for the Court to review Swisher's reasonable delay claim so as to warrant supplementation. Swisher's specific requests, to which the Court now turns, do not change its conclusion.

A. The FDA's Plans for Reviewing the Influx of Applications in September 2020

Swisher's first request encompasses three categories of documents regarding the FDA's review process. Mot. at 18–22. Swisher contends that these documents are crucial to the failure-to-act analysis, as they show that the FDA inadequately prepared to review the deluge of reports received in 2020. Id. at 18; Reply at 15.

1. Documents reflecting the FDA's Plan for Reviewing SE Reports

First, Swisher seeks to add documents concerning the FDA's preparations for processing the incoming premarket applications in advance of the September 2020 deadline. During the Deeming Rule's notice-and-comment period, the FDA received concerns about the agency's ability to adjudicate reports in a one-year timeframe. Mot. at 18–19. The FDA responded that it had taken steps to address its existing backlog. Id. at 19 (citing 81 Fed. Reg. at 29,002). Swisher seeks documents from agency decisionmakers outlining the agency's game plan for winnowing its backlog and managing the new submissions, including documents referenced in the Zeller article. Reply at 15.

Swisher contends that these documents should be added to the record because they (1) exist and (2) could reveal whether the FDA's delay in adjudicating Swisher's reports is reasonable. Mot. at 19. But Swisher has not shown that the FDA improperly withheld these documents from the record. That documents detailing the agency's review process exist is not

"concrete proof" that the documents were considered by the agency. Butte County v. Chaudhuri, 887 F.3d 501, 507 (D.C. Cir. 2018) ("[D]ocuments do not necessarily become part of an administrative record even if the agency *possessed* them at the time of the decision."). A lack of specificity also dooms the request. See Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs, No. 16-cv-1534 (JEB), 2019 WL 2028709, at *3 (D.D.C. May 8, 2019) (noting that requesters "may not satisfy their burden to identify specific documents by asking for amorphous categories of information that may or may not exist or have been before the agency"). The Zeller article, moreover, does not reference any documents in a way that would suggest that the agency "considered" them for record-review purposes, such as "to support a factual assertion." Oceana, 290 F. Supp. 3d at 80 (noting that "[t]he use of a document to justify an assertion or proposition indicates that the [agency] consulted and thought about—and therefore considered—that document"). Documents that are merely cited as a "source of further information for the reader" need not be included in the administrative record unless the agency considered them. Id.

Alternatively, Swisher claims that the record should be supplemented because the documents are needed for judicial review. As discussed above, however, the Court anticipates that the present record, as updated by the government, will be sufficient for it to assess whether the FDA applied a rule of reason to its review of Swisher's SE Reports. The Court will thus deny this first request.

2. Documents About the FDA's Randomization Process

Swisher next seeks to add to the record documents regarding the FDA's decision to adopt the randomized review process outlined in the Zeller article. But as discussed, Swisher has disavowed any challenge to the randomized process as arbitrary or unreasonable. Tr. at 11–12. Thus, any documents reflecting the relative merits of alternative methods the agency may have

considered would not appear to be relevant to the rule-of-reason analysis. Swisher seemed to shift gears at the hearing, suggesting that documents reflecting the FDA's purported failure to adjust its procedures after falling behind in the review are relevant to the Court's merits analysis. Id. at 11–14. But Swisher has not shown that agency-decisionmakers are relying on documents regarding the randomization process in deciding whether, or how, to adjust the process going forward. The Zeller article, moreover, already explains that the FDA's decision to channel a subset of the PMTAs into a separate queue was aimed at achieving "the greatest public health impact most quickly." A.R. at FDA-22954-000110. The Court will accordingly deny Swisher's request as to documents underlying the randomization process.

3. Internal Communications and Guidance Documents Regarding Review Plans

In the last request in this category, Swisher seeks further documents detailing the mechanics of the current review process. The company specifically requests the addition of (1) more emails from the Director of the FDA's Division of Regulatory Project Management, Cristi Stark, describing the FDA's plans for reviewing the influx of SE Reports and (2) guidance documents supplied to SE Report review teams, including internal review guides and checklists.

To start, Swisher observes that the earliest email from Ms. Stark in the record is from January 2022, more than two years after the 2020 submission period and more than six years after the FDA had informed commenters that it had taken steps to speed up its review process. Mot. at 20. Swisher suggests that Stark, or some other official, was presumably sending internal updates prior to January 2022. Id. But the proposition that similar emails *must have been* sent prior to January 2022 is insufficient to show that they were indeed sent, let alone that any emails were relied on by agency officials in connection with any decision that is relevant to the rule-of-reason analysis. So Swisher has not met the standard for completing the record. Nor is

supplementation necessary because the Stark emails that are already in the record provide considerable detail on the logistics of the review process, including target timeframes for each review wave. Opp'n at 25–26; A.R. FDA-22954-000075–89; see also Veloxis Pharms., Inc. v. FDA, 109 F. Supp. 3d 104, 125 (D.D.C. 2015) (denying motion to supplement record with meeting minutes, in part, because they were "cumulative").

Swisher next urges the Court to include in the record information from a host of project management tools being employed by the FDA in its review process, including timeline trackers, task assignments listed in an internal software application called "Rhapsody," and review team status emails, among others. Mot. at 21. The Court concurs with the FDA that these materials consist of the minutiae of daily agency work product that ordinarily do not belong in an administrative record. Opp'n at 28. Although the record should "consist[] of all documents and materials that the agency directly or indirectly considered, no more and no less," Oceana, 290 F. Supp. 3d at 77, Swisher has not shown that such documents reflecting the day-to-day operations of agency staff have been considered by agency decisionmakers in any material sense, Am. Soc'y for Prevention of Cruelty to Animals v. Animal & Plant Health Inspection Serv., No. 21-cv-1600 (CRC), 2023 WL 3073609, at *6 (D.D.C. Mar. 22, 2023) (holding that "notes of a single line inspector are insufficient proof that agency decision-makers were aware of and took these" notes into account in formulating agency-wide policy). And, as explained previously, the data reflecting the FDA's overall process and documentation of the handling of Swisher's reports currently in the record should be sufficient for the Court to assess the TRAC factors. Supplementation of the record with the intricacies of the agency's review of each wave of reports therefore appears unnecessary.

B. Documents regarding Swisher's SE Reports

Swisher's second category of requests broadly encompasses documents regarding the status of its reports. Swisher first seeks Rhapsody screenshots and email correspondence among review team members that detail actions taken on Swisher's reports and show where the reports are in the review process at a given time. Mot. at 26. But again, Swisher has not demonstrated that agency decisionmakers have considered these materials in any relevant sense. Nor would swimming in the weeds of review teams' daily actions on Swisher's reports materially aid judicial review, for the reasons discussed previously.

Next, Swisher seeks the addition of kick-off emails for the waves of the review process involving other manufacturers' reports. Id. at 23–24. Once again, Swisher has not shown that these emails were considered by the agency. And the Court does not need this granular data on the intermediate steps of each wave of review to assess the extent of the delay Swisher has experienced. The overall expected timing of each wave, which the agency has agreed to update, should suffice. Tr. at 20, 28.

C. Documents Regarding the FDA's Progress in Clearing Backlog

The last broad category of documents Swisher seeks concerns the FDA's progress in reviewing applications received since September 2020, including any backlog from earlier submission cycles. Mot. at 27. Not to sound like a broken record, but Swisher has neither shown that any specific documents were "before the agency" nor established that this data would advance the Court's merits review.

D. Discovery

Separately, Swisher contends it is entitled to discovery because the FDA has certified an incomplete record and, as a result, Swisher is unsure of what other documents the FDA might

have excluded. Id. at 28–29. This purportedly "limited" discovery request would entail document requests, interrogatories, requests for admissions, and three depositions of agency officials. Id. at 30–31.

When reviewing agency action under the APA, "a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." Dallas Safari Club v. Bernhardt, 518 F. Supp. 3d 535, 538 (D.D.C. 2021) (citing Dep't of Com. v. New York, 588 U.S. ——, ——, 139 S. Ct. 2551, 2573 (2019)). "Exceptions to that rule are quite narrow and rarely invoked[,]" and mostly limited to cases where the "procedural validity of the agency's action remains in serious question." CTS Corp. v. EPA, 759 F.3d 52, 64 (D.C. Cir. 2014) (cleaned up). But Swisher has failed to show that the FDA has engaged in bad faith or improper behavior, Conservation Force v. Salazar, No. 10-cv-1262 (BJR), 2012 WL 11947683, at *6 (D.D.C. Feb. 6, 2012) (cleaned up), or that the administrative record contains irregularities.[6] In any case, when an administrative record is not sufficient for judicial review, usually "the proper course is not to gather evidence de novo," but rather, to have the agency provide further reasoning for its decision. Lillemoe v. U.S. Dep't of Agric., Foreign Agric. Serv., No. 15-cv-2047 (DLF), 2019 WL 4750241, at *3 (D.D.C. Sept. 30, 2019) (cleaned up). Swisher therefore is not entitled to discovery.

[6] Swisher suggests that the agency's omission of four acceptance letters from the initial certified record indicates that its compilation and certification of the record were procedurally invalid. Mot. at 28–29. But the company offers nothing to suggest that the exclusion of the letters, which Swisher obviously had, was anything more than a harmless oversight.

IV. Conclusion

For these reasons, it is hereby

ORDERED that [83] Plaintiff's Motion to Complete and Supplement the Administrative Record and for Limited Discovery is **DENIED.**

SO ORDERED.

CHRISTOPHER R. COOPER
United States District Judge

Date: September 26, 2023