UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVA OCULUS PARTNERS, LLC,
f/k/a THE EYE MACHINE, LLC,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 20-cv-1174 (DLF)

MEMORANDUM OPINION

Nova Oculus brings various claims against the Food and Drug Administration (FDA) after it denied Nova Oculus's request for Breakthrough Device Designation. Before the Court is the FDA's Motion to Dismiss, Dkt 12. For the reasons that follow, the Court will grant the motion.

I. BACKGROUND

The Court takes the well-pleaded factual allegations in the Complaint, Dkt. 1, as true. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The Federal Food, Drug, and Cosmetic Act permits the FDA to grant expedited and prioritized review for certain "breakthrough" medical devices. *See* 21 U.S.C. § 360e-3. The statute provides specific criteria that a device must satisfy in order to receive breakthrough device designation. *Id.* § 360e-3(b). Nova Oculus first applied for breakthrough status on January 25, 2019. Compl. ¶ 7, Dkt. 1. Its device was the Nova Oculus III System, which was made to treat the symptoms of geographic atrophy, a "dry age-related macular degeneration that is associated with central vision loss and gradual progression without

regression." *Id.* After requesting additional information from Nova Oculus, *id.* ¶ 8, the FDA's Center for Devices and Radiological Health denied the application and explained why Nova Oculus's device failed to meet the statutory criteria. *Id.* ¶ 10. On June 4, 2019, the agency participated in a conference call with Nova Oculus to further discuss the denial. *Id.* ¶ 11. Nova Oculus then submitted a "slightly revised" application. *Id.* ¶ 12. On October 4, 2019, the agency again denied the application, explaining that Nova Oculus had not satisfied the statutory criteria. *Id.* ¶ 13. The parties then held two more conference calls, during which the agency again reiterated that Nova Oculus had not met the statutory criteria and recommended that Nova Oculus pursue a different program, the Early Feasibility Study process. *Id.* ¶ 14.

The FDA submitted a letter explaining the denial to Nova Oculus. *See* Mot. to Dismiss Ex. F, Dkt. 12-7 (sealed) ("Denial Letter").[1] The letter contained detailed scientific analyses explaining why Nova Oculus's submission did not satisfy the statutory criteria. *Id.* The FDA concluded that [redacted]

[1] Although the Court cannot consider materials outside of the pleadings when deciding a motion to dismiss, *see* Fed. R. Civ. P. 12(d), a "district court may consider a document that a complaint specifically references without converting the motion into one for summary judgment." *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1133 (D.C. Cir. 2015); *see, e.g.*, *Scott v. Dist. Hosp. Partners, L.P.*, 60 F. Supp. 3d 156, 161 (D.D.C. 2014), *aff'd*, 715 F. App'x 6 (D.C. Cir. 2018). In particular, documents "which [a]re appended to [a] motion to dismiss and whose authenticity is not disputed" can be considered at this stage if "they are referred to in the complaint and are integral" to the plaintiff's claims. *Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004). Here, while Nova Oculus specifically referenced the FDA's denial in its complaint, *see* Compl. ¶¶ 10, 13, it did not append the denial letter to its complaint. But because the denial is integral to Nova Oculus's claims that the denial violated the APA and the Constitution, *and* there is no dispute that the denial is authentic, *see generally* Pl.'s Resp., Dkt. 11, it is properly considered as part of the pleadings at this stage. *See, e.g.*, *Int'l Bhd. of Teamsters v. Atlas Air, Inc.*, 435 F. Supp. 3d 128, 135 (D.D.C. 2020); *Ward v. D.C. Dep't of Youth Rehab. Servs.*, 768 F. Supp. 2d 117, 119 (D.D.C. 2011).

[redacted] *Id.*; Mot. to Dismiss at 7 n.4 (sealed). [redacted] *See* Denial Letter at 2. [redacted]. *Id.* Further, the FDA noted several issues with the scientific literature that Nova Oculus cited. *Id.* [redacted] The letter [redacted] *Id.* at 4; Mot. to Dismiss at 2. And it concluded by informing Nova Oculus of its right to seek supervisory review of the FDA's denial decision, which Nova Oculus did not pursue. Denial Letter at 4; Mot. to Dismiss at 2; *see generally* Compl.

In a separate legal action, Nova Oculus sued the FDA under the Freedom of Information Act (FOIA). *See Nova Oculus Partners, LLC f/k/a The Eye Machine, LLC, et al. v. FDA*, No. 19-cv-2950 (D.D.C. October 1, 2019). In the course of that litigation, the FDA released an instant message chain between two Center for Devices and Radiological Health employees. Compl. ¶ 17. In that chain, one employee mentioned that a different employee in the agency thought they "should grant [Nova Oculus's application] at this point . . . as long as they fix their IFU regarding the intended population." *Id.* The employee later sent the other employee a link to an SEC press release announcing an enforcement action against Nova Oculus and asks: "did you read this?"; the other responds: "yes, i read this, leonid has lot of stories about it." *Id.* ¶ 18.

They continued: "oh" "so this is same company?"; "it seems that way. may i call you in a few mins, after i finish with gene?" *Id.* Nova Oculus does not allege that the employees discussed the SEC matter further in the instant message chain or that anyone else specifically mentioned it elsewhere. *Id.*; *see generally* Compl.

Nova Oculus now argues that, based on this instant message exchange, the FDA violated several provisions of the Administrative Procedure Act in denying its breakthrough application. It also argues that the FDA violated its constitutional right to procedural due process by not providing Nova Oculus a hearing, although it has not alleged that it requested one.

II. LEGAL STANDARDS

Rule 12(b)(6) of the Federal Rules of Civil Procedure allows a defendant to move to dismiss the complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion, a complaint must contain factual matter sufficient to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A facially plausible claim is one that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. This standard does not amount to a specific probability requirement, but it does require "more than a sheer possibility that a defendant has acted unlawfully." *Id.*; *see also Twombly*, 550 U.S. at 557 ("Factual allegations must be enough to raise a right to relief above the speculative level."). A complaint need not contain "detailed factual allegations," but alleging facts that are "merely consistent with a defendant's liability . . . stops short of the line between possibility and plausibility." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted).

Well-pleaded factual allegations are "entitled to [an] assumption of truth," *id.* at 679, and the Court construes the complaint "in favor of the plaintiff, who must be granted the benefit of

all inferences that can be derived from the facts alleged," *Hettinga v. United States*, 677 F.3d 471, 476 (D.C. Cir. 2012) (internal quotation marks omitted). The assumption of truth does not apply, however, to a "legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted). An "unadorned, the defendant-unlawfully-harmed-me accusation" is not credited; likewise, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Ultimately, "[d]etermining whether a complaint states a plausible claim for relief [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

When deciding a Rule 12(b)(6) motion, the Court may consider only the complaint itself, documents attached to the complaint, documents incorporated by reference in the complaint, and judicially noticeable materials. *EEOC v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997). A Rule 12(b)(6) dismissal "is a resolution on the merits and is ordinarily prejudicial." *Okusami v. Psychiatric Inst. of Wash., Inc.*, 959 F.2d 1062, 1066 (D.C. Cir. 1992).

III. ANALYSIS

Nova Oculus brings five claims: count I: arbitrary and capricious agency action in violation of the APA; count II: agency action in excess of statutory authority in violation of the APA; count III: nonstatutory review of ultra vires agency action; count IV: agency action without observance of procedure required by law in violation of the APA; and count V: agency action contrary to a constitutional right in violation of the APA. *See* 5 U.S. Code § 706(2).

As an initial matter, nonstatutory review of an ultra vires agency action (count III) is applicable "if a plaintiff is *unable* to bring his case predicated on either a specific or a general statutory review provision . . . ." *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1327 (D.C. Cir. 1996) (emphasis added); *see also Adamski v. McHugh*, 304 F. Supp. 3d 227, 236–37

(D.D.C. 2015). Here, Nova Oculus is able and indeed does bring its case based on specific review provisions of the APA. *See generally* Compl. Thus, the doctrine of nonstatutory review is inapposite. In any case, Nova Oculus has not pleaded sufficient facts to state a case on nonstatutory review or its four other APA claims.

On counts II, III, and IV, Nova Oculus relies on largely the same allegations for each of the claims. First, Nova Oculus asserts that the "FDA was required under 21 U.S.C. § 360e-3 to determine whether Plaintiff satisfied the statutory criteria for Breakthrough Device Designation. That criteria is clearly established in the statute." Compl. ¶ 32 (agency action in excess of statutory authority), ¶ 41 (nonstatutory review), ¶ 48 (agency action without observance of procedure required by law). Second, Nova Oculus alleges that the "FDA issued its denial of Plaintiff's application after explicitly considering as part of its analysis SEC allegations against Plaintiff, which certainly were not part of the statutory criteria for Breakthrough Device Designation." *Id.* ¶ 33 (agency action in excess of statutory authority), ¶ 42 (nonstatutory review), ¶ 49 (agency action without observance of procedure required by law). And third, Nova Oculus claims that the FDA's decision was "based on a pre-determination by FDA." *Id.* ¶ 34 (agency action in excess of statutory authority), ¶ 43 (nonstatutory review), ¶ 50 (agency action without observance of procedure required by law). These allegations are not sufficient to state a claim that the FDA violated the APA or otherwise acted outside of its lawful authority.

The statute that governs the FDA grants the agency the authority to administer the breakthrough program and sets forth the statutory criteria for administering the program. *See* 21 U.S.C. § 360e-3. It states that: "[t]he Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—(1) that provide for more effective treatment or diagnosis of life-threatening or

irreversibly debilitating human disease or conditions; and (2)(A) that represent breakthrough technologies; (B) for which no approved or cleared alternatives exist; (C) that offer significant advantages over existing approved or cleared alternatives, . . . or (D) the availability of which is in the best interest of patients." *Id.* § 360e-3(b).

Nova Oculus asserts that the FDA violated this statutory directive, and more generally acted outside of its lawful authority, because two Center for Devices and Radiological Health employees exchanged an instant message indicating they were aware of an SEC enforcement action against Nova Oculus. *See* Compl. ¶ 49. However, Nova Oculus does not allege facts indicating that the ultimate decisionmakers (or any agency employee) improperly relied on the SEC enforcement action in denying Nova Oculus's breakthrough application—only that some employees were aware that it existed. *See id.* ¶ 18.

Further, Nova Oculus does not attempt to address the FDA's asserted bases for denying its breakthrough request. The denial letter included an extensive substantive explanation for the denial, noting the problems with Nova Oculus's evidence and explaining why its application did not satisfy the statutory criteria. *See generally* Denial Letter. Yet Nova Oculus's complaint includes no factual allegations that support an inference that the FDA's extensive reasoning in the denial letter was somehow implausible or incorrect. *See generally* Compl.

Nova Oculus instead relies on *Connecticut v. Dep't of Interior*, 363 F. Supp. 3d 45, 64 (D.D.C. 2019), for the proposition that it need not rebut the reasoning the FDA provided in its Denial Letter and that it plausibly alleged that the FDA's reasoning was pretextual. *See* Pl.'s Resp. to Mot. to Dismiss at 2, Dkt. 11. However, that case does not provide support for those propositions. In *Connecticut*, the Court found that the plaintiffs had plausibly alleged improper influence over an agency decision in part because the "allegation that the Secretary suddenly

reversed course creates the plausible inference that political pressure may have caused the agency to take action it was not otherwise planning to take." 363 F. Supp. 3d at 64 (internal quotation marks and alterations omitted). *See also ATX, Inc. v. U.S. Dep't of Transp.*, 41 F.3d 1522, 1529 (D.C. Cir. 1994) ("If the decision maker were suddenly to reverse course or reach a weakly-supported determination … we might infer that pressure did influence the final decision."). There was no such reversal in this case. Indeed, the FDA was consistent throughout its denial letters and other communications with Nova Oculus. *See* Compl. ¶¶ 10–14. The *Connecticut* Court further based its decision on the "vague, cursory reasoning provided in the Secretary's return letter—the only decision-related record before the Court" which provided "the Court with no basis . . . to conclude that the decision to neither approve or deny Plaintiffs' proposed procedure amendments was based on appropriate considerations." 363 F. Supp. 3d at 65 (internal quotation marks omitted). Here, by contrast, the FDA's explanation was neither cursory nor vague. It was specific, substantive, and centered around the criteria established by the statute. *See* Denial Letter; *supra* at 2–3. In particular, the FDA's [redacted] *Id.*

Rather than explain why the stated reasons are pretextual, Nova Oculus speculates that because at least two employees were aware of the SEC enforcement action, the agency must have acted improperly. But Courts need not "accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint," *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 193 (D.C. Cir. 2006) (internal quotation marks omitted), and this theory,

without factual allegations to support it, is too speculative to state a claim. *See Twombly*, 550 U.S. at 555.

So too, on count I, Nova Oculus fails to allege sufficient facts that the FDA engaged in arbitrary and capricious agency action contrary to the APA. Nova Oculus states in conclusory fashion that the FDA's denial "(1) is not rationally connected to the evidence before FDA; (2) is based upon a clear error of judgment; and (3) has not adequately taken into account evidence that does not support" the denial. Compl. ¶ 22. But, as noted, Nova Oculus makes no attempt to explain why the FDA's reasoning was not rationally connected to the evidence Nova Oculus provided. Nor does it suggest any other evidence that FDA should have taken into account. Because "[the Court is] not bound to accept as true a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), Nova Oculus has failed to allege that the FDA acted arbitrarily and capriciously in violation of the APA.

Finally, as to count V, Nova Oculus has not stated a claim that the FDA violated its constitutional right to procedural due process. To evaluate a procedural due process claim, "[the Court] must first ask whether the asserted individual interests are encompassed within the Fourteenth Amendment's protection of life, liberty or property; if protected interests are implicated." *Ingraham v. Wright*, 430 U.S. 651, 672 (1977) (internal quotation marks omitted). "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it . . . . He must, instead, have a legitimate claim of entitlement to it." *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972).

Nova Oculus has failed to plead any facts indicating that it had a property interest in the benefit of the FDA's breakthrough program. Instead, Nova Oculus only alleges that it had a property interest in its treatment system itself. *See* Compl. ¶ 57 ("Plaintiff's ownership of the

Nova Oculus III System is a property right protected by the Due Process Clause of the Fifth Amendment to the U.S. Constitution."). But there is no allegation that the FDA deprived Nova Oculus of ownership of its own system—only that it denied the system breakthrough status. *See id.* ¶¶ 29–38. And Nova Oculus does not otherwise allege that it held a property interest in the FDA's Breakthrough Device Designation. *See id.*

In any case, Nova Oculus declined to pursue supervisory review of the FDA's decision, even when it was offered. *See* Ex. F at 4 (sealed) ([redacted]). Nor does it allege that it ever requested a hearing from the FDA. *See generally* Compl. Because Nova Oculus has not identified any process it was deprived of, it has failed to state a procedural due process claim.

CONCLUSION

For the foregoing reasons, the Motion to Dismiss is granted. A separate order consistent with this decision accompanies this memorandum opinion.

DABNEY L. FRIEDRICH
United States District Judge

Date: November 18, 2020