UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 0:24-CV-62413-DAMIAN

HYBRID PHARMA LLC,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.
_____ /

DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS AND FOR LEAVE TO CONDUCT LIMITED DISCOVERY

In seeking to compel extra-record discovery of FDA documents and testimony from agency personnel, Hybrid Pharma LLC proceeds under a false premise. To resolve Hybrid Pharma's Administrative Procedure Act (APA) claim, there is *no* "need for . . . fact-finding" by the Court. ECF No. 38 (Pl. Mot.) at 2. Rather, the Court's "task" is simply "to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985). A court "is *not* generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry." *Id.* at 744 (emphasis added). In other words, Hybrid Pharma's APA claim should be resolved based upon the "voluminous administrative record" produced by FDA, ECF No. 37 at 1, *not* upon "some new record made initially in the reviewing court," *Fla. Power*, 470 U.S. at 743 (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam)).

Nor has Hybrid Pharma borne the heavy burden of proving this case presents a circumstance, recognized by the Supreme Court and Eleventh Circuit, when extra-record discovery might be permitted. The company's argument of agency bad faith or improper conduct is factually baseless. On their face, the few record documents cited by Hybrid Pharma to support this motion are devoid of any hint of impropriety. At most, the motion papers show disagreement with FDA on the merits. That does not provide license for an extra-record fishing expedition; it merely indicates the parties should proceed to summary judgment. The Court should deny this motion to compel and set a new briefing schedule for summary judgment.

BACKGROUND

Hybrid Pharma has long desired to use this APA case as a vehicle for discovery. On June 3, 2025, before the Court had even ruled on FDA's motion to dismiss the *original* complaint, Hybrid Pharma emailed FDA a First Request for Production of Documents, seeking ten broad categories of documents. *See* ECF No. 21-1 at 4. However, the Court dismissed the original complaint for lack of subject-matter jurisdiction. *See* ECF No. 16.

On June 19, 2025, Hybrid Pharma filed an amended complaint, alleging a single APA claim. *See* ECF No. 17 (Am. Compl.) ¶¶ 1, 49-53. Shortly thereafter, before FDA could respond to the amended complaint, the company renewed its First Request for Production of Documents. *See* ECF No. 24-1. And then, on the same day FDA moved to dismiss the amended complaint, *see* ECF No. 20, Hybrid Pharma moved to compel the immediate production of the "[c]ertified administrative record," and potentially "other documents that . . . may not be included in the agency's administrative record." ECF No. 21 at 2 & n.1. Magistrate Judge Valle denied the motion to compel as premature, given the pendency of the motion to dismiss. ECF No. 27.

After the Court denied FDA's motion to dismiss, *see* ECF No. 29, FDA answered the amended complaint, ECF No. 32, and produced the certified administrative record, ECF

No. 33. The administrative record includes more than 7700 pages, spanning from the July 2016 inspection of Hybrid Pharma's facility to the September 2024 final response to the company's citizen petition. *See* ECF No. 33-1. "Given the size of the record," Hybrid Pharma "need[ed] additional time in reviewing the record and preparing its motion" for summary judgment—a request that FDA did not oppose. ECF No. 36 at 1. On April 22, 2026, the Court granted the request, extending the summary judgment schedule due to "the voluminous administrative record." ECF No. 37 at 1.

But only a few weeks later, Hybrid Pharma returned to the Court with this motion to compel production of "documents in response to Plaintiff's First Request for Production of Documents"—the same one from June 2025—and to depose three FDA employees. Pl. Mot. at 1, 9. FDA now opposes the motion.

LEGAL STANDARD

In APA litigation, "[t]he general rule . . . is that the court may not go outside the administrative record." *Nat'l Min. Ass'n v. Sec'y of Lab.*, 812 F.3d 843, 875 (11th Cir. 2016) (quotation omitted). "The district court may order discovery beyond the administrative record only where there is 'a strong showing of bad faith or improper behavior' by the agency." *Marllantas, Inc. v. Rodriguez*, 806 F. App'x 864, 867 (11th Cir. 2020) (quoting *Dep't of Com. v. New York*, 588 U.S. 752, 780 (2019)); *see Nat'l Min. Ass'n*, 812 F.3d at 875; *Ala.-Tombigbee Rivers Coal. v. Kempthorne*, 477 F.3d 1250, 1262 (11th Cir. 2007).

"[T]he party seeking discovery has 'a heavy burden to show'" it "is necessary" to go beyond the administrative record. *Ala.-Tombigbee Rivers Coal. v. Norton*, No. 01-00194-CV-HS-S, 2002 WL 227032, at *3 (N.D. Ala. Jan. 29, 2002) (quoting *United States v. Amtreco, Inc.*, 806 F. Supp. 1004, 1006 (M.D. Ga. 1992)); *see SOSS2, Inc. v. U.S. Army Corps of Eng'rs*, 403 F. Supp. 3d 1233, 1239 (M.D. Fla. 2019). And a court may not determine extra-record discovery is necessary unless it has conducted a "comprehensive review of the administrative record." *Pres. Endangered Areas of Cobb's Hist., Inc. v. U.S. Army Corps*

of Eng'rs, 915 F. Supp. 378, 383 (N.D. Ga. 1995); *see Dep't of Com.*, 588 U.S. at 782 (noting "the District Court should not have ordered extra-record discovery" before reviewing the "complete . . . administrative record").

ARGUMENT

On March 23, 2026, FDA produced a certified administrative record that supports the agency's decisions to issue warning letters in 2018 and 2022, as well as the 2024 response to the company's citizen petition. *Compare* ECF No. 29 at 12-13, *with* ECF No. 33-1. The record comprises more than 7700 pages. It contains extensive documentation from four inspections of Hybrid Pharma (in 2016, 2019, 2021, and 2023), as well as post-inspection correspondence with the company. It contains the 2018 and 2022 warning letters and Hybrid Pharma's responses thereto; subsequent emails between FDA and the company; memoranda documenting the parties' meetings; and the file for the citizen petition. In short, the certified record amply allows the court "to apply the appropriate APA standard of review, 5 U.S.C. § 706, to" FDA's challenged "decision," *Fla. Power*, 470 U.S. at 743–44.

But instead of proceeding to summary judgment as scheduled, Hybrid Pharma hopes to embark on a discovery sideshow. Among other things, it demands "production of all internal agency communications discussing [the] warning letters and opinions and recommendations leading up to issuance of [the] same," as well as depositions of three agency employees. Pl. Mot. at 7, 9. As Hybrid Pharma tacitly acknowledges, *see id.* at 7, these requests are intended to discover information protected by the deliberative process privilege, *see Moye, O'Brien, O'Rourke, Hogan, & Pickert v. Nat'l R.R. Passenger Corp.*, 376 F.3d 1270, 1277-78 (11th Cir. 2004) (discussing deliberative process). But deliberative materials are legally irrelevant to APA review and thus properly excluded from the administrative record. *See, e.g.*, *Blue Mountains Biodiversity Project v. Jeffries*, 99 F.4th 438, 444 (9th Cir. 2024); *Oceana, Inc. v. Ross*, 920 F.3d 855, 865

(D.C. Cir. 2019); *Sierra Club v. U.S. Fish & Wildlife Serv.*, No. 2:20-CV-13-SPC-NPM, 2021 WL 5634131, at *2 (M.D. Fla. Dec. 1, 2021); *Coastal Conservation Ass'n v. Locke*, No. 2:09-cv-641-FtM-29SPC, 2010 WL 1439071, at *4 (M.D. Fla. Apr. 12, 2010).

Hybrid Pharma argues it can nonetheless intrude upon "the mental processes of the decision makers" because FDA purportedly engaged in "bad faith and/or improper behavior." Pl. Mot. at 7. But the company falls well short of the "strong showing" necessary to back up this conclusory allegation. *Ala.-Tombigbee*, 477 F.3d at 1262 (citation omitted).

Hybrid Pharma tipped its hand on this discovery gambit long ago. It initially tried to serve the First Request for Production of Documents in June 2025, *see* ECF No. 21-1 at 4, heedless of how "the standard discovery tools of civil litigation . . . do not apply" in an APA case, *Comprehensive Cmty. Dev. Corp. v. Sebelius*, 890 F. Supp. 2d 305, 312 (S.D.N.Y. 2012), and while FDA's motion to dismiss the original complaint for lack of jurisdiction remained pending. Hybrid Pharma then renewed—and tried to compel compliance with—the discovery requests while FDA's motion to dismiss the amended complaint was pending. *See* ECF Nos. 21, 24-1. Now, despite receiving a voluminous, certified administrative record, Hybrid Pharma still blindly seeks to enforce this illegitimate discovery request. Put bluntly, the company's own conduct strongly suggests this is about pursuing discovery for the sake of discovery, regardless of the APA framework and the actual contents of the record.

Any doubt is dispelled by Hybrid Pharma's proffer of wrongdoing, primarily found in its owner's declaration. *Compare* Pl. Mot. at 2-7, *with* Rajalingam Decl. (ECF No. 38-2). Out of many dozens of documents in the record, *see* ECF No. 33-1, the Rajalingam Declaration mentions only three: the 2016 FDA record of inspectional observations; a

2017 FDA letter requesting further information; the 2018 warning letter.[1] On their face, these documents do not exhibit any agency bad faith or improper behavior. *See* ECF No. 38-2, at 8-24. Nor do any of Hybrid Pharma's gripes about the 2018 warning letter amount to a strong showing of bad faith (or even error).

For instance, the 2018 warning letter mentions that, "[d]uring the [2016] inspection, . . . investigators noted" how some of Hybrid Pharma's drug products "did not include" required "information on the labels." ECF No. 38-2 at 21-22. Hybrid Pharma says this represented bad faith because FDA indicated that Hybrid Pharma's corrected labels were adequate in a 2017 letter. Pl. Mot. at 4-5. But the warning letter explicitly acknowledges the "corrective actions to [the drug product] labels appear to be adequate." ECF No. 38-2 at 23.

In another example, the warning letter states that Hybrid Pharma "failed to submit a report to FDA upon initial registration as an outsourcing facility in January 2015." ECF No. 38-2 at 22. Hybrid Pharma argues "its initial report" was submitted "via email utilizing an [E]xcel spreadsheet" on June 30, 2015. Pl. Mot. at 5-6.[2] But the statute requires "a report to FDA upon initially registering as an outsourcing facility," and then semi-annual reports in June and December thereafter. ECF No. 38-2 at 21 (citing 21 U.S.C. § 353b(b)(2)). Hybrid Pharma's June 2015 semi-annual report has no bearing on the failure to submit an initial report upon registration in January 2015. *See* ECF No. 38-2 at 23 ("your facility failed to submit a report to FDA upon initial registration as an outsourcing facility in January 2015").

Hybrid Pharma also claims it was "demonstrably false" for the warning letter to say that it "had not developed and implemented written processes for the surveillance,

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[1] Though using the abbreviation "2016 WL," Hybrid Pharma apparently refers to the *2018* warning letter. *Compare* Rajalingam Decl. ¶ 12 *and* Pl. Mot. at 4, *with* ECF No. 38-2 at 19-24.

[2] This email chain, *see* ECF No. 38-2, at 26-27, is outside the scope of the certified administrative record.

receipt, evaluation, and reporting of adverse events of drug products," Pl. Mot. at 6, because the FDA investigator "acknowledged" a process existed, Rajalingam Decl. ¶ 28; *see also* ECF No. 38-2 at 22. To be sure, the record of 2016 inspectional observations shows that FDA's investigator reviewed the "procedure for handling complaints and recalls." ECF No. 38-2 at 14 (Observation 7). The record also reveals that the investigator found Hybrid Pharma's adverse-event reporting procedure "deficient" in multiple respects. *Id.* Given those deficiencies, it hardly amounted to bad faith for the warning letter to flag non-compliance with "the requirement to submit adverse event reports to FDA." ECF No. 38-2 at 21 (citing 21 U.S.C. § 353b(b)(5)).[3]

Although styled a motion to compel, Hybrid Pharma's arguments really are about the merits. The question in an APA case is whether "the agency has acted within a zone of reasonableness, and in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). Hybrid Pharma believes that FDA did not. *See* Pl. Mot. at 8-10 ("the 201[8] WL was not warranted given the clear contradicting circumstances"; "the record does not adequately explain the actions"; "There is no reasonable explanation for this decision based on what has been produced.").

But, as courts in this Circuit have held, a motion that "simply repackages" arbitrary-and-capricious arguments "is not a justification for the submission of extra-record evidence" or engaging in extra-record discovery. *Altamaha Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*, No. CIVA CV206-186, 2007 WL 1830864, at *3 (S.D. Ga. June 21, 2007); *see Florida v. United States*, No. 3:21CV1066-TKW-EMT, 2022 WL 2431442, at *2 (N.D. Fla. June 6, 2022) (denying extra-record discovery because argument of agency

[3] Hybrid Pharma does not explain why the absence of action by the Florida Board of Pharmacy, other state regulators, or the Drug Enforcement Agency, or the absence of recalls, Rajalingam Decl. ¶¶ 36-37, means that FDA acted in bad faith when identifying perceived violations of federal law.

bad faith "goes more to the merits of Florida's claims than the adequacy of the administrative record"). A strong showing of bad faith "is not made out by the mere fact that a court may disagree with the agency on the merits or find error, procedural or substantive, by the agency decision-maker." *Scott v. Nelson*, No. 5:23-cv-1041-HNJ, 2026 WL 686608, at *5 (N.D. Ala. March 11, 2026) (quoting *Comprehensive Cmty.*, 890 F. Supp. 2d 305 at 315). Because disagreement does not equal bad faith, Hybrid Pharma has not made the strong showing necessary for extra-record discovery.[4]

Although Hybrid Pharma invokes three other potential bases for extra-record discovery, *see* Pl. Mot. at 9, "the only exception to the record rule actually recognized by the Eleventh Circuit is . . . bad faith or improper behavior by the agency," *Coin Ctr. v. Yellen*, No. 3:22CV20375-TKW-ZCB, 2023 WL 2889736, at *2 (N.D. Fla. Apr. 10, 2023). That is plain from the Eleventh Circuit's decisions in *Marllantas*, 806 F. App'x at 867, *Nat'l Min. Ass'n*, 812 F.3d at 875, and *Kempthorne*, 477 F.3d at 1262. To be sure, "[i]n a footnote contained in *Preserve Endangered Areas of Cobb's History, Inc. v. U.S. Army Corps of Engineers*, 87 F.3d 1242[, 1246 n.1] (11th Cir. 1996), the Eleventh Circuit listed the Ninth Circuit's four exceptions to the rule forbidding extra-record evidence." *Citizens for Smart Growth v. Peters*, No. 07-14122-CIV, 2008 WL 11331898, at *2 n.3 (S.D. Fla. Sept. 24, 2008). But critically, it never "adopt[ed] . . . the Ninth Circuit exceptions." *Id.* While a few district courts misconstrued this footnote (including the one on which Hybrid Pharma relies, *see* Pl. Mot. at 9), the Eleventh Circuit's subsequent decisions have "only recognized the bad faith exception," *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Service*, No. 3:23-CV-936-WWB-LLL, 2024 WL 5717455, at *6–7 (M.D. Fla. Nov. 22, 2024); *see, e.g. Coin Ctr.*, 2023 WL 2889736, at *2–3. And no bad faith exists here.

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[4] And if, as the company argues, FDA's actions are "not sufficiently supported by the record," that would only "work in [Hybrid Pharma's] favor" at summary judgment. *Florida*, 2022 WL 2431442, at *2. Though to be clear, FDA vigorously disputes Hybrid Pharma's views on the merits, as the agency will explain during summary judgment briefing.

Even if the Court did consider the other three bases— *i.e.*, lack of explanation, reliance on documents not in the record, and technical complexity—Hybrid Pharma still fails to establish a need for extra-record discovery. The record extensively documents the basis for the warning letters and FDA's decision not to rescind them. Hybrid Pharma offers only speculation, *not* actual evidence, that FDA relied on undisclosed materials. That won't suffice. *See, e.g.*, *Donjon-SMIT, LLC v. Schultz*, No. 2:20-CV-011, 2020 WL 1666073, at *4 (S.D. Ga. Apr. 3, 2020) (denying motion to complete and supplement the record as based on "pure speculation"). And Hybrid Pharma offers no explanation why the "multi-tiered approval process" and the "technical steps the warning letters went through before approval," Pl. Mot. at 10, warrants departing from the APA's default record review procedures.

Turning to the request to depose three FDA employees, "inquiry into the mental processes of administrative decisionmakers is usually to be avoided." *United States v. Morgan*, 313 U.S. 409, 422 (1941). As with any request for extra-record discovery, "a strong showing of bad faith or improper behavior" must be made, *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420–21 (1971), and that standard has not been met here. Even if the court did find a strong showing of bad faith, depositions are not generally the "most expeditious" way to inquire into the agency's actions. *See id.*

The court will analyze the certified administrative record in this case—more than 7700 pages long—at the summary judgment stage. "If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course" is *not*, as Hybrid Pharma now urges, to embark upon extra-record discovery; rather, it is, as the Supreme Court directed, "to remand to the agency for additional investigation or explanation." *Fla. Power*, 470 U.S. at 744. Fortunately, the question of remedies is not only premature but will never arise

because, as FDA's summary judgment briefing will explain, the agency acted well "within a zone of reasonableness." *Prometheus Radio Project*, 592 U.S. at 423.

CONCLUSION

For the foregoing reasons, the Court should deny Hybrid Pharma's motion and set a new briefing schedule for summary judgment.

June 5, 2026

Respectfully submitted,

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