

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA and FLORIDA
AGENCY FOR HEALTH CARE
ADMINISTRATION,

Plaintiffs,

v.

Case No: 8:22-cv-1981-TPB-JSS

FOOD AND DRUG
ADMINISTRATION, DEPARTMENT
OF HEALTH AND HUMAN
SERVICES, ROBERT M. CALIFF and
XAVIER BECERRA,

Defendants.

_____ /

ORDER

Plaintiffs move the court for an order directing Defendants to substantively respond to Plaintiffs' discovery requests. (Motion, Dkt. 46). The court held a hearing on the Motion on February 17, 2023. For the reasons stated below, the Motion is granted in part.

BACKGROUND

Plaintiffs State of Florida and Florida Agency for Health Care Administration bring this action against Defendants, the U.S. Food & Drug Administration and its Commissioner and the U.S. Department of Health and Human Services and its Secretary, alleging that Defendants violated the Administrative Procedures Act by unreasonably delaying and unlawfully withholding adjudication of Plaintiffs' Section

804 Importation Program Proposal (SIP Proposal), which seeks to import prescription drugs from Canada. Plaintiffs allege that the “SIP Proposal has been pending for over 700 days without adjudication, causing considerable damage to Plaintiffs and the citizens of Florida.” (Dkt. 46 at 4.)

On October 25, 2022, Plaintiffs served their First Set of Interrogatories, First Set of Requests for Production, and First Set of Requests for Admission, which Plaintiffs claim are aimed at determining whether Defendants have unreasonably delayed or withheld adjudication of the SIP Proposal. In response to these requests, Defendants filed a motion for a protective order, arguing that Plaintiffs’ claim must be resolved solely on the administrative record. In the order denying the motion for a protective order, the court specifically noted:

The presumptive limit on the scope of discovery in agency actions (including agency inaction cases) is the administrative record. *See, e.g., Tribe v. Bureau of Land Management*, 2022 WL 1778525, at *2 (E.D. Cal. June 1, 2022). However, Plaintiffs may be entitled to discovery on their agency inaction claim depending upon the circumstances. *See id.* at *3-5. As such, the Court will not limit Plaintiffs’ ability to file discovery requests following the filing of the administrative record, and any issues concerning those specific requests may be addressed through appropriate motion practice. The parties are strongly encouraged to amicably resolve disputes as to the scope and content of discovery.

(Dkt. 34.)

On December 29, 2022, Defendants filed the 4,616-page administrative record. (Dkts. 37–42.) On January 6, 2023, Plaintiffs served their Second Set of Interrogatories and Second Set of Requests for Production. Defendant opposed Plaintiffs requests

contending discovery is inappropriate in this Administrative Procedures Act action, and alternatively, the information sought was produced as part of the administrative record, irrelevant, or barred from discovery on the basis of privilege. In response, Plaintiff filed the instant Motion. (Dkt. 46.)

APPLICABLE STANDARDS

The Administrative Procedures Act (APA) requires federal agencies to address and conclude matters presented to them “within a reasonable time.” 5 U.S.C. § 555(b). Under the APA, “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . is entitled to judicial review thereof.” 5 U.S.C. § 702. Though the APA generally limits causes of action to those challenging final agency action, “[i]f the agency action is ‘unlawfully withheld or unreasonably delayed,’ the APA directs a reviewing federal court to compel the agency to act.” *Otto v. Mayorkas*, No. 8:22-cv-1172-WFJ-SPF, 2023 WL 2078270, at *3 (M.D. Fla. Feb. 17, 2023) (citing 5 U.S.C. §§ 702, 706(1)). In short, “under section 706, federal courts may review two types of claims: those seeking to compel certain required agency actions not yet taken (§ 706(1)), and those seeking to set aside arbitrary ‘agency actions’ and determinations (§ 706(2)).” *Ass’n of Civilian Technicians, Inc. v. United States*, 601 F. Supp. 2d 146, 159 (D.D.C. 2009), *aff’d*, 603 F.3d 989 (D.C. Cir. 2010) (citation omitted). Plaintiffs’ claim is one of agency inaction/unreasonable delay brought pursuant to 5 U.S.C. § 706(1).

Generally, courts are confined to a review of the administrative record in determining actions under the APA. 5 U.S.C. § 706; *Pres. Endangered Areas of Cobb’s*

History, Inc. (PEACH) v. U.S. Army Corps of Engineers, 87 F.3d 1242 (11th Cir. 1996) (noting that “while certain circumstances may justify going beyond the administrative record, a court conducting a judicial review is not ‘generally empowered’ to do so”) (quoting *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985)). Nevertheless, discovery outside the administrative record in APA cases may be allowed in certain circumstances. For example, courts may turn to extra-record evidence “where agencies are sued under § 706(1) for a failure to take action.” *Democracy Forward Found. v. Pompeo*, 474 F. Supp. 3d 138 (D.D.C. 2020) (citing *Esch v. Yeutter*, 876 F.2d 976, 991 & n.166 (D.C. Cir. 1989)). In these types of cases, courts have held that judicial review cannot be “limited to the record as it existed at any single point in time, because there is no final agency action to demarcate the limits of the record.” *Nat’l Law Ctr. on Homelessness & Poverty v. U.S. Dept. of Veterans Affairs*, 842 F. Supp. 2d 127, 130–31 (D.D.C. 2012) (quoting *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 560 (9th Cir. 2000)); see also *Cherokee Nation v. U.S. Dep’t of the Interior*, 531 F. Supp. 3d 87, 97 (D.D.C. 2021) (finding that review under § 706(1) “is not limited to the administrative record”; *Nio v. DHS*, 314 F. Supp. 3d 238, 242 (D.D.C. 2018) (noting that a § 706(1) claim “entitles Plaintiffs to rely upon material that is outside the scope of the administrative record” and moreover, that the court’s review will require a fact intensive inquiry that applies the *TRAC* factors); *W. Watersheds Project v. Pool*, 942 F. Supp. 2d 93, 100 (D.D.C. 2013) (“Because this case is about agency inaction . . . rather than agency action, this case may not be resolved solely based on the administrative

record.”); *Sierra Club v. Dep’t of Energy*, 26 F. Supp. 2d 1268, 1271 (D. Co. 1998) (“Extra record evidence may be allowed in cases where an agency is being sued for failure to act if the record before the court is insufficient for the court to determine whether the agency unlawfully withheld compliance with a statutory mandate.”).

This court has previously ruled that limited discovery is permissible in this agency inaction case. *See* (Dkt. 34.) Accordingly, the issue before the court is whether Plaintiffs’ discovery requests are appropriate in this case.

DISCUSSION

In their Motion, Plaintiffs contend that the requested discovery is relevant to the determination of whether Defendants have unreasonably delayed or withheld adjudication of the SIP Proposal. Plaintiffs seek to compel responses to their discovery requests because, as they allege, the administrative record “contains no new materials,” “consists of documents that Plaintiffs already attached to their Amended Complaint,” and is “inadequate.” (Dkt. 46 at 5.) Specifically, Plaintiffs contend that the information they seek would allow the court to meaningfully review the factors set forth in *Telecomms. Rsch. & Action Ctr. v. FCC (TRAC)*, 750 F.2d 70, 80 (D.C. Cir. 1984), which courts look to when “consider[ing] whether a federal agency has followed a rule of reason in how it reviews applications, whether human health and welfare are at issue, the interests prejudiced by delay, and whether impropriety is present.” (Dkt. 46 at 2.)

“The central question in evaluating a claim of unreasonable delay is whether the agency’s delay is so egregious as to warrant mandamus.” *In re Core Commc’ns, Inc.*,

531 F.3d 849, 855 (D.C. Cir. 2008) (quotation marks omitted). To determine whether agency action has been unreasonably delayed, courts have applied the six-factor test established by *TRAC*, 750 F.2d 70.¹ Under that test, the court must balance the following:

(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 court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find “any impropriety lurking behind agency lassitude” in order to hold that agency action is unreasonably delayed.

750 F.2d at 80 (citations omitted). These factors “are not ‘ironclad,’ but rather are intended to provide ‘useful guidance in assessing claims of agency delay.’” *In re Core Commc’ns, Inc.*, 531 F.3d at 855 (quoting *TRAC*, 750 F.2d at 80).

According to Plaintiffs, the discovery they seek is related to specific *TRAC* factors. (Dkt. 46 at 9.) Although Defendants filed the 4,616-page administrative record, Plaintiffs argue that “discovery is necessary because the [administrative record] provides no new information relevant to the *TRAC* factors.” (*Id.* at 8). Specifically,

¹ Although the Eleventh Circuit has not expressly adopted the *TRAC* factors, several district courts in this circuit have used these factors to assess claims of agency delay. See *Osechas Lopez v. Mayorkas*, No. 22-cv-21733-WILLIAMS, 2023 WL 152640, at *5 (S.D. Fla. Jan. 10, 2023) (citing *Santiago v. Mayorkas*, 554 F. Supp. 3d 1340, 1353 (N.D. Ga. 2021)); *Mondragon Tinoco v. Mayorkas*, No. 1:20-cv-4787-MLB, 2021 WL 3603373, at *9 (N.D. Ga. Aug. 13, 2021).

Plaintiffs argue that “[t]he AR provides nothing that might shed light on why Defendants sat on Plaintiffs’ SIP Proposal for nearly two years, what Defendants’ expected timeline is for review (either for Florida’s SIP Proposal or for SIP proposals generally), whether human health and welfare is at stake, or why Defendants sent Plaintiffs a lengthy Request for Information (RFI) months after litigation began in this case.” (*Id.* at 9.)

As the court has previously decided that limited, “targeted discovery” will be permitted, the court will consider whether the discovery sought should be compelled under Federal Rule of Civil Procedure 26. *See Edakunni v. Mayorkas*, No. 2:21-cv-393-TL, 2022 WL 16949330, at *4 (W.D. Wash. 2022) (limiting discovery in agency inaction case “to the materials most relevant to determining whether relief should be granted” and finding a Rule 30(b)(6) deposition request in an agency inaction case to be overbroad); *Cherokee Nation*, 531 F. Supp. 3d at 100 (discussing discovery in APA case and addressing plaintiff’s requests for production by evaluating relevancy and proportionality of each request); *Frito-Lay, Inc. v. U.S. Dep’t of Labor*, No. 3:12-cv-1747-B-BN, 2013 WL 12253035, at *3 (N.D. Tex. 2013) (reviewing a plaintiff’s discovery requests in an APA inaction case using relevancy principles).

Parties may obtain discovery regarding any non-privileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case. Fed. R. Civ. P. 26(b)(1). In determining proportionality, the court considers several factors, including the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the

importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Fed. R. Civ. P. 26(b)(1). Information within this scope of discovery need not be admissible in evidence to be discoverable. Fed. R. Civ. P. 26(b)(1). Notably, although the scope of discovery is broad, “the discovery rules do not permit the [parties] to go on a fishing expedition.” *Porter v. Ray*, 461 F.3d 1315, 1324 (11th Cir. 2006).

A party, “[o]n notice to other parties and all affected persons,” may move to compel discovery. Fed. R. Civ. P. 37(a)(1). “The Federal Rules of Civil Procedure strongly favor full discovery whenever possible,” but the trial court “is given wide discretion in setting the limits of discovery.” *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985); *Com. Union Ins. Co. v. Westrope*, 730 F.2d 729, 731 (11th Cir. 1984). “The party resisting discovery has the burden to show that the requested discovery is not relevant and that the production of such discovery would be unduly burdensome.” *Benavides v. Velocity IQ, Inc.*, No. 8:05-cv-1536-T-30, 2006 WL 680656, at *2 (M.D. Fla. Mar. 15, 2006).

Plaintiffs’ discovery requests largely seek information that is included in the administrative record provided by Defendants. *See* (Dkts. 37–42.) According to Defendants, the discovery requested in Plaintiffs’ interrogatory numbers 3, 7–10, 12, 13, 20, requests for production 3–4 and requests for admissions 1–2, 7–9 are included in the administrative record. Accordingly, Defendants shall supplement their discovery responses by identifying the bates numbers corresponding to the discovery requests within thirty days. *See Cates v. Zeltiq Aesthetics, Inc.*, 6:19-cv-1670-Orl-40LRH,

2020 WL 13413676, at *5 (M.D. Fla. Dec. 4, 2020) (requiring defendant that produced over 50,000 pages in discovery to identify relevant Bates numbers for various discovery requests); *Ecolab Inc. v. Int'l Chem. Corp.*, No. 6-18-cv-1910-Orl-41GJK, 2020 WL 109693, at *5 (M.D. Fla. Jan. 8, 2020) (directing the defendant, in the alternative, to specify the records by Bates number or other mark sufficient to enable the plaintiff to locate and identify records containing answer to discovery request); *Pepperwood of Naples Condo. Ass'n, Inc. v. Nationwide Mut. Fire Ins. Co.*, No. 2:10-cv-753-FTM-36, 2011 WL 4382104, at *6 (M.D. Fla. Sept. 20, 2011) (referencing documents produced without pointing specifically to where in the files the information could be found does not comply with Rule 33(d) of the Federal Rules of Civil Procedure); *see also Haughton v. Dist. of Columbia*, No. 12-cv-1767 (KBJ-AK), 315 F.R.D. 424, 427 (D.D.C. 2014) (same).

Additionally, Defendants maintain that Plaintiffs' discovery requests seek documents barred from disclosure based on privilege. Specifically, Defendants maintain that interrogatory requests 16–19, 22–23 and requests for production 4 and 7 are predecisional documents that are exempt from disclosure. “[A]n agency’s documents that are both predecisional and deliberative are exempt from disclosure and immaterial to judicial review of an agency’s action.” *Sierra Club v. U.S. Fish and Wildlife Service*, No. 2:20-cv-13-SPC-NPM, 2021 WL 4478329, at *3 (M.D. Fla. Sept. 30, 2021). “Documents are ‘predecisional’ if they were generated before the agency’s final decision on the matter, and they are ‘deliberative’ if they were prepared to help the agency formulate its position.” *Sierra Club v. U.S. Fish and Wildlife Serv.*, 141 S. Ct. 777,

785–86 (2021). This principle exempting disclosure is known as the deliberative-process privilege. As the Supreme Court has reasoned, “the deliberative process privilege shields from disclosure ‘documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.’” *Id.* at 785 (quoting *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975)). As such, the privilege protects not only documents, but also the integrity of the deliberative process itself. *See Dudman Commc’ns Corp. v. Dep’t of the Air Force*, 815 F.2d 1565, 1568 (D.C. Cir. 1987); *see also Moye, O’Brien, O’Rourke, Hogan, & Pickert v. Nat’l R.R. Passenger Corp.*, 376 F.3d 1270, 1278 (11th Cir. 2004) (“the disclosure of deliberative documents would inhibit the agency’s decision-making process and discourage candid discussion within the agency and, thereby, undermine the agency’s ability to perform its functions”); *Schell v. Health & Hum. Servs.*, 843 F.2d 933, 940 (6th Cir. 1988) (“Because [the privilege] is concerned with protecting the deliberative process itself, courts now focus less on the material sought and more on the effect of the material’s release.”). Upon consideration and review, the discovery requested in Plaintiffs’ interrogatory requests 16–19, 22–23 and requests for production 4 and 7 seek predecisional documents that are exempt from disclosure. As predecisional documents are privileged and exempt from disclosure, discovery of the privileged documents is not permitted here.

Plaintiffs further seek documents that Defendants maintain are neither relevant nor proportional to the needs of the case. Upon consideration and review, interrogatory request 11, requests for production 6, 8, 9, and request for admissions 10

are not proportional to the needs of the case. *See Gonzalez v. GEICO Gen. Ins. Co.*, No. 8:15-cv-240-T-30TBM, 2016 WL 7734076, at *2 (M.D. Fla. Apr. 15, 2016) (“Although the federal rules generally allow for liberal discovery in civil matters, such is not unbounded. The Court must consider proportionality to the needs of the case.”); *Mey v. Interstate Nat’l Dealer Servs., Inc.*, No. 1:14-cv-01846-ELR, 2015 WL 11257059, at *2 (N.D. Ga. June 23, 2015) (“While the Court is mindful that discovery is intended to be an open process, so as to better facilitate the free flow of information between litigants, parties are not permitted to go on ‘fishing expeditions’ which extend beyond the legitimate scope of discovery.”). For example, interrogatory request 11 and request for admissions 10 exceed the scope of Plaintiff’s agency inaction claim. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64, 67 (2004). Request for production 6 also seeks information outside the scope of APA review. *See Sierra Club v. U.S. Dep’t of Energy*, 26 F. Supp. 2d 1268, 1271–72 (D. Colo. 1998) (declining to permit discovery into “the identities of agency personnel and all related documents involved with the decisions made”). Requests for production 8 and 9 are overly broad, and Plaintiffs have failed their initial burden of showing the documents it seeks are relevant and non-speculative. *See Salvato v. Miley*, No. 5:12-cv-635-Oc-10PRL, 2013 WL 2712206, at *2 (M.D. Fla. June 11, 2013) (holding that, without a clearer showing, plaintiff was not allowed access to private material and was simply requesting permission to conduct a fishing experiment with the mere hope that private statements and electronic communication would expose relevant material).

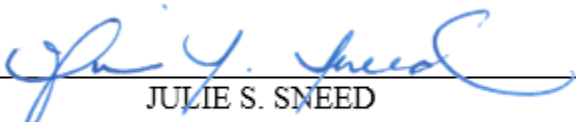
Additionally, Defendants maintain that interrogatory requests 1, 2, 14, 15, 21, 24, requests for production 1, 5, 6, and requests for admissions 3–6 are not relevant to the determination of whether Defendants unreasonably delayed or withheld adjudication of the SIP Proposal. Fed. R. Civ. P. 26(b)(1); *Washington v. Brown & Williamson Tobacco Corp.*, 959 F.2d 1566, 1570 (11th Cir. 1992) (“Discovery should be tailored to the issues involved in the particular case.”). Upon consideration and review, the court agrees for similar reasons discussed above. For example, interrogatory requests 1, 2, 21 and requests for production 1 and 6 seek information that is not relevant to an agency inaction claim. *See Sierra Club*, 26 F. Supp. 2d at 1271–72. As for interrogatory request 24, Plaintiffs have failed to demonstrate that the information they seek in this request is non-speculative and moreover, is more akin to a fishing expedition with mere hopes of exposing relevant information. *See Salvato*, 2013 WL 2712206 at *2. Interrogatory requests 14, 15 and request for production 5 seek information relating to matters outside the scope of Plaintiffs’ agency inaction claim, which the court finds would not be helpful to the court in determining the issue of unreasonable delay. As for requests for admissions 3–6, the court finds these requests are irrelevant as they will not lead to more discoverable evidence or narrow the issues for the court to resolve.

Lastly, Defendants state that interrogatory requests 5, 6 and request for production 2 seek information that would be in the record if it existed, had been considered by FDA, and was properly part of the record. Upon consideration and

review, the court find these requests irrelevant to the issue before the court of whether the delay thus far has been unreasonable.

Accordingly, Plaintiffs' Motion to Compel (Dkt. 46) is **GRANTED** in part.

ORDERED in Tampa, Florida, on March 17, 2023.



JULIE S. SNEED
UNITED STATES MAGISTRATE JUDGE

Copies furnished to:
Counsel of Record