UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MELINTA THERAPEUTICS, LLC, *et. al*,	:		
	:		
Plaintiffs,	:	Civil Action No.:	22-2190 (RC)
	:		
v.	:	Re Document No.:	5, 6
	:		
U.S. FOOD & DRUG ADMINISTRATION, *et. al*,	:		
	:		
Defendants,	:		
	:		
	:		
NEXUS PHARMACEUTICALS, INC.,	:		
	:		
Intervenor-Defendant.	:		

MEMORANDUM OPINION

GRANTING PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION, AS CONSOLIDATED WITH THE MERITS; GRANTING PLAINTIFFS' MOTION FOR LEAVE TO FILE DOCUMENT UNDER SEAL

I. INTRODUCTION

Plaintiffs Melinta Therapeutics, LLC and its wholly owned subsidiary Rempex Pharmaceuticals, Inc. (collectively, "Melinta") have moved for a temporary restraining order and preliminary injunction, asking the Court to set aside or suspend the Food and Drug Administration's ("FDA") approval of an Abbreviated New Drug Application ("ANDA") for a generic version of the drug Minocin, which treats certain bacterial infections. Compl. ¶¶ 1–2, 12–14, ECF No. 1. Nexus Pharmaceuticals, Inc. ("Nexus"), the generic drug manufacturer, moved to intervene on July 27, 2022. Federal Defendants[1] and Nexus each filed an opposition

[1] Federal Defendants are FDA, the Department of Health and Human Services ("HHS"), Robert M. Califf in his official capacity as Commission of FDA, and Xavier Becerra in his official capacity as Secretary of HHS.

on August 3, 2022. Melinta filed a reply on August 4, 2022. Federal Defendants and Nexus each filed surreplies at the Court's invitation on August 12, 2022, and the Court held a hearing on September 15, 2022. In response to the Court's request, Melinta and Federal Defendants have agreed to collapse the motion for a temporary restraining order and preliminary injunction into consideration on the merits under Fed. R. Civ. P. 56.[2] *See* Joint Notification at 1. Accordingly, the Court treats this as a motion for summary judgment, which it grants for Melinta.

II. BACKGROUND

A. Statutory and Regulatory Framework

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), drug manufacturers must obtain approval from FDA before marketing a new drug by demonstrating the safety and effectiveness of their products for their intended use. 21 U.S.C. § 355(a). An innovator drug manufacturer seeking FDA approval submits a "New Drug Application," or "NDA," which

[2] Pursuant to Fed. R. Civ. P. 65(a)(2), the Court notified the parties of its intent to advance to the merits and requested objections during a hearing and in a subsequent minute order on September 15, 2022. On September 22, 2022, the parties jointly filed notification that Federal Defendants and Melinta agreed to advance to the merits, but that Nexus did not agree due to "potential additional genuine disputes of fact." Joint Notification at 1–2, ECF No. 32. Nexus cited two such potential disputed facts: (1) when actual notice was received, under the statutory framework outlined in Section II.A. of this opinion; and (2) whether the doctrine of unclean hands precludes relief. The former is a factual determination to be made by FDA on remand and the latter is a legal question that was fully briefed for purposes of the present motion. Accordingly, the Court agrees with Federal Defendants that "resolving this case on the merits would not involve exploration of additional factual issues" and proceeds to the merits because "doing so does not result in prejudice to either party." *Id.* at 1*; Morris v. District of Columbia*, 38 F. Supp. 3d 57, 62–63 & n.1 (D.D.C. 2014). As Nexus does not make any counter or cross claims, the Court's entry of judgment in favor of Melinta is dispositive. *See* Morris, 38 F. Supp. 3d. at 62 n.1 (advancing to consideration on the merits even without prior notification because "the relief sought in the complaint is the same relief sought in the preliminary injunction, and there will remain no other issues to litigate once the preliminary injunction is resolved"); *Strait Shipbrokers Pte. v. Blinken*, 560 F. Supp. 3d 81, 91 (D.D.C. 2021) ("A preliminary injunction 'is a stopgap measure, generally limited as to time, and intended to maintain a status quo or to preserve the relative positions of the parties until a trial on the merits can be held.'") (quoting *Sherly v. Sebelius*, 689 F.3d 776, 781–82 (D.C. Cir. 2012)).

contains detailed information on the composition and production of the drug and the full reports of clinical trials and investigations that establish its safety and efficacy. 21 U.S.C. § 355(b)(1)(A). Preparing an NDA "can be a time-consuming and costly process." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). "Prior to 1984, a firm that wished to make a generic version of an approved drug was required to file a new NDA, complete with new safety and effectiveness studies." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001). But in 1984, Congress passed the Hatch-Waxman Amendments, which established the "Abbreviated New Drug Application," or "ANDA." Pub. L. No. 98-417, 98 Stat. 1585. By filing an ANDA, a generic drug company can rely on the previously submitted clinical data in an already approved NDA, thus allowing the generic drug to more quickly reach consumers. 21 U.S.C. § 355(j).

At the same time, "[t]he Hatch–Waxman Amendments also sought to afford an NDA holder some patent protection, to lower the risk to innovation posed by the simplified ANDA process." *Am. Bioscience, Inc.*, 269 F.3d at 1079. An ANDA must therefore include for each patent which claims the NDA drug, "(1) that no patent has been filed with the FDA; (2) that the patent has expired; (3) that the patent has not expired, but will expire on a particular date; or (4) that the patent is either invalid or the generic drug will not infringe it (a 'Paragraph IV certification')." *Id.*; 21 U.S.C. § 355(j)(2)(A)(vii).

An ANDA applicant who makes a Paragraph IV certification is statutorily obligated to give notice to "each owner of the patent," "the holder of the approved [new drug] application" (*i.e.* the innovator), or "a representative . . . designated to receive such a notice" on behalf of the owner or holder. 21 U.S.C. § 355(j)(2)(B)(iii). The notice must include a "detailed statement of the factual and legal basis" for the applicant's contention that the patent is invalid or will not be

infringed. § 355(j)(2)(B)(iv). Once notice is "received," the patent holder has 45 days in which to initiate a patent infringement suit. § 355(j)(5)(B)(iii). If a suit is brought within that 45-day window, the approval of the ANDA is automatically stayed, subject to limited exceptions, for thirty months "beginning on the date of the receipt of the notice" or until the infringement dispute is resolved. *Id.*

FDA regulations detail the process an ANDA applicant must follow to satisfy the statutory requirement to provide notice of Paragraph IV certification to the patent holder. *See* 21 C.F.R. § 314.95. Most relevant here, the regulations provide that an applicant must amend its ANDA to "provide documentation of the date of receipt of the notice." § 314.95(e). FDA requires separate documentation of when the notice was sent and when it was received:

> FDA will accept, as adequate documentation of the date the notice was *sent*, a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service . . . . FDA will accept as adequate documentation of the date of *receipt* a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person provided the notice.

Id. (emphasis added). Otherwise, "[a]n applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance." *Id.* If these requirements are met, "FDA will presume the notice to be complete and sufficient." § 314.95(f).

B. Factual and Procedural Background

Melinta is the innovator company and patent holder for Minocin for Injection, an "intravenous minocycline product approved by the FDA . . . for the treatment of certain serious and life-threatening bacterial infections." Pls.' Mot. Temp. Restraining Order & Prelim. Inj. ("TRO") at 6, ECF No. 5-2; *see also* Fed. Defs.' Opp'n at 5, ECF No. 21. Nexus submitted an ANDA to FDA seeking approval to manufacture and market a generic version of Minocin for Injection on October 16, 2020. Intervenor Nexus Pharmaceuticals, Inc.'s Opp'n ("Nexus's

Opp'n") at 4, ECF No. 18. Nexus sent Melinta's general counsel notice ("the Notice") of its Paragraph IV certification by FedEx, which was dated December 7, 2020 and delivered December 8, 2020. *Id.*

As documentation proving Melinta's receipt of the Notice, Nexus submitted a FedEx "proof-of-delivery" slip to FDA. Ex. A to Compl. at 117, ECF No. 1-1. That slip indicates that the Notice was delivered to Melinta at 10:38 on December 8, 2020 and that it was signed for by "A.MELNTA." *Id.* In the signature box, it contains the notation, "C-19", consistent with a FedEx Covid-19 contactless delivery policy in place at the time, which provided in relevant part:

> In most cases, after making contact with the recipient, the [FedEx] team member will collect the recipient's first initial and last name and enter "C-19" in place of the signature image. If an adult signature was requested by the shipper, the driver will collect the recipient's first initial and last name, and then attempt to collect a signature by the recipient using an acceptable stylus or writing instrument, depending on the driver's device; if the recipient refuses to sign or doesn't have access to an acceptable stylus or writing instrument for the driver's device, the driver will enter "C-19" in place of the signature image.

Ex. A to Compl. at 6 n.20.

Melinta claims that it did not actually receive the Notice until March 31, 2021. Compl. ¶ 42. Melinta subsequently notified FDA of "Nexus's deficient paragraph IV certification" on May 7, 2021, initiated a patent infringement action against Nexus in the Northern District of Illinois on May 14, 2021, *see Melinta Therapeutics v. Nexus Pharm.*, No. 21-cv-5995, and filed a citizen petition (the "Petition") with FDA on October 16, 2021. Compl. ¶¶ 43, 47. The Petition sought a determination that the notice date for purposes of triggering the 45-day window to file a patent infringement suit and the corresponding 30-month statutory stay of approval of Nexus's ANDA would be March 31, 2021, and further requested a determination that Nexus "failed to meet the standard for documenting receipt" of the Notice. Ex. A to Compl. ("Petition") at 2–3.

On July 22, 2022, FDA denied the Petition and approved Nexus's ANDA. Fed. Defs.' Opp'n. at 8–9. On July 25, 2022, Melinta initiated this suit to challenge those agency actions. *See* Compl.

III. LEGAL STANDARDS

A. Administrative Procedure Act

Plaintiffs bring their claims pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 101–913, which governs the conduct of federal administrative agencies. The APA permits a court to "compel agency action unlawfully withheld or unreasonably delayed," and to "hold unlawful and set aside agency action, findings and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." § 706.

B. Summary Judgment

In a typical case, a court may grant summary judgment to a movant who "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also *Winston & Strawn, LLP v. McLean*, 843 F.3d 503, 505 (D.C. Cir. 2016). But when assessing a motion for summary judgment in an APA case, "the district judge sits as an appellate tribunal," *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001), limited to determining whether, as a matter of law, the evidence in the administrative record supports the agency's decision. *Citizens for Resp. & Ethics in Wash. v. SEC*, 916 F.Supp.2d 141, 145 (D.D.C. 2013). Accordingly, the Court's review "is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously." *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009).

C. Arbitrary and Capricious

"The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 141 S. Ct.

1150, 1158 (2021). The burden of proof rests with the challenging party, *Nat'l Lifeline Assoc. v. Fed. Commc'ns Comm'n*, 983 F.3d 498, 507 (D.C. Cir. 2020), and the court "is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). However, while the agency is entitled to "substantial deference," *Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1008 (D.C. Cir. 2014) (internal citations omitted),

> judicial review is not toothless: a court will find an Agency acted arbitrarily or capriciously "if it has relied on factors Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, or offered an explanation either contrary to the evidence before the agency or so implausible as to not reflect either a difference in view or agency expertise."

Taylor Made Software v. Cuccinelli, 453 F. Supp. 3d 237, 242 (D.D.C. 2020) (quoting *Defs. of Wildlife v. Jewell*, 815 F.3d 1, 9 (D.C. Cir. 2016)). "An agency action is arbitrary and capricious if an agency fails to 'comply with its own regulations.'" *Am. Tunaboat Assoc. v. Ross*, 391 F. Supp. 3d 98, 107 (D.D.C. 2019) (citing *Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014)).

IV. ANALYSIS

Melinta challenges two agency actions as arbitrary and capricious: (1) FDA's denial of its citizen petition; and (2) FDA's subsequent approval of Nexus's ANDA. Compl. ¶¶ 68, 70. The parties agree that the "dispositive" question on which both challenges turn is whether the FedEx proof-of-delivery slip that Nexus submitted to FDA to prove the date of receipt of the Notice qualified as "signature proof of delivery by a designated delivery service" under 21 C.F.R. § 314.95(e). TRO at 13; Fed. Defs.' Opp'n at 11; Nexus's Opp'n at 7.

In its Petition, Melinta argued that the FedEx proof-of-delivery slip that Nexus submitted to FDA did not qualify as signature proof of delivery under 21 C.F.R. § 314.95(e). Specifically,

Melinta contended that, because no one at the company went by the name "A.MELNTA" and the "C-19" notation in the signature box merely referred to FedEx's contactless delivery policy and did not purport to be an actual signature, "no actual employee at Melinta received delivery on December 8, 2020." Petition at 9. FDA disagreed, arguing that, "[a]lthough FedEx may have suspended physical signature requirements in December 2020 due to the COVID-19 public health emergency, FedEx still provided signature proof of delivery in this case." Ex. B to Compl. ("Petition Denial") at 7, ECF No. 1-2. FDA explained that the "FedEx signature proof of delivery for the Nexus Letter shows the 'C-19' signature designation, consistent with the process described in the FedEx COVID-19 Policy," and concluded that this "signature proof of delivery is valid and sufficient on its face." *Id.* at 7-8.

Agency interpretations of their own regulations are not entitled to deference unless, after "carefully consider[ing] the text, structure, history, and purpose of [the] regulation," the regulation is found to be ambiguous. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (cleaned up). Even where a regulation is found to be ambiguous, agency interpretations are not entitled to deference unless, among other things, "the agency's interpretation . . . in some way implicate[s] its substantive expertise." *Id*. at 2416–17. Accordingly, there is a "strong judicial role in interpreting [agency] rules." *Id.* at 2418.

A. 21 C.F.R. § 314.95(e) Is Unambiguous

The Court agrees with Melinta that the term "signature proof of delivery," as used in 21 C.F.R. § 314.95(e), unambiguously requires the signature of the recipient or a designated representative, and therefore that FDA is not entitled to deference in its interpretation that it does not. *See* TRO at 13; Melinta's Reply at 7, ECF No. 22. The text, structure, history, and purpose of the regulation all compel this answer.

The statutory and regulatory framework demonstrate a purpose to ensure receipt of the notice by the patent holder or a designated representative. Broadly, that Congress established an intricate system whereby patent holders must be put on notice of Paragraph IV certifications and then entitled to an automatic 30-month stay of ANDA approval after filing timely patent infringement litigation reflects, at the most basic level, an intent to make the patent holder aware that a generic entrant may challenge the enforceability of its patent. Accordingly, the statute and regulations speak in terms of "receipt" of notice of Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(5)(B)(iii) ("[T]he approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice . . . is *received*, an action is brought for patent infringement . . . . If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the *receipt* of the notice . . . ." (emphasis added)); 21 C.F.R. § 314.95(e) ("The applicant must amend its ANDA to provide documentation of the date of *receipt* of the notice . . . by each person provided the notice. . . . FDA will accept as adequate documentation of the date of *receipt* a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person provided the notice." (emphasis added)).

Federal Defendants argue that the "plain language" of the regulations does not require the signature of the recipient or a representative because "[n]otably absent from the provision relating to 'signature proof of delivery by a designated delivery service' is any requirement regarding the person who must provide such signature." Fed. Defs.' Surreply at 6–7, ECF No. 27. Similarly, Nexus argues that it is consistent with the text of 21 C.F.R. § 314.95(e) to "look[] to the evidenced date of *delivery* to presume receipt." Nexus's Opp'n at 10 (emphasis in original). But the statute and regulations leave no ambiguity concerning who must receive the

notice: "each owner of the patent that is the subject of the [paragraph IV] certification (or a representative of the owner designated to receive such notice)" and "the holder of the approved [new drug] application . . . (or a representative of the holder designated to receive such a notice)." 21 C.F.R. § 355(j)(2)(B)(iii). The implementing regulations mirror this formulation. *See* 21 C.F.R. § 314.95(a) (requiring, in relevant part, that notice be provided to "[e]ach owner of the patent . . . or the representative designated by the owner to receive the notice"). The Court declines to hold that the statutory and regulatory framework would in one breath require that notice be received by the patent holder or a designated representative, and in the next define adequate documentation of the date of receipt to include a signature by someone who is not the patent holder or a designated representative. *See Watson Labs. v. Sebelius*, 2012 WL 6968224 *1, *16 (D.D.C. October 22, 2012) (explaining that "the statute requires that the ANDA applicant notify the patent holder and then notify FDA that the notice was actually received").[3]

The structure of the regulation confirms this interpretation. Specifically, as Melinta points out, the regulation distinguishes "adequate documentation of the date the notice was sent" from "adequate documentation of the date of receipt." 21 C.F.R. § 314.95(e); TRO at 3, 10. An applicant can prove the date the notice was sent with "a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service." § 314.95(e) By contrast, an applicant can prove the date the notice was received only with "a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person

[3] Defendants say *Watson Laboratories* is irrelevant because the facts are not analogous and the quoted text was dicta. *See* Nexus's Opp'n at 12; Fed. Defs.' Opp'n at 15. It is true that *Watson Laboratories* does not bind the Court or answer the specific interpretive question about the meaning of "signature proof of delivery" that controls this case, but it is certainly relevant evidence about the purpose of the statutory framework that another court in this district interpreted Congress as intending to ensure actual receipt of notice.

provided the notice."[4] *Id.* If these and the other requirements concerning the notice are met, "FDA will presume the notice to be complete and sufficient." § 314.95(f). Put simply, FDA will believe notice was sent if the applicant provides receipt proof, but FDA will only believe the notice was received if the applicant provides signature proof. To believe that the mail service could provide signature proof instead of the recipient or a designated representative would be to collapse the distinction between receipt proof and signature proof. If the "strong judicial role in interpreting [agency] rules" means anything, it is that the Court cannot ignore such strong interpretive evidence from the text and structure of the regulation. *Kisor*, 139 S. Ct. at 2418.

The balance of case law supports this reading. Melinta cites principally to five cases from state and other federal courts for the proposition that the mark "C-19" does not constitute a signature by the recipient. TRO at 5–6. In these cases, the courts held unequivocally that "C-19" or "COVID-19" does not constitute a signature by the recipient for purposes of meeting service of process requirements under the applicable state or federal rules. *See, e.g.*, *CUC Props. VI v. Smartlink Ventures*, 178 N.E. 3d 556, 560 (Ohio Ct. App. 2021) ("When the carriers in this case marked "Covid 19" or "C19" on the return receipt, they assumed the role of both the deliverer and the recipient . . . [W]e cannot see how 'Covid-19' or 'C19' constitutes a 'signature' or a receipt 'signed' by a person."); *Copeland v. Internal Revenue Serv.*, 2021 WL 3713071, at *6 (N.D. Tex. Aug. 4, 2021) (finding that, because the return receipt contained "C19" instead of the recipient's name, defendant was not properly served).

[4] Furthermore, to adopt Defendants' reading that "signature proof of delivery" does not require the signature of the recipient would be inconsistent with the other two types of adequate documentation of the date of receipt listed under 21 C.F.R. § 314.95(e) – "return receipt" or "a letter acknowledging receipt by the person provided the notice." *See Massachusetts v. Morash*, 490 U.S. 107, 114–115 (1989) ("[W]ords grouped in a list should be given related meaning." (internal quotation omitted)).

In response, Defendants argue that these cases do not apply because the relevant laws explicitly required the signature of the recipient, unlike here where all that was required was "signature proof of delivery by a designated delivery service." Fed. Defs.' Surreply at 2; Nexus's Surreply at 3, ECF No. 25. But for the reasons stated in this opinion, the Court finds that "signature proof of delivery," as used in 21 C.F.R. § 314.95(e), does require the signature of the recipient or a designated representative, so these cases are in fact directly relevant, albeit not binding, in the Court's consideration of whether the "C-19" mark constitutes as much.[5] Defendants also cite two cases – *Colo. Bankers Life Ins. Co. v. AT Denmark Invs.*, 526 F. Supp. 3d 118 (E.D.N.C. 2021) and *Macias v. Grange Ins. Co.*, 2020 WL 4913215 (W.D. La. Aug. 20, 2020) – that they claim point in their direction. Fed. Defs.' Surreply at 5; Nexus's Surreply at 3, 5. The *Colo. Bankers* court fleetingly rejected an affidavit submitted by the defendant alleging that the delivery receipt was signed by the FedEx driver pursuant to a Covid-19 policy as insufficient to overcome a presumption of valid service under North Carolina law. *Colo. Bankers Life Ins. Co.*, 526 F. Supp. 3d at 124–25. Whatever support Defendants gain from this case is sharply limited by the fact that the relevant legal framework did not require the signature of the recipient. *See N.C. Gen. Stat.* § 1-75.10(a)(5) (requiring an affidavit by the serving party averring, in relevant part, that the summons and complaint "was in fact received as evidenced by the attached delivery receipt or other evidence satisfactory to the court of delivery to the addressee").

[5] For the same reason, Defendants' attempt to distinguish these cases on grounds that "the stakes are particularly high" in the service of process context is likewise unavailing. Fed. Defs.' Surreply at 4; Nexus's Surreply at 4–5. The Court is skeptical that compliance with carefully crafted federal statutes and regulations to govern generic pharmaceutical market entry is low stakes, but regardless the cases still stand for the proposition that "C-19" or a similar mark does not constitute the signature of the recipient.

Defendants find more support from *Macias*, in which the court denied defendants' motion to dismiss for failure to effect service in part based on a finding that the return receipt bearing a "C-19" mark was sufficient proof of service. *Macias* 2020 WL 4913215 at *2. While this does offer support to Defendants, the persuasiveness of the court's one-paragraph analysis is tempered by the fact that the court also relied on other evidence of receipt – specifically, plaintiffs' submission of "an explanation from the Postmaster that the mail piece was delivered to Kyle Smith at the address listed." *Id.* Similarly, *Nexus* also points to *Demarco v. Rakmanov*, 2021 WL 8998911 at *2 (N.D. Ga. Aug. 13, 2021), in which the court found a return receipt with a "C-19" mark to comply with Georgia's service of process rules. Nexus's Surreply at 5. Again, however, its applicability to this case is limited by the fact that, unlike here, the "overnight delivery was signed for by an 'R.RINA.'" *Id.* Taken together, the Court finds that the clear balance of authority supports a finding that a "C-19" mark on a delivery receipt does not constitute the signature of the recipient.

In addition, reading 21 C.F.R. § 314.95(e)'s list of adequate forms of documentations to implicitly provide FDA broad discretion to relax the "signature proof of delivery" requirement would be inconsistent with the sentence that follows, which provides that "[a]n applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance." 21 C.F.R. § 314.95(e). In this way, as Melinta points out, the regulation anticipates that situations could arise that would require flexibility – for example, a pandemic – and created an exclusive way for FDA to provide that flexibility. *See* TRO at 14. FDA's denial of Melinta's Petition and Defendants' submissions point to the fact that the "C-19" notation entered in the signature box on the FedEx proof-of-delivery slip complied with FedEx's COVID-19 contactless delivery policy. Petition Denial at 7; Fed. Defs.' Opp'n at 11–12; Nexus's Opp'n at 10–11. But

it is uncontested that "C-19" did not represent the signature of Melinta or a designated representative and that Nexus did not seek, nor did FDA provide, advance approval to substitute the FedEx Covid-19 contactless delivery policy for the "signature proof of delivery" requirement in 21 C.F.R. § 314.95(e).

The regulatory history also is consistent with reading "signature proof of delivery" to require the signature of the recipient or a designated representative. When it was originally issued in 1994, 21 C.F.R. § 314.95(e) permitted as adequate documentation of the date of receipt only a "return receipt or a letter acknowledging receipt by the person provided the notice." Abbreviated New Drug Application Regulations, 50 Fed. Reg. 50338, 50366 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 60). In 1998, FDA proposed to expand allowable methods of delivery to include email and facsimile, and to expand what qualified as adequate documentation of the date of receipt to include "a verification of receipt that contains the date notice was delivered, the address to which notice was delivered, and the signature of the recipient." New Drugs for Human Use, 63 Fed. Reg. 11174, 11177 (Mar. 6, 1998).

Defendants argue that this proposed language, which was withdrawn in 2000 in the face of critical comments,[6] shows that "when FDA intends to require a signature by the recipient, the agency will so specify." Fed. Defs.' Surreply at 7; Nexus's Surreply at 12–13 ("[T]he stark contrast in the proposed language between the 1998 proposal and the current regulation further confirms that personal delivery is ***not*** required." (emphasis in original)). For the reasons stated above, the Court finds that the language "signature proof of delivery," as used in the regulation,

[6] If anything, the withdrawal supports Plaintiffs' restrictive view of the regulation, as FDA withdrew the proposed rule "based on comments regarding the inability of large corporations to track receipt of deliveries by means other than certified mail, return receipt requested." New Drugs for Human Use, 65 Fed. Reg. 12154 (Mar. 8, 2000).

does specify a requirement to obtain the signature of the recipient or a designated representative. Importantly, however, the 1998 proposal also explicitly stated that facsimile and email receipts "need not include the recipient's signature." New Drugs for Human Use, 63 Fed. Reg. at 11177. The main teaching of the 1998 proposal, therefore, is actually the inverse of what Defendants claim: where FDA intends *not to* require a signature by the recipient, it will make that unmistakably clear.[7] The current formulation contains no such exemption.

More broadly, Defendants argue that the regulatory history, and in particular FDA's 2016 addition of "signature proof of delivery by a designated delivery service" as a form of adequate documentation of the date of receipt, indicates "the agency's increasing openness to accepting additional forms of delivery of notice – and, consequently, additional types of documentation of the date of receipt." Fed. Defs.' Surreply at 7; *see* Nexus's Surreply at 12 ("Directionally, this regulatory purpose alone supports FDA's view, because the revised regulation encouraged broader and more flexible avenues for sending notice letters."). The impetus for the 2016 change, according to FDA, was the "the frequency with which FDA receives requests to send notice by overnight delivery services." Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. 6802, 6839 (Feb. 6, 2015) (to be codified at 21 C.F.R. pts. 314, 320). A single amendment to permit use of overnight delivery services while still requiring signature

[7] Federal Defendants argue that the fact that the "proposed amendment contemplated permitting notice by email or fax without requiring a signature" demonstrates that "even this withdrawn proposal was not as bound by past restrictions as Melinta suggests." Fed. Defs.' Surreply at 8. This argument is unavailing, as the departure from "past restrictions" was the very reason, in the face of critical stakeholder comments, that FDA withdrew the proposal. *See* New Drugs for Human Use, 65 Fed. Reg. at 12154–55 ("After careful consideration of these comments, FDA has concluded that the current system, which requires only that an applicant send notice by USPS registered or certified mail, return receipt requested, is not overly burdensome. This requirement *is intended to provide maximum assurance that the notice will be received* by the patent holder and the NDA holder, and that such receipt will be documented adequately." (emphasis added)).

proof of delivery hardly indicates that FDA has embraced creative new ways to prove receipt. And regardless, speculation about FDA's possible "openness" to other ways to prove receipt of notice in the future is irrelevant to interpreting its current regulations.

B. FDA Is Otherwise Not Entitled to Deference

Even if the Court found 21 C.F.R. § 314.95(e) to be ambiguous, FDA's interpretation still would not be entitled to deference because the question of whether the mark "C-19" on a FedEx proof-of-delivery slip constitutes adequate documentation of the date of receipt in no way implicates the substantive expertise of the agency. *See Kisor,* 139 S. Ct. at 2417 (2019) (holding that "the agency's interpretation must in some way implicate its substantive expertise" in order to be entitled to deference); *Serono Laboratories*, 158 F.3d at 1320 (explaining that "FDA's determination . . . rests on the agency's evaluations of scientific data within its area of expertise, and hence is entitled to a high level of deference" (cleaned up)). While even "prosaic-seeming questions" may implicate an agency's substantive expertise, "[s]ome interpretive issues may fall more naturally into a judge's bailiwick." *Kisor*, 139 S. Ct. at 2417. The adequacy of documentation that notice was received is such an issue. *Compare, e.g.*, *Sagarwala v. Cissna*, 387 F. Supp. 3d 56, 66–67 (D.D.C. 2019) (deferring to agency interpretation of the type of education required in order to be eligible for an H1-B visa, based in part on finding that the issue falls "within the agency's substantive expertise") *with Ovalle v. Attorney General United States*, 791 Fed. Appx. 333, 336 (3d Cir. 2019) ("Because the scope of the [Board of Immigration Appeals]'s *sua sponte* jurisdiction is precisely the kind of interpretive issue that falls more naturally into our bailiwick, deference to the BIA's interpretation . . . is no longer warranted." (cleaned up)).

Absent pre-approval of an alternate method by FDA, 21 C.F.R. § 314.95(e) unambiguously requires the signature of the recipient or a designated representative as adequate documentation of the date of receipt of a Paragraph IV certification. FDA denied Melinta's Petition on the ground that the FedEx proof-of-delivery slip with the "C-19" notation was "consistent with the process described in the FedEx COVID-19 Policy" and "constitute[d] adequate documentation of the date of receipt of notice under 21 CFR 314.95(e)." Petition Denial at 7–8. FDA therefore refused to consider Melinta's factual allegations, including about its own COVID-19 policies, that would otherwise have been relevant to an inquiry into whether or when Melinta received the Notice. *Id*. at 8 ("Where, as here, the signature proof of delivery is valid and sufficient on its face, FDA will not look beyond that document and resolve disputed factual issues or engage in speculation as to the circumstances of a notice's delivery.")[8] Accordingly, because FDA's interpretation that "signature proof of delivery" did not require the signature of the recipient or a designated representative is contrary to the unambiguous meaning of 21 C.F.R. § 314.95(e), it was arbitrary and capricious for FDA to rely on that interpretation to deny Melinta's citizen petition and approve Nexus's ANDA. *See Am. Tunaboat Assoc.*, 391 F. Supp. 3d at 107 ("An agency action is arbitrary and capricious if an agency fails to 'comply with its own regulations.'") (citing *Nat'l Envtl. Dev. Ass'n's Clean Air Project*, 752 F.3d at 1009 (D.C. Cir. 2014)).

[8] Along these lines, in a footnote FDA expressed concerns about administrative burden, explaining that "[i]f a facially valid and sufficient signature proof of delivery were open to challenge on grounds like those Melinta alleges here, it would be impractical, if not impossible, for FDA to adjudicate such factual issues as whether a given signature was genuine." Petition Denial at 8 n.17. This concern is not implicated here, as the Court finds that the FedEx proof-of-delivery slip was not "facially valid and sufficient proof of delivery" under 21 C.F.R. § 314.95(e). In addition, it bears notice that it was in never in question in this case whether "C-19" was a "genuine signature." The parties agree it was a mark made by a FedEx employee.

C. Doctrine of Unclean Hands Does Not Apply

Nexus argues that Melinta is not entitled to relief because it comes before the Court with unclean hands, based on allegations that Melinta instructed FedEx to deliver the Notice as it did.[9] Nexus Opp'n at 11–12; Nexus Surreply at 12. Melinta responds that Nexus improperly relies on evidence outside the administrative record, disputes Nexus's factual allegations based on that evidence, argues that even if the allegations are true they do not prove unclean hands, and asserts that if anyone has unclean hands it is Nexus (relying on its own extra-record evidence). Pl.'s Reply at 17–19. The Court does not wade deeply into these allegations because its review of FDA's actions is confined to the administrative record. *Hill Dermaceuticals v. Food & Drug Admin.*, 709 F.3d 44, 47 (D.C. Cir. 2013) ("[I]t is black-letter administrative law that in an APA case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." (internal quotation omitted)).

Even if the Court did consider the extra-record evidence, it would not be enough to prove that Melinta has unclean hands. Nexus's opposition cites to two emails from FedEx to support its allegation of unclean hands. Nexus's Opp'n at 12. The first, from December 8, 2021, states that "[s]ome time before this shipment, [the FedEx courier] was instructed by the office manager of Melinta Therapeutics . . . to just leave the packages outside the door since no one is in the office." Ex 1. to Nexus's Opp'n at 1, ECF No. 19-1. The second, from January 4, 2022, states that the "courier said he spoke to a white lady, possibly mid 50s, with brown hair during the summer of 2020 and she explained to him that the office was still primarily closed and . . . [s]he

[9] Nexus suggested that this is an issue to be considered after adjudication of Melinta's motion for a temporary restraining order and preliminary injunction. Joint Notification at 1–2. However, because a finding of unclean hands could preclude the relief sought in the motion before the Court, and because the issue was fully briefed, *see* Nexus's Opp'n at 11–12; Melinta's Reply at 17–19; Nexus's Surreply at 12, the Court considers it here.

instructed him to leave the packages at the door on the second floor." Ex. 2 to Nexus's Opp'n at 2, ECF No. 19-2. Melinta disputes that any Melinta employee gave such an instruction and calls into question the credibility of FedEx's descriptions. Melinta's Reply at 18–19.

But even if Nexus succeeded in proving the allegations in the FedEx emails, the emails include no evidence of bad faith on the part of Melinta in general, and certainly not with respect to this case in particular. *See Keystone Driller Co. v. Gen'l Excavator Co.*, 290 U.S. 240, 245 (1933) ("[H]e who asks relief must have acted in good faith. The equitable powers of this court can never be exerted in behalf of oen [*sic*] who has acted fraudulently, or who by deceit or any unfair means has gained an advantage." (internal quotation omitted)); *Lee v. Christian Coalition of America*, 160 F. Supp. 2d 14, 34 (D.D.C. 2001) ("The Supreme Court has held that a party asserting an unclean-hands defense must show an 'immediate and necessary relation' between the instant case and the alleged misconduct." (quoting *Keystone Driller*, 290 U.S. at 245)). Whether or not a Melinta employee told a FedEx courier to drop packages at the door also does not bear on Nexus's ability to have specifically requested a signature for the package containing the Notice, *see* Melinta's Reply at 19, or on Nexus's ability to have requested approval from FDA to submit alternative documentation of the date of receipt. Nexus thus falls short of meeting its burden to show that Melinta has unclean hands.[10] *Saint-Jean v. District of Columbia*,

[10] Nexus's opposition cites a single case, from 1974, to support its unclean hands claim. Nexus's Opp'n at 11–12. In that case, the Court indicated, though did not hold, that "the defense of 'unclean hands' may well preclude relief." *Neal-Cooper Grain Co. v. Kissinger*, 385 F. Supp. 769, 779 (D.D.C. 1974). But that case is not analogous to the case before the Court. In *Neal-Cooper Grain*, plaintiff sought to prevent disclosure to the Mexican government of information provided to the U.S. Customs Service pursuant to his fertilizer importation business. However, the government invoked the unclean hands doctrine based on its assertion that "the fertilizer in question may have been imported by plaintiffs in violation of Mexican law prohibiting the export of such commodities" and that the U.S. government "is now investigating possible criminal violations of United States law arising from the same importation." *Id.* at 778. By contrast, in

846 F. Supp. 2d 247, 258 (D.D.C. 2012) ("[Defendant] bears the burden of showing that unclean hands bars equitable relief." (internal quotation omitted)).

V. CONCLUSION

For the foregoing reasons, Melinta's motion for a temporary restraining order and preliminary injunction (ECF No. 5), as consolidated with the merits, is GRANTED and JUDGMENT IS ENTERED for Melinta. FDA's approval of Nexus's ANDA is vacated and the case is remanded to FDA for further action consistent with this opinion. In addition, Melinta's motion for leave to file a document under seal (ECF No. 6), is GRANTED. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: October 7, 2022

RUDOLPH CONTRERAS
United States District Judge

the present case, there is no direct link between the alleged instruction to FedEx and the delivery "in question" and no evidence of bad faith, let alone illegal behavior.