UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GENUS LIFESCIENCES, INC., Plaintiff, v. **ALEX M. AZAR II**, et al., Defendants, **LANNETT CO., INC.**, Intervenor-Defendant.	Case No. 1:20-cv-00211 (TNM)

MEMORANDUM ORDER

The Court granted partial summary judgment to Plaintiff Genus Lifesciences, Inc. ("Genus") on Count III of its Complaint and deferred ruling on Counts I and II. *See* Order, ECF No. 64. At a telephonic status conference, the Court ordered the parties to brief the appropriate remedy for Count III and scheduled briefing on motions for reconsideration proposed by the Federal Defendants ("FDA") and Intervenor-Defendant Lannett Company, Inc. ("Lannett"). *See* Docket Entry dated October 7, 2020. Now ripe are Motions for Reconsideration filed by FDA and Lannett (collectively, the "Defendants"), Genus's Motion to Vacate FDA's approval of Lannett's drug product Numbrino, and Genus's Motion to Supplement the Record.

I.

First up is Genus's Motion to Complete the Administrative Record. Genus seeks to add documents obtained in a related FOIA action. *See Latham & Watkins LLP v. FDA*, No. 1:20-cv-0509-TNM (D.D.C.). Specifically, Genus requests that the Court order FDA to add to the administrative record 33 pages of email communications that Genus claims are relevant to

FDA's approval of Numbrino and should have appeared in the record that FDA compiled. *See* Pl. Genus Lifesciences, Inc.'s Mot. to Compete the Admin. R. ("Genus Record Br.") at 8, ECF No. 54.[1] Genus also asks the Court to review *in camera* unredacted versions of the documents to determine whether the redactions were proper. *Id.* at 28. FDA counters that Genus has failed to rebut the strong presumption that the record was complete, and it contends that the documents contain information that is immaterial or cumulative of material that appears elsewhere in the record. *See* Federal Defs.' Resp. in Opp'n to Pl. Genus Lifesciences, Inc.'s Mot. to Complete the Admin. R. ("FDA Record Br.") at 12–22, ECF No. 58. FDA also maintains that *in camera* review would be unnecessary and inappropriate. *Id.* at 22–25.

To be sure, the record produced by an agency in an APA challenge "is entitled to a strong presumption of regularity." *Univ. of Colorado Health at Mem'l Hosp. v. Burwell*, 151 F. Supp. 3d 1, 13 (D.D.C. 2015). So "a plaintiff must do more than simply assert that [missing] materials were relevant or were before an agency when it made its decision," as it "must identify reasonable, non-speculative grounds for its belief that the [missing] documents were considered by the agency." *Id.* (cleaned up). What the agency "considered" extends to "all information it considered either directly or indirectly." *Stand Up for California! v. U.S. Dep't of Interior*, 315 F. Supp. 3d 289, 293 (D.D.C. 2018). "The goal, ultimately, is for the Court to have before it a record that delineates the path by which the agency reached its decision." *Standing Rock Sioux Tribe v. U.S. Army Corps of Engineers*, No. CV 16-1534 (JEB), 2019 WL 2028709, at *2 (D.D.C. May 8, 2019) (cleaned up). So the complete record should cover "any document that might have influenced the agency's decision and not merely those documents the agency expressly relied on in reaching its final determination." *Id.* (cleaned up).

[1] All page citations refer to the pagination generated by the Court's CM/ECF system.

Genus has met its burden. It does not rely on pure conjecture, as it seeks to add 33 specific pages out of the thousands of pages obtained in the FOIA action. *See* Genus Record Br. at 8; *cf. Stand Up for California!*, 315 F. Supp. 3d at 295 (rejecting motion to supplement the record that relied on "speculation that other documents may exist"). Genus also distinguishes three categories of documents, sufficiently explaining the import of each and how the communications played a role in FDA's decision. *See id.* at 15–28. In so finding, the Court does not necessarily adopt Genus's interpretation of every communication in every document; FDA is free to contest and contextualize the contents in future briefing. But Genus has made a reasonable, non-speculative showing that the documents were *considered* by FDA yet not included in the record. *See id*.

The documents mainly contain communications among relevant FDA personnel. While internal email communications about FDA application timelines would typically fall outside an administrative record, the relative timelines of these drug applications had outsized implications and are critical to resolving the unique claims in this case. More, when the documents include "deliberative" communications unsuitable for an administrative record, FDA has already had a chance to redact those portions. *See Stand Up for California!*, 315 F. Supp. 3d at 293 (noting that intra-agency deliberative documents are usually privileged). The unredacted portions at the very least clarify when FDA officials were confronting decisions about Lannett's application that Genus now challenges. And they help "delineate[] the path by which the agency reached its decision." *Standing Rock Sioux Tribe*, 2019 WL 2028709, at *2. FDA should supplement the record with the 33 pages that Genus attached to its motion. *See* Genus Record Br. at Exs. A, B, and C, ECF Nos. 54-2, 54-3, 54-4.

As for *in camera* review, the Court does not find it necessary now to review any of the redacted material. *See DeFraia v. CIA*, 311 F. Supp. 3d 42, 50 (D.D.C. 2018) ("the mere possibility of" erroneous redaction "does not warrant *in camera* review").

II.

Next up are the Motions for Reconsideration. FDA and Lannett both seek reconsideration of the Court's decision under Federal Rule of Civil Procedure 54(b). *See* Intervenor-Def. Lannett Co., Inc.'s Mot. for Recons. and Opp'n to Mot. for Vacatur ("Lannett Mot.") at 6, ECF No. 67; Federal Defs.' Mem in Support of their Mot. for Recons. and in Opp'n to Pl.'s Mot. to Vacate ("FDA (Mot.") at 7, ECF No. 70-1. Courts may grant reconsideration "as justice requires," considering "whether the court 'patently' misunderstood a party, made a decision beyond the adversarial issues presented to the court, made an error in failing to consider controlling decisions or data, or whether a controlling or significant change in the law or facts has occurred since the submission of the issue to the Court." *Youssef v. Holder*, 62 F. Supp. 3d 96, 98 (D.D.C. 2014) (citation omitted). This is a discretionary matter. The Court may reverse course even if the appropriate legal standard is unmet but "there are other good reasons for doing so." *Id.* at 99.

The Defendants suggest that the Court's ruling went beyond the adversarial issues presented when it concluded that FDA erred by not requiring Lannett to submit a patent certification with its drug application and not considering the associated timelines for approval. *See* Lannett Mot. at 6; FDA Mot. at 7; *see also Genus Lifesciences, Inc. v. Azar*, No. 1:20-CV-00211 (TNM), 2020 WL 5530218, at *10–13 (D.D.C. Sept. 15, 2020). Even if this were true, the Court had requested supplemental briefing on this point. It ordered the parties to address "whether Romanette ii requires the FDA to approve Lannett's application within the timeframes

prescribed in 21 U.S.C. § 355(c)(3)." Order at 5–6, ECF No. 53. That obligation stems from the timelines applicable to Section 505(b) applications with patent certifications. So that inquiry included the question of if Lannett's application did have or should have had a patent certification. Lannett recognized as much, explaining in its supplemental brief why it believed that Lannett did not have to submit a patent certification. *See* Intervenor-Def. Lannett Company, Inc.'s Supplemental Br. in Support of Cross-Motion for Summary Judgment at 4, ECF No. 55. FDA's brief focused instead on the ramifications of Lannett's application not containing a certification. *See* Federal Defs.' Supplemental Br. at 5, ECF No. 56. The Defendants may now wish that they had made more "fulsome" arguments on whether a patent certification was required, *see* Lannett Mot. at 6, but this was not for lack of opportunity.[2]

In any event, the Defendants' latest motions do not sway the Court. The plain text of the statute states that every Section 505(b)(2) application "shall also include" a patent certification. 21 U.S.C. § 355(b)(2)(A). FDA's regulations emanating from this statute confirm that the certification is mandatory. *See* 21 C.F.R. § 314.50(i)(1) ("A 505(b)(2) application is required to contain the following: . . . "). An applicant who believes that there are no relevant patents must submit a certification with specific language to that effect. *See* § 314.50(i)(1)(ii). FDA's novel arguments to the contrary require the Court to interpret the word "drug" as meaning a "drug product" and not also a "drug substance," and that the statute meant to refer only to a "listed drug"—that is, a drug product already approved by FDA and appearing in its "Orange Book."

[2] The Court's Order requesting supplemental briefing granted the parties "no more than 10 pages per brief." Mem. Order at 5, ECF No. 53. FDA and Lannett each submitted fewer than seven full pages.

FDA Mot. at 8–14; Lannett Mot. at 6–7. Of course, Congress did not use those words. *See* 21 U.S.C. § 355(b)(2).

More, this interpretation is still at odds with the most relevant portions of FDA's own regulations. Section 314.50(i) directs applicants to submit certifications for "the drug substance or drug product" that were the subject of investigations relied on by the applicant. And it states without qualification that when the applicant believes that "there are no patents described in paragraph (i)(1)," an application must contain a "no relevant patents" certification.[3] 21 C.F.R. § 314.50(i)(1)(ii). The Court does not regret its conclusion that "FDA takes a position so clearly in opposition to its regulations," and that FDA erred. *Genus Lifesciences*, 2020 WL 5530218, at *11.

The Defendants also assert that the Court should reconsider its ruling on Count III because any error by FDA was harmless. Lannett Mot. at 5; FDA Mot. at 9–10. The Administrative Procedure Act directs reviewing courts to take "due account . . . of the rule of prejudicial error." 5 U.S.C. § 706; *see PDK Labs. Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("In administrative law, as in federal civil and criminal litigation, there is a harmless error rule."). The error here was no mere technicality—like a "wrong citation or clerical error" that could not have affected the outcome of the agency decision. *PAM Squared At Texarkana, LLC v. Azar*, 436 F. Supp. 3d 52, 59 (D.D.C. 2020) (noting the "fine line between 'harmless error' and 'arbitrary and capricious'"). Lannett neglected to submit a patent certification, and FDA

[3] Lannett wonders why an FDA reviewer even had the option of checking a box marked "No patent certifications are required" in FDA's 505(b)(2) assessment of Lannett's application, if such a certification is mandatory. *See* Intervenor-Def. Lannett Co., Inc.'s Reply in Support of Mot. for Recons. at 10, ECF No. 74. So does the Court. But the Court again notes that it is the only option on FDA's form that fails to cite to any statutory or regulatory basis. *See* J.A. 1787–88. The unchecked "No relevant patents" option cites 21 C.F.R. § 314.50(i)(1)(ii).

could have rejected the application on that basis. FDA's failure to require a certification and consider the associated timelines rested not on an accident but on an apparent mistaken interpretation of the governing statute and regulations. And mistaken *analysis* crosses the border into arbitrary and capricious territory. *Id.* Nor is it clear to the Court precisely how FDA would have handled the situation had it realized then that Lannett's application was deficient in this way. *Cf. Combat Veterans for Cong. Political Action Comm. v. Fed. Election Comm'n*, 795 F.3d 151, 156 (D.C. Cir. 2015) (harmless error where plaintiffs "failed to show any likelihood that any material [agency] action or decision would have been different"). FDA's error was not so minor and the outcome so clear as to justify now waiving it away as no practical error at all.

III.

The proper remedy is a different question. Genus urges vacatur of FDA's approval of Numbrino. *See* Pl. Genus Lifesciences, Inc.'s Mot. to Vacate ("Genus Mot.") at 5–14, ECF No. 66. When an agency action was arbitrary and capricious, the court ordinarily should "hold unlawful and set aside [the] agency action." 5 U.S.C. § 706(2)(A). But despite Genus's doubts about the legality of a court remanding to an agency *without* vacatur, *see* Genus Mot. at 6–7, under binding circuit precedent the Court must consider it, *see Allied-Signal, Inc. v. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993); *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 518–19 (D.C. Cir. 2020). The Court will examine "first, the seriousness of the [agency action's] deficiencies, and, second, the likely disruptive consequences of vacatur." *Am. Great Lakes Ports Ass'n*, 962 F.3d at 518 (cleaned up).

The first prong concerns "the likelihood that 'deficiencies' in an [agency action] can be redressed on remand, even if the agency reaches the same result." *Black Oak Energy, LLC v. F.E.R.C.*, 725 F.3d 230, 244 (D.C. Cir. 2013) (cleaned up); *see also United States Sugar Corp. v.*

Envtl. Prot. Agency, 830 F.3d 579, 630 (D.C. Cir. 2016) (characterizing factor as "likelihood of cure on remand"). So this inquiry differs from the Court's retrospective assessment that FDA's flawed analysis did not amount to harmless error. *See supra* at 6–7.

Genus contends that FDA cannot cure the procedural defects on remand without violating its regulations, and that Lannett will have to submit a new application. *See* Genus Mot. at 7. That is far from clear. Genus relies on several provisions that address ancillary matters, but none speak directly to the issue. In contrast, FDA credibly asserts that it could cure the procedural defects and confirm its decision to approve Lannett's application, and it suggests possible options on remand. *See* FDA Mot. at 16–17. The Court will not prejudge FDA's choices before its personnel make them; the agency must take the first pass at interpreting and applying its regulations. *See Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 545–46 (1978). But the Court believes that FDA can likely cure the deficiencies on remand. *Cf. Allied-Signal*, 988 F.2d at 151 (remanding without vacatur where there was "at least a serious possibility that the Commission will be able to substantiate its decision on remand").

The Court also considers the disruptive consequences of vacatur. "[A] quintessential disruptive consequence arises when an agency cannot easily unravel a past transaction in order to impose a new outcome." *Am. Great Lakes Ports Ass'n*, 962 F.3d at 519. Here vacatur would dissolve FDA's approval of Numbrino, meaning Lannett would have to pull the drug from the market until at least 2022. Lannett Mot. at 12–13. Genus does not dispute these facts but suggests that any harm would be "economic harm" restricted to Lannett. *See* Pl. Genus Lifesciences, Inc.'s Opp'n to Defs.' and Intervenor-Def.'s Mots. for Recons. and Reply in Support of Mot. to Vacate at 25, ECF No. 72. Not so, as it would also affect the consumers and healthcare providers who rely on Numbrino for medical treatment. *See* Lannett Mot. at 12–13.

Nor would remand without vacatur frustrate the objectives of the Federal Food, Drug, and Cosmetic Act. To be sure, courts must be wary of an easier-to-seek-forgiveness attitude toward required regulations. *See Standing Rock Sioux Tribe v. U.S. Army Corps of Engineers*, No. 20-5197, 2021 WL 244862, at *12 (D.C. Cir. Jan. 26, 2021) (expressing concern over incentivizing agencies to purposefully skip "fundamental procedural steps," undertaking them on remand only if challenged). But there is no hint of bad faith here on the missing certification. There is no suggestion, for example, that Lannett or FDA tried to game the system by not, respectively, filing and requiring a patent certification stating that there were no applicable patents. And while the byzantine statutory and agency provisions require the certification, no one would characterize the omitted procedural step as "fundamental." *See id.* (analogizing to entirely "bypass[ing] required notice and comment rulemaking"). Remand without vacatur has been characterized as an "exceptional remedy" by many courts who have ordered it, *see, e.g.*, *Am. Great Lakes Ports Ass'n*, 962 F.3d at 519, but the Court finds it appropriate here.

The Court, however, does not ignore Genus's understandable concerns over the prejudice that remand without vacatur on Count III could pose. *See* Genus Mot. at 13–14. If FDA is in fact unable to cure the defects on remand, and vacatur of Lannett's approval is necessary, Genus would be prejudiced for every day of market exclusivity lost. Counts I and II also remain pending. So while the Court presumes FDA will act expeditiously, it will ensure that this is so by imposing a 60-day deadline. If in that time FDA fails to cure the deficiencies and justify why Numbrino's approval is proper, the Court will vacate the prior approval. *Cf. A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (staying vacatur for 90 days while on remand with FDA); *NAACP v. Trump*, 298 F. Supp. 3d 209, 245 (D.D.C. 2018) (staying vacatur for 90 days pending agency action on remand).

IV.

Therefore, it is hereby

ORDERED that Plaintiff Genus Lifesciences, Inc.'s [54] Motion to Complete the Administrative Record is hereby GRANTED. On or before February 27, 2021, FDA shall file an amended administrative record in conformity with this order; it is further

ORDERED that Intervenor-Defendant Lannett Co., Inc.'s [67] Motion for Reconsideration is DENIED; it is further

ORDERED that Federal Defendants' [70] Motion for Reconsideration is DENIED; it is further

ORDERED that Plaintiff Genus Lifesciences, Inc.'s [66] Motion to Vacate is GRANTED. FDA's approval of Intervenor-Defendant Lannett Company, Inc.'s drug product Numbrino is VACATED; it is further

ORDERED that the vacatur of Numbrino's approval is STAYED 60 days for FDA to reconsider Lannett's application and take actions it deems necessary based on the Court's ruling that every Section 505(b)(2) application must include a patent certification; it is further

ORDERED that the matter is REMANDED to FDA for further action consistent with this Order and the Court's [63] Memorandum Opinion dated September 15, 2020; and it is further

ORDERED that on or before March 19, 2021, FDA shall submit a status report informing the Court of the actions taken by the agency to comply with this Order.

SO ORDERED.

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Dated: January 27, 2021

TREVOR N. McFADDEN, U.S.D.J.