UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 24-62413-CIV-DAMIAN

HYBRID PHARMA LLC,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.
_____/

ORDER ON MOTION TO DISMISS AMENDED COMPLAINT [ECF NO. 20]

THIS CAUSE is before the Court on Defendant, Food and Drug Administration's ("FDA" or "Defendant"), Motion to Dismiss the First Amended Complaint [ECF No. 20] ("Motion"), filed July 17, 2025.

THE COURT has reviewed the Motion, the parties' briefing [ECF Nos. 23 and 26], the applicable law, and the relevant portions of the record and is otherwise fully advised. For the reasons that follow, the Motion to Dismiss is denied.

I. BACKGROUND

Plaintiff, Hybrid Pharma LLC ("Hybrid Pharma" or "Plaintiff"), filed a Complaint pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701–706 ("APA"), challenging the FDA's decision to issue two warning letters and seeking declaratory and injunctive relief. *See generally* ECF No. 1 ("Complaint"). On June 9, 2025, this Court granted in part the FDA's Motion to Dismiss the Complaint upon finding that Hybrid Pharma's Complaint failed to demonstrate an injury-in-fact that is traceable to the challenged agency action as required to establish standing. *See* ECF No. 16, at 9. This Court granted Hybrid Pharma leave to amend

the Complaint to correct the allegations and establish whether it meets the requirements of Article III standing. *See id.* at 13.

On June 19, 2025, Hybrid Pharma filed its First Amended Complaint, the operative pleading. [ECF No. 17 ("Amended Complaint")]. As alleged in the Amended Complaint, Hybrid Pharma operates as a registered "outsourcing facility" under section 503B of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353b. Am. Compl. ¶ 2. Hybrid Pharma specializes in compounding and dispensing vital pharmaceuticals to mitigate drug shortages and fill specific needs for hospitals, physician clinics, and clinical trials. *Id.* ¶ 3.

Following two separate inspections of Hybrid Pharma's facility, on November 30, 2018, and June 7, 2022, the FDA issued two separate warning letters to Hybrid Pharma. *Id.* ¶¶ 6, 24–36. Copies of the two warning letters are attached to the Amended Complaint. *Id.* at 12–22. Hybrid Pharma alleges the warning letters were issued by the FDA without considering and meeting all pre-requisites for the issuance of such notices as set forth in the FDA's Regulatory Procedures Manual. *Id.* ¶ 6.

As further alleged in the Amended Complaint, Hybrid Pharma compounds pharmaceuticals for important clinical trials around the country seeking new therapies for conditions without a cure. *Id.* ¶ 8. According to Hybrid Pharma, warning letters, such as the letters at issue, "substantially affect" such clinical trials as they delay the progress and completion of the trials. *Id.* Hybrid Pharma alleges that, on August 23, 2023, it submitted a Citizen Petition to the FDA requesting that the 2018 and 2022 Warning Letters be rescinded as the agency had allegedly failed to follow its own policies and procedures, set forth in the Regulatory Procedures Manual, with regard to the warning letters. *Id.* ¶ 37. Hybrid Pharma

alleges the FDA issued a final response on September 10, 2024, denying the Citizen Petition to rescind the warning letters. *Id.* ¶ 38.

Warning letters issued by the FDA are published on its website and are accessible to the public. *Id.* ¶ 39. Hybrid Pharma alleges such warning letters "have a devastating effect of not only causing reputational damage but causing economic harm to the recipients, including a loss of business and revenue." *Id.* Hybrid Pharma further alleges that "[a]s a result of the improperly issued warning letters in the instant action, such notices have caused a loss of business and revenue for Plaintiff." *Id.* ¶ 40. More specifically, Hybrid Pharma alleges that a clinical trial with Yale University "was forced to stop and placed on an indefinite pause despite Plaintiff's continuous efforts to address the concerns of [the FDA]." *Id.* ¶ 44. According to the allegations in the Amended Complaint, "[a]s a direct result of such stoppage and indefinite pause, Yale University cancelled all pending and future orders for drug products with Plaintiff to be utilized in the clinical trial causing a loss of business and revenue for Plaintiff." *Id.* ¶ 45. Hybrid Pharma alleges that "but for the [FDA]'s warning letters, Yale University would not have stopped the clinical trial, and no loss of revenue would have been suffered by Plaintiff." *Id.*

In addition to the allegations concerning the Yale University clinical trial, Hybrid Pharma alleges in the Amended Complaint that the warning letters "have also caused other states to deny applications to operate within their state which has led to a loss of business and revenue for Plaintiff." *Id.* ¶ 46. Hybrid Pharma alleges that in February 2025 it received a request to purchase drug products from Wintzer Acupuncture LLC ("Wintzer") located in the State of Washington. *Id.* ¶ 47. Hybrid Pharma further alleges that it immediately filed an

application for an outsourcing license with the State of Washington in order to operate in that state but, "due to the outstanding warning letters issued and published by [the FDA], the State of Washington has refused to issue an outsourcing license to Plaintiff which in turn directly caused Plaintiff to lose an order with and revenue from Wintzer." *Id.*

On July 17, 2025, the FDA filed the Motion to Dismiss now before the Court seeking dismissal of the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). The Motion is fully briefed and ripe for adjudication.

II. APPLICABLE LEGAL STANDARDS

A. Constitutional Standing.

Article III of the Constitution limits the jurisdiction of federal courts to "cases" and "controversies," and "[s]tanding to sue is a doctrine rooted in the traditional understanding of a case or controversy." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (quotation marks omitted). To have standing, plaintiffs must therefore establish that they "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Id.*

The three elements of Article III standing—injury, causation, and redressability—must be supported "with the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). *See also 31 Foster Children v. Bush*, 329 F.3d 1255, 1263 (11th Cir. 2003) ("How much evidence is necessary to satisfy [the standing requirement] depends on the stage of litigation at which the standing challenge is made."). At the "pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we 'presum[e] that

general allegations embrace those specific facts that are necessary to support the claim.'" *Bennett v. Spear*, 520 U.S. 154, 168 (1997) (citation omitted). *See also Moody v. Warden*, 887 F.3d 1281, 1286 (11th Cir. 2018).

B. Sufficiency Of The Pleadings.

Federal Rule of Civil Procedure 12(b)(6) provides that a defendant may move to dismiss a complaint that does not satisfy the applicable pleading requirements for "failure to state a claim upon which relief can be granted." In considering a Rule 12(b)(6) motion to dismiss, the court's review is generally "limited to the four corners of the complaint." *Wilchombe v. TeeVee Toons, Inc.*, 555 F.3d 949, 959 (11th Cir. 2009) (quoting *St. George v. Pinellas County*, 285 F.3d 1334, 1337 (11th Cir. 2002)). The Court must review the complaint in the light most favorable to the plaintiff, and it must generally accept the plaintiff's well-pleaded facts as true. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984). However, pleadings that "are no more than conclusions[ ] are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Dismissal pursuant to a Rule 12(b)(6) motion is warranted "only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations of the complaint." *Shands Teaching Hosp. & Clinics, Inc. v. Beech St. Corp.*, 208 F.3d 1308, 1310 (11th Cir. 2000) (internal quotation marks omitted) (quoting *Hishon*, 467 U.S. at 73).

Federal Rule of Civil Procedure 8(a)(2) also requires that a pleading contain a "short and plain statement of the claim" showing the pleader is entitled to relief. The complaint must

"give the defendant fair notice of what the claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up).

III. DISCUSSION

In the Motion, the FDA argues that the Amended Complaint should be dismissed because Hybrid Pharma does not plead sufficient facts to satisfy the causation and redressability elements for Article III standing. *See* Mot. at 4–8. The FDA further argues that the Amended Complaint does not plausibly allege an APA claim. *Id.* at 8–11. Each argument is addressed in turn below.

A. Whether Hybrid Pharma Has Established Article III Standing.

The FDA argues that Hybrid Pharma lacks standing for two reasons: (1) it fails to show traceability between the FDA's challenged conduct and the independent actions of Yale University (to pause a clinical trial) and the State of Washington (to deny a business license); and (2) it fails to show that these independent third parties would respond to a favorable judicial ruling in a way that redresses Hybrid Pharma's purported injury. *See* Mot. at 4.

As for the first Article III standing requirement, this Court finds that Hybrid Pharma has sufficiently alleged an injury-in-fact in the Amended Complaint. Hybrid Pharma alleges that it has suffered economic harm in the form of "a loss of business and revenue" when Yale University canceled all orders for drug products for the clinical trial and when the State of Washington denied a business license which, in turn, caused Hybrid Pharma to "lose an order . . . and revenue" for drug products with Wintzer. Am. Compl. ¶¶ 40–47. Such economic harm is a well-established injury for purposes of Article III standing. *See, e.g.*, *Chevron Corp. v. Donziger*, 833 F.3d 74, 120 (2d Cir. 2016) ("Any monetary loss suffered by the plaintiff satisfies

the injury-in-fact element."). The alleged economic injury is also concrete and particularized, and actual and imminent, because Hybrid Pharma alleges that it suffered lost revenue for pending and future orders for drug products relating to the Yale University clinical trial. *See Lujan*, 504 U.S. at 560–61; *see also Wyndham Vacation Ownership, Inc. v. Clapp Business Law, LLC*, 411 F. Supp. 3d 1310, 1317 (M.D. Fla. 2019) (finding plaintiffs sufficiently alleged they suffered an injury due to "lost revenue").

Next, to satisfy Article III's causation requirement, a plaintiff must allege that its injuries are "connect[ed] with the conduct of which [it] complains." *Trump v. Hawai'i*, 585 U.S. 667, 698 (2018). *See also Duke Power Co. v. Envtl. Study Grp.*, 438 U.S. 59, 75 n.20 (1978) (explaining that Article III standing "require[s] no more than a showing that there is a substantial likelihood" of causation) (quotation marks omitted). Significantly, "[p]roximate causation is not a requirement of Article III standing, which requires only that the plaintiff's injury be fairly traceable to the defendant's conduct." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014). "[E]ven harms that flow indirectly from the action in question can be said to be 'fairly traceable' to that action for standing purposes." *Focus on the Family v. Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1273 (11th Cir. 2003). A plaintiff therefore need not show (or, as here, allege) that "the defendant's actions are the very last step in the chain of causation." *Bennett*, 520 U.S. at 168–69. *See also Moody*, 887 F.3d at 1285 (explaining that we "must not confuse weakness on the merits with absence of Article III standing") (citation and quotation marks omitted).

In the Amended Complaint, Hybrid Pharma alleges that "[a]s a result of the improperly issued warning letters in the instant action, such notices have caused a loss of

business and revenue for Plaintiff." Am. Compl. ¶ 40. Hybrid Pharma alleges that the clinical trial with Yale University "was forced to stop and placed on an indefinite pause despite Plaintiff's continuous efforts to address the concerns of [the FDA]." *Id.* ¶ 44. According to the allegations in the Amended Complaint, "[a]s a direct result of such stoppage and indefinite pause, Yale University cancelled all pending and future orders for drug products with Plaintiff to be utilized in the clinical trial causing a loss of business and revenue for Plaintiff." *Id.* ¶ 45. Hybrid Pharma alleges that "but for the [FDA]'s warning letters, Yale University would not have stopped the clinical trial, and no loss of revenue would have been suffered by Plaintiff." *Id.* Hybrid Pharma further alleges that "due to the outstanding warning letters issued and published by [the FDA], the State of Washington has refused to issue an outsourcing license to Plaintiff which in turn directly caused Plaintiff to lose an order with and revenue from Wintzer." *Id.* ¶ 47.

Given these allegations, which this Court accepts as true at the pleading stage, a fair inference can be made that the FDA's issuance of the warning letters (and its refusal to rescind those letters as requested by Hybrid Pharma in the Citizen Petition) has negatively affected Hybrid Pharma's business in the drug compounding industry. *See Bennett*, 520 U.S. at 168 ("While . . . it does not suffice if the injury complained of is the result of the *independent* action of some third party not before the court, that does not exclude injury produced by determinative or coercive effect upon the action of someone else." (internal citations omitted) (cleaned up)). Stated differently, "[b]ecause Article III 'requires no more than *de facto* causality,' traceability is satisfied here." *Dept. of Commerce v. New York*, 588 U.S. 752, 768 (2019) (citation omitted). The FDA's argument that the warning letters issued to Hybrid

Pharma were "advisory" in nature is insignificant to this Court's standing analysis because, as noted above, "even harms that flow *indirectly* from the action in question can be said to be 'fairly traceable' to that action for standing purposes." *Focus on the Family v. Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1273 (11th Cir. 2003) (emphasis added).

As for the third element for Article III standing, a plaintiff need not demonstrate anything "more than . . . a substantial likelihood" of redressability. *Duke Power Co.*, 438 U.S. at 79. *See also Made in the USA Found. v. United States*, 242 F.3d 1300, 1310–11 (11th Cir. 2001) (explaining that even partial relief suffices for redressability). The economic injuries here consist of the lost revenue from the canceled orders and lost business opportunities based on the alleged improperly issued warning letters. In the Amended Complaint, Hybrid Pharma does not seek relief in the form of damages for its lost revenue. If Hybrid Pharma were to prevail on its claim under the APA, it could obtain the declaratory and injunctive relief it does seek — rescission of the warning letters at issue as arbitrary or capricious. Thus, Hybrid Pharma has sufficiently alleged that the requested relief would redress Hybrid Pharma's alleged economic harm for purposes of standing. *See, e.g.*, *Union of Concerned Scientists v. Wheeler*, 377 F. Supp. 3d 34, 42 (D. Mass. 2019) (finding plaintiff sufficiently alleged redressable injury by requested declaratory relief to rescind agency directive, as required for Article III standing).

In sum, Hybrid Pharma has sufficiently alleged that it suffered an injury in fact that is concrete and particularized, actual and imminent, and fairly traceable to the conduct complained of in the Amended Complaint — the FDA's issuance of the warning letters and the agency's refusal to rescind the warning letters. Further, Hybrid Pharma has sufficiently

alleged that its injury is likely to be redressed by the declaratory and injunctive relief it seeks, *i.e.*, require the FDA to rescind the warning letters. Therefore, the Amended Complaint alleges sufficient facts to support Hybrid Pharma's claim of standing to challenge the FDA's issuance of the warning letters and refusal to rescind same. The Motion is therefore due to be denied on that basis.[1]

B. Whether Hybrid Pharma Has Stated A Plausible Claim Under The APA.

As a second basis for dismissal, the FDA argues that Hybrid Pharma does not plausibly allege an APA claim. According to the FDA, the warning letters are not "final agency action" within the meaning of the APA's judicial review provision, and the Amended Complaint fails to allege that the FDA's response to the Citizen Petition (which the FDA recognizes as the only "final agency action") was arbitrary or capricious. Mot. at 8–11. Hybrid Pharma responds that it has sufficiently alleged an APA claim. Resp. at 7–8.

The Administrative Procedure Act authorizes judicial review of "final agency action" by "a person suffering legal wrong because of [that] agency action, or adversely affected or aggrieved by [the] agency action." 5 U.S.C. §§ 702, 704. The Supreme Court has explained the interplay between Sections 702 and 704 of the APA:

> Section 702 authorizes persons injured by agency action to obtain judicial review by suing the United States or one of its agencies, officers, or employees. *See Abbott Laboratories v. Gardner*, 387 U.S. 136, 140–141, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967). It provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. We have explained that § 702 "requir[es] a litigant to show, at the outset of the case, that he is injured in fact by agency action." *Director, Office*

[1] This Court previously addressed whether Hybrid Pharma has established prudential standing. *See* ECF No. 16, at 9–12.

> *of Workers' Compensation Programs v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 127, 115 S.Ct. 1278, 131 L.Ed.2d 160 (1995). Thus, a litigant cannot bring an APA claim unless and until she suffers an injury.
>
> While § 702 equips injured parties with a cause of action, § 704 limits the agency actions that are subject to judicial review. Unless another statute makes the agency's action reviewable . . . , judicial review is available only for "final agency action." § 704. In most cases, then, a plaintiff can only challenge an action that "mark[s] the consummation of the agency's decisionmaking process" and is "one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–178, 117 S.Ct. 1154, 137 L.Ed.2d 281 (1997) (internal quotation marks omitted). Note that § 702's injury requirement and § 704's finality requirement work hand in hand: Each is a "necessary, but not by itself . . . sufficient, ground for stating a claim under the APA." *Herr*, 803 F.3d, at 819.

Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys., 603 U.S. 799, 807–08 (2024). "In this Circuit, finality is jurisdictional." *See Fla. Agency for Health Care Admin. v. Administrator for Ctrs. for Medicare & Medicaid Servs.*, 161 F.4th 765, 776 (11th Cir. 2025).

In the Amended Complaint, Hybrid Pharma alleges that, on August 23, 2023, it submitted a Citizen Petition to the FDA "requesting that [the FDA] rescind the 2018 and 2022 Warning Letters as the agency had failed to follow and even consider its own policies and procedures with regard to warning letters set forth in the Manual." Am. Compl. ¶ 37. Hybrid Pharma further alleges that the FDA "issued a final response to the Petition denying Plaintiff's Petition [and] refusing to rescind the warning letters." *Id.* ¶ 38.

In its Response, Hybrid Pharma asserts that it can seek review of the actions (*i.e.*, the 2018 and 2022 Warning Letters) leading to the agency's response to the Citizen Petition. Resp. at 7. Hybrid Pharma points out that the Citizen Petition challenged the issuance of the warning letters through rescission of same, and in response to the Citizen Petition, the FDA denied the request. *Id.*

As this Court explained in its prior Order on the Motion to Dismiss the original Complaint, a citizen petition is a procedure followed by the FDA in which any citizen can submit a request for the agency to issue, amend, or revoke any regulation or order, or take or refrain from taking any other form of administrative action. *See* 21 C.F.R. § 10.30. "[T]he FDA's response to a citizen petition would constitute final agency action." *Holistic Candlers & Consumer Ass'n v. U.S. Food & Drug Admin.*, 770 F. Supp. 2d 156, 164, n.13 (D.D.C. 2011) (citing 21 C.F.R. § 10.45(d)); *see also Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 WL 11505836, at *3 (D. Wyo. Nov. 16, 2010) ("Because the warning letters . . . indicate the FDA's intention in the future to institute enforcement action against Petitioners, this Court finds those letters do not constitute final agency action as they do not 'mark the consummation of the agency's decisionmaking process.' Had the FDA made its determination about the product at the conclusion of an enforcement action ***or in response to a citizen petition***, that determination would constitute a final agency action.") (internal citation omitted); *Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1, 6 (D.D.C. 1989) ("The Commissioner's determination on a citizen petition is final agency action subject to judicial review.").

Again, the FDA does not dispute Hybrid Pharma's contention that a response to a citizen petition constitutes final agency action. *See generally* Reply at 3–4. Rather, the FDA argues that Hybrid Pharma's APA claim is "directed at the issuance of and basis for the warning letters," and "the decision to issue a warning letter does not transform into a reviewable, final agency action simply because the FDA responds to a citizen petition." *Id.* In other words, the FDA contends that Hybrid Pharma cannot seek judicial review of the

warning letters by way of the FDA's response to the Citizen Petition. *Id.* The undersigned disagrees. The warning letters at issue are the reason why Hybrid Pharma initiated a citizen petition in the first place and subsequently filed this lawsuit under the APA after the FDA made its final determination, with respect to the issuance of the warning letters, in response to the citizen petition. Based on the facts presented in the Amended Complaint, this Court finds that the FDA's decision to refuse to rescind the warning letters, as requested by Hybrid Pharma in the citizen petition, constitutes final agency action. Therefore, Hybrid Pharma has stated a cognizable claim under the APA.

IV. CONCLUSION

Accordingly, based on the foregoing, it is

ORDERED AND ADJUDGED as follows:

1. Defendant's Motion to Dismiss **[ECF No. 20]** is **DENIED**.
2. Defendant shall file an answer to Plaintiff's Amended Complaint within **fourteen (14) days** of the date of this Order.

DONE AND ORDERED in Chambers at Fort Lauderdale, Florida, this 29th day of January, 2026.

MELISSA DAMIAN
UNITED STATES DISTRICT JUDGE

cc: Counsel of record