UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDA PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

Civil Action No. 1:22-cv-2775 (CJN)

MEMORANDUM OPINION

The Federal Food, Drug, and Cosmetic Act requires the FDA to grant or hold a hearing on new drug applications within a specified period of time. The FDA concedes that it has done neither in this case and that the deadline has passed. The agency nevertheless contends that the Court should not require it to act. The Court disagrees, and accordingly grants Vanda's motion for summary judgment in part, denies the FDA's motion for summary judgment in part, and orders the FDA to either finally resolve Vanda's application or commence a hearing by March 5, 2024.

I. Background

This case concerns the process by which the FDA approves or denies new drug applications.

1. Start with the statute. It requires that "within one hundred and eighty days after the filing of [a new drug] application . . . the Secretary shall either . . . approve the application . . . or . . . give the applicant notice of an opportunity for a hearing before the Secretary . . . on the question [of] whether such application is approvable." 21 U.S.C. § 355(c)(1). Thus, once an application has been filed, the FDA must within 180 days either approve it or let the

applicant know it can request a hearing. The same provision goes on to say that "[i]f the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree." *Id.* § 355(c)(1)(B). The applicant thus has 30 days after it gets notice of an opportunity for a hearing in which to accept; if it does so, the agency has 90 days after that 30-day period has elapsed to begin the hearing. Adding these steps together (and assuming the applicant accepts the opportunity for a hearing), the entire process from application to commencement of hearing should take no longer than 300 days.

2. The FDA has adopted regulations governing this process, which institute a different timeline. Under the regulations, when the FDA receives an application, it is not deemed "filed" until 60 days thereafter. *See* 21 C.F.R. § 314.101. Then, if the FDA "determines that [it] will not approve the application . . . in its present form," the agency will (by a date not spelled out in the regulations) "send the applicant a complete response letter." *Id.* § 314.110(a).

After receiving a "complete response letter, the applicant must" either resubmit the application after addressing any deficiencies, withdraw the application, or request an opportunity for a hearing. *Id.* § 314.110(b). But requesting an opportunity for a hearing does not trigger a hearing. Rather, such a request obligates FDA to provide notice of an opportunity for the applicant to submit a second request for a hearing: "Within 60 days of the date of the request for an opportunity for a hearing, or within a different time period to which FDA and the applicant agree, the agency will either approve the application . . . or refuse to approve the application [and] give the applicant written notice of an opportunity for a hearing." *Id.* § 314.110(b)(3). The regulations appear to permit the agency to satisfy this obligation by giving private notice to the applicant under

§ 314.200(b): "FDA will provide the notice of opportunity for a hearing to applicants . . . by delivering the notice in person or by sending it by . . . mail."

The regulations also require the FDA to provide public notice. The relevant provision states that "FDA will publish the notice in the Federal Register and will state that the applicant . . . has 30 days after the date of publication of the notice to file a written notice of participation and request for hearing." *Id.* § 314.200(a)(2). The regulations do not appear to include a deadline by which FDA must issue public notice. *See* Ex. D, Hughes Decl., ECF No. 14-4 (FDA taking this position in correspondence with Vanda). But public notice triggers the 30-day period by which the applicant must submit the second request for a hearing. *See* 21 C.F.R. §§ 314.200(a)(2), (c)(1)(i). That is important because "[i]f the Commissioner grants a hearing, it will begin within 90 days after the expiration of time for requesting the hearing." *Id.* § 314.200(g)(5).

The FDA has also adopted what it calls "summary judgment" procedures. Those procedures permit the agency to deny an applicant a hearing "if it conclusively appears . . . that there is no genuine and substantial issue of fact which precludes the refusal to approve the application." *Id.* § 314.200(g)(1).

3. This case concerns the drug Hetlioz® (tasimelteon), which the FDA approved in 2014 to treat non-24-hour sleep-wake disorder, "a condition in which an individual's circadian rhythms become misaligned with the 24-hour day." Pl.'s Mem. in Supp. of Mot. for Summ. J. at 7, ECF No. 13-1 ("Pl.'s Br."). After conducting "several clinical trials and studies to examine whether tasimelteon may be an effective treatment for Jet Lag Disorder," on October 16, 2018, Vanda filed a supplemental new drug application with the FDA for approval of the drug to be used to treat Jet Lag Disorder. *Id.* On August 16, 2019 (304 days later), FDA issued a complete response letter

stating that it would not approve the application in its present form. Ex. A, Hughes Decl., ECF No. 14-1.[1]

After unsuccessful informal attempts to change the agency's view, Pl.'s Br. at 8, Vanda eventually requested an opportunity for a hearing on July 1, 2022, Ex. B, Hughes Decl., ECF No. 14-2. On August 26, 2022 (56 days later) the FDA gave Vanda a private notice of opportunity for a hearing, but did not publish the notice in the Federal Register. Ex. C, Hughes Decl., ECF No. 14-3. Vanda accepted the private notice and requested a hearing under it. Ex. E, Hughes Decl., ECF No. 14-5.

On September 13, 2022—74 days after Vanda's request for an opportunity for a hearing—the FDA had still not published public notice, and Vanda filed this action. Compl., ECF No. 1. Vanda's complaint focused primarily on FDA's alleged failure to timely provide public notice. *See generally id.*

On October 11, 2022 (now 102 days after Vanda's request for an opportunity for a hearing), FDA published public notice in the Federal Register. Ex. F, Hughes Decl., ECF No. 14-6. Thirty days later, Vanda requested a hearing under that public notice. Ex. G, Hughes Decl., ECF No. 14-7. Ninety-eight days later, the FDA had not scheduled a hearing (or otherwise acted on Vanda's application), and Vanda filed an amended complaint adding claims regarding FDA's failure to provide a timely hearing. *See generally* Am. Compl., ECF. No. 11.

On June 12, 2023—two hundred and sixty-two days after Vanda's most recent request for a hearing—the FDA's Center for Drug Evaluation and Research (CDER) submitted a proposed

[1] The parties agree that the statutes and regulations covering new drug applications also apply to supplemental new drug applications. *See* Pl.'s Br. at 4–5; Def.'s Mem. in Supp. of Cross-Motion for Summ. J. at 2–3, ECF No. 21-1 ("Def.'s Br.").

order to the Secretary suggesting that the Secretary grant summary judgment against Vanda and thereby deny Vanda a hearing. Ex. 2, Pl's Status Rep., ECF. No. 29-2.

4. As these events were unfolding, both parties moved for summary judgment on all claims and on various grounds. Vanda seeks several forms of relief targeting different perceived defects in FDA's process. *See* Pl.'s Mot. for Summ. J., ECF No. 13. The FDA argues that some of Vanda's claims are moot and, most relevant here, that the Court should not order it to commence a hearing by a date certain.

At the January 11, 2024 oral argument on the parties' motions, FDA represented that it was anticipating that the Secretary would decide within the next six months whether to adopt CDER's proposed order and grant summary judgment against Vanda. Following oral argument, the FDA filed a status report stating that, as of January 25, 2024, it "currently anticipates" that it will issue a decision on whether to grant Vanda a hearing by April 12, 2024. ECF No. 30. The agency has not, however, stated a date by which it would commence a hearing in the event that it decides that summary judgment is not warranted.

This opinion and associated order address Vanda's claims that the Court should compel the FDA to commence a hearing.

II. Discussion

The FDA "concedes that it has not commenced the hearing here within the time required by the statute"—*i.e.*, that it "has violated the statute." Jan. 11, 2024 Hearing. It would be untenable to contend otherwise. After all, the statute requires that a hearing shall commence within 300 days after an application is filed. Vanda's application has been pending for almost 2,000 days and it has been over 500 days since Vanda made its most recent request for hearing. FDA nevertheless contends that the Court should not require it to comply with the statutory (or even regulatory) deadlines.

1. The Administrative Procedure Act directs that courts "shall . . . compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706. Relying on that provision, Vanda asks the Court to compel the FDA to commence a hearing. Both parties agree that such relief is appropriate only if warranted by the principles laid out in *Telecomm. Research and Action Ctr. [TRAC] v. F.C.C.*, 750 F.2d 70 (D.C.Cir.1984). *See* Pl.'s Br. at 31–32; Def.'s Mem. in Supp. of Cross-Motion for Summ. J. at 20, ECF No. 21-1 ("Def.'s Br.").

TRAC explained: (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).

2. The Court concludes that under those principles, the FDA's delay in this case warrants judicial intervention. Start with the first two factors. Congress has indeed provided a timetable here that the agency acknowledges it has exceeded. The FDA's arguments for why its "actions are nonetheless reasonable," Def.'s Br. at 21, are unavailing.

The agency argues that the hearing is not *that* delayed relative to the timeline contemplated in its regulations, which "provide that, if the Commissioner grants a hearing, it will begin within 120 days after the notice is published in the Federal Register." Def.'s Br. at 21. There are two

flaws with this argument. First, even if the FDA achieves the timetable it currently "anticipates," it will make a decision about whether to hold a hearing approximately 430 days after it was required to do so by the regulations. (According to FDA's current representations, that decision will be made about 550 days after public notice was published, when the regulations required action within 120 days).

Second, the FDA's regulations conflict with the tighter statutory requirements, "and a regulation contrary to a statute is void," *Orion Reserves Ltd. P'ship v. Salazar*, 553 F.3d 697, 703 (D.C. Cir. 2009). In particular, treating the date of public notice as the relevant date for analysis ignores two statutory commands. For one, FDA's focus on public notice is flawed because the clock started when the FDA gave Vanda private notice. The statute states that FDA shall either approve an application or "give the applicant notice of an opportunity for a hearing," and "[i]f the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days." 21 U.S.C. § 355(c)(1). Thus, once the agency "give[s] the applicant notice of an opportunity for a hearing," the clock starts (assuming the applicant accepts). And here, when FDA gave Vanda private notice, it "g[a]ve the applicant notice of an opportunity for a hearing" and therefore started the clock. FDA cannot avoid that result by issuing regulations that tie the timeline for a hearing to only a second form of notice (that itself has no deadline). The 120-day clock for a hearing thus began on August 26, 2022 and the agency is on track to miss its deadline by about 480 days (not just 430 days).

More fundamentally, substantial delays preceded either form of notice. Congress expressly required that "within one hundred and eighty days after the filing of an application . . . the Secretary shall either . . . approve the application . . . or . . . give the applicant notice of an

opportunity for a hearing before the Secretary . . . on the question [of] whether such application is approvable." 21 U.S.C. § 355(c)(1). But here the FDA issued no notice until 1,400 days after Vanda submitted its application. Taking that initial period of time into account, the FDA's contention that it has engaged in only a modest delay seems all the more tenuous.[2]

The agency also contends that injunctive relief is not warranted here because, under its regulations, Vanda delayed by not requesting a hearing after the FDA issued its complete response letter. Def.'s Br. at 22. But the statute requires the agency to either approve the application or provide notice of an opportunity for a hearing within 180 days. Here, in contrast, it took the FDA 304 days after Vanda's submission (or 242 days after the application was "filed" under the regulations, which institute a 60-day delay before a submission is deemed filed) to issue a complete response letter.

The FDA also argues that it was impracticable to commence a hearing on the statutorily mandated schedule because Vanda's submission in support of its hearing request was voluminous, totaling "nearly 14,000 pages." Def.'s Br. at 21–22. But it appears that Vanda submitted a merely 77-page substantive brief and included the full text of referenced articles and declarations in its submission—one of FDA's own declarations itself describes Vanda's filing as a "77-page submission." Stein Decl. ¶ 14, ECF No. 21-2. Moreover, much of the delay in this case seems to

[2] Of course, the statutory hearing deadline is not directly predicated on the date of filing. Rather, the hearing deadline is based on the date notice was issued and the date by which notice must be issued is tied to the date of filing. For the purposes of *TRAC* analysis, the Court's discussion treats the agency's delays holistically. For one, doing so makes sense when assessing the reasonableness of the delay and whether judicial intervention is warranted. For another, the agency itself points to Vanda's conduct before notice to justify the FDA's delay. *See* Def.'s Br. at 22. In any event, even if the Court were to ignore everything that came before notice and consider only the delay between notice and the commencement of a hearing, FDA's delay is substantial, and the Court's analysis would remain the same.

stem from the FDA's own staffing, resource, and procedural choices, not the complexity of Vanda's filings alone. *See infra* p. 10.

3. FDA's arguments on the third, fourth, and fifth *TRAC* factors focus heavily on *In re Barr Labs, Inc.*, 930 F.2d 72 (D.C. Cir. 1991). *See* Def.'s Br. at 23–26. In that case, the Court of Appeals concluded that despite the FDA's failure to comply with a 180-day deadline for processing generic drug applications, no action was warranted because an order putting the plaintiff "at the head of the queue [would] simply move[] all others back one space and produce[] no net gain." 930 F.2d at 75.

Here, in contrast, there is no evidence that Vanda is attempting to jump a long queue. Including the application at issue here, the FDA issued only four notices of an opportunity for a hearing in the five years preceding summary judgment briefing in this case. *See* Stein Decl. ¶ 9. And the FDA has not presented any evidence identifying any other delinquent hearing on a new drug application currently scheduled ahead of Vanda's that would be pushed back if the Court ordered FDA to promptly commence a hearing on Vanda's application. To the contrary, there is no single decisionmaker that adjudicates all hearings. The agency appoints different presiding officers for different hearings, making any tradeoff between Vanda's and another hearing even less likely. *See* Linowes Decl. ¶ 16, ECF No. 21-3.

Moreover, any potential burdens on the FDA that swiftly commencing a hearing might trigger have only dissipated over time. One of the FDA's declarations (submitted in March of 2023) repeatedly emphasized that it is "the lack of a proposed order" by the agency sub-component and lack of "response by Vanda" that would make commencing a hearing promptly "particularly difficult." Linowes Decl. ¶¶ 14, 15, 16. The proposed order and Vanda's response have now been on the books for months.

Overall, there appears to be real play in the joints. At oral argument, the FDA told the Court that the "agency's determination" that it needed six more months based on "the agency's weighing of . . . priorities" "should be dispositive." Jan. 11, 2024 Hearing. Yet after oral argument, the agency found the ability to cut about three months from that previously required timeframe. *See* Def.'s Jan. 24, 2024 Status Rep.

That is not surprising because at least some of the FDA's delay stems from the agency's extra-statutory choices. For instance, the FDA has chosen to engage in a lengthy summary judgment process (not present in *Barr*) before determining whether to move to a hearing. In fact, FDA has spent more than fourteen months evaluating whether to grant summary judgment against Vanda. The agency could shorten[3] or forego that step and provide hearings more promptly.

The Court has no desire to superintend FDA's process. But where Congress has codified deadlines that the agency claims it cannot meet because of steps it has added to the process, it is fair to question whether the agency's hands really are tied.

Another difference between this case and *Barr* is that *Barr* was decided in the context of an FDA "personnel crisis that began in the summer of 1988." *Barr*, 930 F.2d. at 74. Congress has since "ameliorated" "the funding drought" to which *Barr* pointed. *Sandoz, Inc. v. Leavitt*, 427 F. Supp. 2d. 29, 40 (D.D.C. 2006). Indeed, potentially "responding to the D.C. Circuit's suggestion" in *Barr* "that 'perhaps Congress should earmark more funds'" to allow the FDA to act more

[3] Even if the agency were to maintain such a summary judgment procedure (assuming doing so is statutorily permissible), it is not required to utilize layers of review that bog down the process. Here for example, FDA did not simply review Vanda's filings and issue a summary judgment decision in one shot. Instead, CDER spent the better part of a year issuing a proposed order suggesting that the Commissioner issue summary judgment against Vanda. The agency then told the Court that it needs another year from the issuance of that proposed order before it can decide whether to accept or reject that proposed order. Cutting down on these layers of review (which, again, were not present in *Barr*) could speed the process up.

quickly, Congress "create[ed] the [(Prescription Drug User Fee Act)] as a mechanism for making additional funds available for . . . the review of human drug applications." *Id.* (cleaned up). Through that Act, Congress authorized the FDA to charge a fee to those who submit a new drug application, which the agency can dedicate to deciding applications like Vanda's. For example, in Fiscal Year 2024, an applicant must pay the FDA more than $4,000,000 to review its application. Prescription Drug User Fee Rates for FY 2024, 88 Fed. Reg. 48,881, 48,887 (2023). The FDA set that fee in part based on its assessment of its needs for "strategic hiring and retention" and "the resource capacity needs for the process for the review of human drug applications." *Id.* at 48,882. At the very least, the FDA does not appear to be suffering under the same types of staffing and budgetary problems that the Court of Appeals highlighted in *Barr*.

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In sum, the Court decides that the *TRAC* factors favor ordering the FDA to promptly commence a hearing in this case.[4]

III. Conclusion

For these reasons, Vanda's Motion for Summary Judgment is GRANTED in part and the FDA's Cross Motion for Summary Judgment is DENIED in part. An order will issue contemporaneously with this opinion compelling the agency to either finally resolve Vanda's application or commence a hearing on or before March 5, 2024.

DATE: January 26, 2024

CARL J. NICHOLS
United States District Judge

[4] Because the Court will issue relief under the APA, it need not address Vanda's request for similar relief under the Mandamus Act. *See Ashtari v. Pompeo*, 496 F. Supp. 3d 462, 471 (D.D.C. 2020).