UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDA PHARMACEUTICALS, INC. **Plaintiff,** **v.** **FOOD AND DRUG ADMINISTRATION, et al.** **Defendants.**	**Civil Action No. 19-301 (JDB)**

MEMORANDUM OPINION & ORDER

Vanda Pharmaceuticals, Inc., ("Vanda") wants to conduct a 52-week clinical trial of the drug tradipitant as a treatment for gastroparesis, a serious, chronic digestive disorder. The Food and Drug Administration ("FDA") imposed a partial clinical hold that prevents Vanda from continuing the clinical trial beyond 90 days until Vanda conducts additional chronic toxicity studies in animals. Vanda filed suit against FDA under the Administrative Procedure Act, alleging that FDA's clinical hold was arbitrary and capricious and contrary to law because FDA failed to address substantial scientific evidence Vanda submitted and because FDA relied on a non-binding guidance document as if it imposed regulatory requirements. Compl. [ECF No. 1] ¶¶ 1–26.

A week after the summons issued, FDA moved for a voluntary remand of its decision and a stay of the case for 75 days to reevaluate its position in light of the procedural issues that Vanda raised in its complaint. Mem. in Supp. of Defs.' Mot. for a Voluntary Remand to the Agency & for a Stay of the Case ("FDA Remand Mot.") [ECF No. 6-1] at 1. FDA also requested that the case be remanded without vacatur of the clinical hold to protect patient safety during the period of reconsideration. Id. at 7. Vanda does not oppose FDA's request for a voluntary remand or stay,

but Vanda insists that vacatur of the clinical hold is appropriate because the "FDA's motion effectively admits that the partial clinical hold . . . has no legal basis." Pl.'s Partial Opp'n to Defs.' Mot. ("Vanda Opp'n") [ECF No. 7] at 1. Vanda also argues that the agency should be given 30 days, not 75 days, to reconsider its position. Id. at 2.*

Upon consideration of the parties' filings addressing FDA's motion for voluntary remand, as well as relevant case authority and the entire record, the Court grants FDA's motion for voluntary remand without vacatur and stays the case up to and including April 28, 2019.

I. Voluntary Remand Is Appropriate

Out of respect for administrative agencies' "inherent power to reconsider their own decisions," courts in this Circuit "commonly grant motions to remand an administrative record to allow an agency to consider new evidence" or otherwise "cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete." Sierra Club v. Van Antwerp, 560 F. Supp. 2d 21, 23 (D.D.C. 2008) (quoting Prieto v. United States, 655 F. Supp. 1187, 1191 (D.D.C. 1987); Ethyl Corp. v. Browner, 989 F.2d 522, 524 (D.C. Cir. 1993)). Voluntary remand is appropriate so long as "an agency's concern is substantial and legitimate" rather than "frivolous or in bad faith." Id. at 23–24 (comparing Citizens Against Pellissippi Parkway Extension, Inc. v. Mineta, 375 F.3d 412, 417 (6th Cir. 2004), and Lutheran Church–Mo. Synod v. FCC, 141 F.3d 344, 349 (D.C. Cir. 1998)).

The Court agrees with both parties that a voluntary remand to the agency is appropriate. FDA has identified "substantial and legitimate concerns" related to the completeness and accuracy

* Additionally, Vanda moves for leave to file a surreply and, in the alternative, requests oral argument. Pl.'s Mot. for Leave to File Surreply & for Oral Arg. ("Mot. for Leave to File") [ECF No. 9] at 1. FDA objects. Defs.' Opp'n to Mot. for Leave to File ("Opp'n to Mot. for Leave to File") [ECF No. 10] at 1. Because Vanda's proposed surreply neither addresses issues newly raised in FDA's reply nor would assist the Court in its determination of FDA's motion, leave to file a surreply is denied. See Banner Health v. Sebelius, 905 F. Supp. 2d 174, 187 (D.D.C. 2012). The Court also declines Vanda's request for oral argument. See Fed. R. Civ. P. 27(e).

of the agency's explanation for the clinical hold, and there is no reason to believe that FDA's request for a voluntary remand is frivolous or in bad faith. A voluntary remand will allow FDA to cure its mistakes and will avoid wasting the Court's and the parties' resources reviewing a record that FDA acknowledges to be incomplete. Hence, FDA's request for voluntary remand is granted.

II. Vacatur Is Not Appropriate

The Court declines to vacate the partial clinical hold. As a threshold matter, the Court has reason to question whether it has authority to vacate an agency action before issue has been joined, without an administrative record, and in the absence of a request for emergency relief such as a temporary restraining order. See Carpenters Indus. Council v. Salazar, 734 F. Supp. 2d 126, 135–36 (D.D.C. 2010) (concluding that the Court lacked authority to vacate an agency decision without conducting an independent determination on the merits). FDA's filings do not concede that the clinical hold order is invalid, only that the agency intends to reevaluate its decision. FDA Remand Mot. at 5–7. Thus, no grounds for vacating the clinical hold are currently before the Court.

Even if the Court could vacate the partial clinical hold, it would not do so. Under the factors set out in Allied-Signal, courts assessing remand with or without vacatur are to consider "the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n, 988 F.2d 146, 150–51 (D.C. Cir. 1993); see also Heartland Regional Med. Ctr. v. Sebellius, 566 F.3d 193 (D.C. Cir. 2009) (analyzing Allied-Signal factors). The first prong of this analysis "deals with the likelihood that a rule's deficiencies can be redressed on remand, 'even if the agency reaches the same result.'" Am. Forest Res. Council v. Ashe, 946 F. Supp. 2d 1, 44 (D.D.C. 2013); see also U.S. Sugar Corp. v. EPA, 830 F.3d 579, 630 (2016) (describing factor as simply likelihood of "cure on remand"). Here, the

procedural defects that Vanda alleges in its complaint are likely to be corrected on remand, even if FDA keeps the clinical hold in place. And as noted above, the clinical hold has not been pronounced deficient, so its deficiency does not weigh in favor of vacatur.

The second Allied-Signal factor considers the practical impact of vacatur, including whether remand with vacatur "may have unpredictable and irreversible consequences" and whether remand without vacatur will "unduly prejudice[]" any party. Id. at 46. Here, Vanda is not prejudiced because it will receive part of the relief that it seeks—reevaluation of the partial clinical hold—in a much shorter time than it would following review of the order on the merits. See Compl. at 55 (asking in part that FDA reevaluate Vanda's proposed 52-week trial under the proper regulatory factors). The fact that risks to patient safety from a clinical trial could be "unpredictable and irreversible" further supports remand without vacatur. See Am. Forest Res. Council, 946 F. Supp. 2d at 44. Both Allied-Signal factors, then, support remand without vacatur, and hence, assuming that the Court has authority to vacate the rule at this juncture, it nevertheless would conclude under Allied-Signal that vacatur is inappropriate.

As to timing, FDA stated in its initial filing on February 14, 2019, that it seeks remand for 75 days and added in its reply that FDA has "already has begun the process of reevaluating the scientific submissions and addressing the issues acknowledged in the remand motion." Reply in Supp. of FDA Remand Mot. at 10. Vanda argues that a stay should last no more than 30 days, which is the amount of time that FDA would normally have to consider "an entirely new IND application." Vanda Opp'n at 24. A compromise is appropriate here. The Court will stay the case for 45 days from the date of this order—up to and including April 28, 2019—which happens to equal approximately 75 days from the date that FDA filed its motion for a voluntary remand.

CONCLUSION

Upon consideration of [6] FDA's motion for a voluntary remand without vacatur and stay of the case, [9] Vanda's motion for leave to file a surreply, the parties' filings in support of and in opposition to each motion, and the entire record herein, and for the reasons given above, it is hereby

ORDERED that [9] Vanda's motion for leave to file a surreply is DENIED; it is further

ORDERED that [6] FDA's motion for a voluntary remand without vacatur is GRANTED; it is further

ORDERED that the FDA's partial clinical hold order is REMANDED to the agency for further consideration; it is further

ORDERED that this case is STAYED pending FDA's reevaluation of its partial clinical hold order, up to and including April 28, 2019; and it is further

ORDERED that the parties shall file, jointly if possible, a status report by not later than April 29, 2019, which shall propose a schedule for further proceedings in this case.

SO ORDERED.

/s/
JOHN D. BATES
United States District Judge

Dated: March 14, 2019