**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| LANNETT COMPANY, INC. and LANNETT HOLDINGS, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. 16-1350 (RBW) |
| UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., | ) | |
| Defendants. | ) | |

**MEMORANDUM OPINION**

The plaintiffs, Lannett Company, Inc. and Lannett Holdings, Inc. (collectively, "Lannett"), bring this action against the defendants, the United States Food and Drug Administration (the "FDA") and the United States, for judicial review of the FDA's decision to rescind "the marketing approval for one of [their] generic drugs[, Temozolomide,] based on the agency's argument that the approval was 'mistakenly granted.'" Complaint ("Compl.") at 2. Specifically, Lannett petitions this Court to "[s]et aside the FDA's rescission of [its] [Abbreviated New Drug Application ("ANDA")] approval" of Temozolomide, to "[d]eclare [the] FDA's rescission of [its] ANDA approval unlawful," and to "[e]njoin [the] FDA from revoking the ANDA approval for [its] Temozolomide Capsules in the future without a hearing, and without following the procedures established by 21 U.S.C. § 355(e) [(2012)]." Id. at 18. Currently before the Court are the Plaintiffs' Motion for Summary Judgment ("Pls.' Mot."), ECF No. 16, the Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment ("Defs.' Summ. J. Mot."), ECF No. 37, and the Defendants'

Motion to Strike Extra-Record Documents ("Defs.' Mot."). After careful consideration of the parties' submissions and the administrative record ("A.R."),[1] the Court concludes for the reasons set forth below that it must deny the plaintiffs' motion for summary judgment, grant the defendants' cross-motion for summary judgment, and deny as moot the defendants' motion to strike.

## I. STATUTORY AND REGULATORY BACKGROUND

The Food, Drug, and Cosmetic Act (the "FDCA") provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to . . . this section is effective with respect to such drug." 21 U.S.C. § 355(a). In order to obtain approval, a new drug application (a "NDA") must include, among other things, "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use." Id. § 355(b)(1)(A). Because this process is "costly and time[-]consuming," Congress amended the FDCA in 1984 to "permit[] a manufacturer of a generic alternative to a pioneer drug to seek FDA approval by submitting an [ANDA]," Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1316 (D.C. Cir. 1998), which references and relies on the prior approval of the pioneer drug, Astellas Pharma US, Inc. v. FDA, 642 F. Supp. 2d 10, 13–14 (D.D.C. 2009). So, "[r]ather than requiring the [ANDA] applicant to make an independent showing that the proposed generic is itself safe and effective, the amended statute requires a showing that the proposed generic operates in the same manner as the pioneer drug on

[1] In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Memorandum in Support of Plaintiffs' Motion for Summary Judgment ("Pls.' Mem."); (2) the Defendants' Memorandum in Support of Cross-Motion for Summary Judgment in Opposition to Plaintiffs' Motion for Summary Judgment ("Defs.' Mem."); (3) the Plaintiffs' Opposition to Defendants' Cross-Motion for Summary Judgment and Reply in Support of Motion for Summary Judgment ("Pls.' Reply"); (4) the Defendants' Reply to Plaintiffs' Opposition to, and in further Support of, Defendants' Cross-Motion for Summary Judgment ("Defs.' Summ. J. Reply"); (5) the plaintiffs' Opposition to Motion to Strike ("Pls.' Opp'n"); and (6) the defendants' Reply to the Plaintiffs' Opposition to Motion to Strike ("Defs.' Reply").

which it is based." Id.

To that end, FDA regulations require that an ANDA include information comparing, among other things, the proposed generic drug's "[a]ctive ingredients," "[r]oute of administration, dosage form, and strength" to the "reference listed drug." 21 C.F.R. §§ 314.94(a)(5–6) (2016). The ANDA must also contain "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug." 21 U.S.C. § 355(b)(1)(D); see also 21 C.F.R. § 314.94(a)(9)(i). For ANDA approval, the FDA must find that these requirements, commonly referred to as current Good Manufacturing Practice ("cGMP"), "are []adequate to assure and preserve [the generic drug's] identity, strength, quality, and purity." 21 U.S.C. § 355(j)(4)(A). To make this assessment, the

> FDA assesses cGMP compliance by inspecting the facility or facilities where the drug will be manufactured. If the finished drug manufacturer will use an active pharmaceutical ingredient manufactured by a different company, [the] FDA will review the compliance status of each named facility and inspect the facilities of both the finished drug manufacture and the active pharmaceutical ingredient manufacturer as needed.

Pls.' Mem. at 5. Once the FDA approves an ANDA, the ANDA sponsor may begin "market[ing] its drug lawfully in interstate commerce." Id. at 6; see also 21 U.S.C. § 355.

The FDCA also sets forth the process for the withdrawal of an ANDA approval, outlining the circumstances in which the FDA is required to rescind an ANDA approval or when it may do so in its discretion. See 21 U.S.C. § 355(e). Under either scenario, the FDCA requires "due notice and opportunity for hearing to the applicant" before the FDA withdraws its ANDA approval. Id. Relevant to this case, the FDA may withdraw ANDA approval on the basis of "new information" regarding non-compliance with cGMP:

> The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted . . . on the basis of new information before him, evaluated together with the evidence before him

> when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

Id. (emphasis added).[2] However, the FDA is not limited to these statutorily provided circumstances for withdrawing ANDA approval, as it may also rescind an ANDA approval under its "inherent authority" if done within a reasonable period of time and if Congress has not otherwise spoken. See Ivy Sports Med., L.L.C. v. Burwell, 767 F.3d 81, 86 (D.C. Cir. 2014) ("[A]dministrative agencies are assumed to possess at least some inherent authority to revisit their prior decisions, at least if done in a timely fashion. . . . [However,] an agency may not rely on inherent reconsideration authority 'when Congress has provided a mechanism capable of rectifying mistaken actions.'" (quoting Am. Methyl Corp. v. EPA, 749 F.2d 826, 835 (D.C. Cir. 1984))).

## II. FACTUAL BACKGROUND

Lannett Company, Inc., is a "manufacturer of generic drugs," and Lannett Holdings, Inc. "maintains, owns[,] and manages the intangible assets of its parent company Lannett Company, Inc." Compl. ¶ 3. Lannett Holdings, Inc. owns "the drug approval at issue in this case, and the drug is to be manufactured by Lannett Company, Inc." Id. And the drug, Temozolomide, "is an oral chemotherapy drug used in the treatment of certain cancers." Id. ¶ 18.

On February 15, 2011, "Lannett filed an ANDA with [the] FDA, seeking approval to market generic Temozolomide capsules in a variety of different strengths." Pls.' Mem. at 8

[2] Congress granted the Secretary of Health and Human Services ("HHS") authority to approve and withdraw approval of drug applications. See 21 U.S.C. § 355(b). Because the FDA is part of HHS, the Secretary of HHS is permitted to delegate certain of his congressionally granted powers to the Commissioner of the FDA. See Defs.' Mem. at 8 n.4 (citing FDA Staff Manual Guide 1401.1 and 1401.10, available at http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm136380.htm). Among the powers the Secretary of HHS has delegated to the FDA Commissioner is the power to approve and withdraw approval of drugs. See id.

(citing A.R. at FDA658). In conjunction with its ANDA, Lannett identified Chongqing Lummy Pharmaceutical Co. Ltd. ("Lummy"), a company located in Chayuan, China, "as the proposed manufacturer of the active pharmaceutical ingredient for the finished drug product." Compl. ¶ 18; see also A.R. FDA659. As part of its review of Lannett's ANDA, the FDA, in July 2013, "conducted a pre-approval inspection of Lummy's factory . . . to determine whether Lummy's manufacturing was in accordance with cGMP requirements." Pls.' Mem. at 9; see also A.R. FDA659 n.5. The FDA determined that "Lummy['s] facility had 'an acceptable compliance status,'" and this finding was documented in the FDA's Center for Drug Evaluation and Research's electronic platform used in the review and processing of ANDAs. Pls.' Mem. at 9 (quoting A.R. FDA659 n.5).

From March 14 to 16, 2016, an FDA investigator from the agency's China office conducted a routine inspection at Lummy's facility to confirm that its cGMP compliance remained acceptable. A.R. FDA59, FDA64. The inspection revealed that Lummy was "in the process of moving manufacturing operations from the Chayuan site to the newly established Changshou site located [near] . . . Chongqing city," A.R. FDA68, and thus, the FDA investigator inspected both manufacturing sites, A.R. FDA66. Although the Changshou "facility ha[d] not been registered with the FDA," Lummy "ha[d] already transferred all analytical instrumentation and stability samples [for the Temozolomide batches] to the Changshou site." A.R. FDA70. Based on his inspection, the FDA "investigator . . . conclude[d] that there were significant cGMP compliance problems relating to data integrity, including numerous records relating to manufacturing that [he] determined to have been falsified." Pls.' Mem. at 10 (citing to A.R. FDA4–7); see also Defs.' Mem. at 9–10 (citing various portions of the A.R.). The investigator provided Lummy with the list of objectionable practices and conditions he observed, and

requested that Lummy provide a response indicating its corrective actions. See A.R. FDA79.

On March 15, 2016, the FDA investigator sent an e-mail "to the Office of Compliance . . . and to [the Center for Drug Evaluation and Research's Office of Pharmaceutical Quality's] Office of Surveillance," informing them of his "recommendation that the Lummy facility be classified as [Official Action Indicated ("OAI")]," which is an inspection conclusion "reflect[ing] the fact that 'objectionable conditions were found and a regulatory action is recommended." A.R. FDA659; see also Defs.' Mem. at 11. However, "[b]ecause the investigator's e[-]mail recommendation did not also include the 'field alert' form typically used to trigger entry of an OAI alert into the [electronic p]latform, . . . staff responsible for entering facility status into the [electronic p]latform were not immediately aware that such an alert had not yet been entered." A.R. FDA659. Consequently, the electronic platform still indicated that Lummy maintained an acceptable compliance status with cGMP requirements, see A.R. FDA659 n.5., and on March 23, 2016, the FDA issued a letter indicating that Lannett's ANDA had been approved, see A.R. FDA14 (noting that the "[f]acilities are approve[d] in the [electronic p]latform"); see also A.R. FDA19–20.

On the following day, March 24, 2016,

> employees within [the Office of Surveillance had] became aware of the discrepancy and entered an OAI alert into the [electronic p]latform to flag that the Lummy facility was classified as potential OAI, a designation that should result in [the Office of Pharmaceutical Quality] not recommending for approval or tentative approval any application referencing [that] facility.

A.R. FDA659. On March 31, 2016, Lummy provided the FDA with a corrective action plan addressing the investigator's list of observed objectionable practices and conditions. A.R. FDA32–58.

On April 1, 2016, the FDA sent a letter to Lannett requesting a teleconference to discuss

"a commitment by [Lannett] to not distribute any Temozolomide product" and "[a] necessary withdrawal of [Lannett's] ANDA." A.R. FDA649. The FDA and Lannett conducted the teleconference on April 5, 2016, during which Lannett confirmed that Lummy had notified it of the FDA's March 2016 inspection findings and that it had not distributed any Temozolomide product in the United States. A.R. FDA651–52. Also, Lannett stated that it "would not commit to withdraw[ing]" its ANDA, but its representatives agreed to discuss with Lannett's senior management the FDA's proposed rescission of its approval of Lannett's ANDA, returning it "back to pending status." A.R. FDA652. Two weeks later, the FDA sent a letter to Lannett indicating that the FDA had "erred in approving [Lannett's] ANDA . . . despite the fact that the information available to the agency at the time indicated that the compliance status of a facility identified in [Lannett's] ANDA was not acceptable to support approval." A.R. FDA662. The FDA also informed Lannett of the following three options that Lannett could exercise regarding its ANDA: "request that [the] FDA withdraw approval of the application, . . . agree to immediate rescission of approval, which would put [its] ANDA back into pending status, or . . . [within thirty] days . . . provide information . . . on whether the compliance status of the Lummy facility . . . was acceptable as of the date of approval, March 23, 2016." A.R. FDA662–63. In response, on April 21, 2016, Lannett sent a letter to the FDA proposing a fourth option that would permit Lannett to submit for FDA review "a supplement pursuant to 21 C.F.R. § 314.70, and the Guidelines for Industry-Changes to an Approved NDA or ANDA," addressing a "move to a different manufacturing site for the manufacture of the [Temozolomide capsules]." A.R. FDA667; see also A.R. FDA666–71 (simultaneously asserting legal arguments as to why the FDA could not rescind its approval without complying with statutorily required procedural safeguards).

Having failed to provide the FDA with the requested information regarding Lummy's cGMP compliance status as of the March 23, 2016 ANDA approval date within the allotted thirty-day period, on May 16, 2016, the FDA sent another letter to Lannett advising Lannett that it was "correcting its error and rescinding the approval letter for [Lannett's] ANDA" and placing Lannett's ANDA back "in pending status." A.R. FDA822; see also A.R. FDA818–22 (refuting the legal arguments asserted by Lannett in its April 21, 2016 letter to the FDA). The FDA also attached to its rescission letter a cGMP Complete Response letter, outlining the identified cGMP deficiencies and requiring Lannett to respond in accordance with 21 C.F.R. § 314.110(b). See A.R. FDA824–27.

On June 28, 2016, in light of the parties' unsuccessful efforts to resolve this dispute, Lannett simultaneously filed this civil action in this Court, see generally Compl., and a protective appeal in the District of Columbia Circuit given its exclusive jurisdiction pursuant to § 355(h) to adjudicate appeals of orders withdrawing ANDA approvals based on § 355(e), see Pls.' Mem. at 14. At the appellate level, Lannett petitioned the Circuit to stay "the protective appeal pending the conclusion of the present case," which the Circuit granted. Id. The parties now both move for summary judgment in their favor.

## III. STANDARD OF REVIEW

In cases seeking judicial review of agency action under the Administrative Procedure Act ("APA"), "[s]ummary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review." Loma Linda Univ. Med. Ctr. v. Sebelius, 684 F. Supp. 2d 42, 52 (D.D.C. 2010) (citing Stuttering Found. of Am. v. Springer, 498 F. Supp. 2d 203, 207 (D.D.C. 2007)), aff'd, 408 F. App'x 383 (D.C. Cir. 2010). The APA requires that a court reviewing

agency action "shall review the whole record or those parts of it cited by a party." 5 U.S.C. § 706 (2012). "It is a widely accepted principle of administrative law that the courts base their review of an agency's actions on the materials that were before the agency at the time its decision was made." IMS, P.C. v. Alvarez, 129 F.3d 618, 623 (D.C. Cir. 1997). Due to the limited role a court plays in reviewing agency action based on the administrative record, the typical summary judgment standards of review set forth in Federal Rule of Civil Procedure 56 do not apply. See Stuttering Found. of Am., 498 F. Supp. 2d at 207. Instead, "[u]nder the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas 'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" Id. (quoting Occidental Eng'g Co. v. Immigration & Naturalization Servs., 753 F.2d 766, 769–70 (9th Cir. 1985)). Thus, "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he entire case on review is a question of law." Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (quotation marks omitted).

The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009). It requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). However, "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a 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). Nonetheless, the agency must "examine the relevant data and articulate a

satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" Id. (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)). In any event, courts "will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." Pub. Citizen, Inc. v. FAA., 988 F.2d 186, 197 (D.C. Cir. 1993) (quoting Bowman Transp., Inc. v. Arkansas–Best Freight Sys., Inc., 419 U.S. 281, 286 (1974)).

Where agency action turns on questions of statutory interpretation, courts must utilize the two-step process established in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). First, courts must determine "whether Congress has directly spoken to the precise question at issue." Id. at 842. In resolving this question, courts must exhaust the "traditional tools of statutory construction," including textual analysis, structural analysis, and (when appropriate) legislative history. Id. at 843 n.9. "If the intent of Congress is clear, that is the end of the matter; for . . . court[s], as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. at 842–43. However, if courts conclude that the statute is silent or ambiguous on the specific issue after employing these tools, they move on to step two and defer to the agency's interpretation, so long as it is based on a permissible construction of the statute. See id. at 843. Indeed, "the whole point of Chevron is to leave the discretion provided by the ambiguities of a statute with the implementing agency." Ass'n of Priv. Sector Colls. & Univs. v. Duncan, 681 F.3d 427, 441 (D.C. Cir. 2012) (quoting Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 981 (2005)).

## IV. ANALYSIS

The FDA argues that "the doctrine of exhaustion of administrative remedies militates against this Court's consideration of Lannett's claims at the present time." Defs.' Mem. at 43.

Specifically, the FDA contends that it "has not made a final, judicially reviewable decision on the manufacturing compliance status of the facilities named in Lannett's ANDA," id. at 44, because "[a]fter [it] afforded Lannett due process and properly rescinded the ANDA approval, the application returned to pending status and was subject to regulatory requirements described in [its] Complete Response Letter," id. at 43. Therefore, according to the FDA, "Lannett's premature request for judicial ruling 'amounts to an attempt to bypass the administrative process.'" Id. at 44 (quoting Pub. Citizen Health Res. Grp. v. Comm'r, FDA, 740 F.2d 21, 29 (D.C. Cir. 1984)). In response, Lannett argues that the FDA's "rescission action was the consummation of the agency's decision-making process to revoke the approval (not a tentative or interlocutory decision), and definitively adjudicated and revoked Lannett's legal right to market Temozolomide capsules," and thus, "the rescission action meets the test for a 'final agency action' under the APA." Pls.' Reply at 27 n.16 (quoting Bennett v. Spear, 520 U.S. 154, 177–78 (1997)). Additionally, Lannett asserts that it "was not required to exhaust administrative remedies before filing this case" because the "FDA's rescission action formally and definitively deprived [it] of its legal entitlement to market Temozolomide capsules." Id. (relying on Darby v. Cisneros, 509 U.S. 137 (1993)).

It is well established that "a court may not review a non-final agency action." Conservation Force v. Salazar, 919 F. Supp. 2d 85, 89 (D.D.C. 2013); see also Holistic Candlers & Consumers Ass'n v. FDA, 664 F.3d 940, 943 (D.C. Cir. 2012) ("The APA, however, only provides a right to judicial review of 'final agency action for which there is no other adequate remedy in a court.'" (emphasis in original) (quoting 5 U.S.C. § 704)). "An agency action is final if it '1) marks the consummation of the agency's decision making process' and 2) affects the 'rights or obligations . . . [or the] legal consequences' of the party seeking review."

Conservation Force, 919 F. Supp. 2d at 89 (omission and alteration in original) (quoting Bennett, 520 U.S. at 177–78); see also Darby, 509 U.S. at 143 ("[T]he finality requirement is concerned with whether the initial decisionmaker has arrived at a definitive position on the issue that inflicts an actual, concrete injury." (quoting Williamson Cty. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City, 473 U.S. 172, 193 (1985))). "But[,] an agency action is 'final for the purposes of [the APA]' only after a plaintiff has exhausted all administrative remedies expressly prescribed by statute or agency rule." Holistic Candlers & Consumer Ass'n v. FDA, 770 F. Supp. 2d 156, 163 (D.D.C. 2011) (second alteration in original) (quoting Darby, 509 U.S. at 146), aff'd, 664 F.3d at 940.

"Another 'long-settled rule of judicial administration' is the principle that a court that has been asked to compel an agency to act 'will stay its hand until the plaintiff has exhausted whatever internal remedies the agency provides[.]" Mackinac Tribe v. Jewell, 87 F. Supp. 3d 127, 137 (D.D.C. 2015) (alteration in original) (first quoting Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50 (1938), then quoting Glisson v. Forest Serv., 55 F.3d 1325, 1326 (7th Cir. 1995)). The purposes of exhaustion include: "giving agencies the opportunity to correct their own errors, affording parties and courts the benefits of agencies' expertise, [and] compiling a record adequate for judicial review[.]" Id. (alterations in original) (quoting Avocados Plus Inc. v. Veneman, 370 F.3d 1243, 1247 (D.C. Cir. 2004)). Consequently, "a plaintiff's failure to pursue an administrative process that could remedy [the] plaintiff's claims will preclude judicial review of agency action, so long as the purposes of administrative exhaustion supports such bar." Id.

Here, the Court does not find that the FDA's May 16, 2016 rescission letter and its accompanying Complete Response Letter constitute a final agency action reviewable under the

APA for several reasons. Initially, the Court notes that this issue—whether the FDA's rescission of a mistakenly approved ANDA and placement of that ANDA back into the review process queue is a final agency action—appears to be one of first impression, as the Court was unable to locate any legal authority addressing this precise issue. Notwithstanding the lack of guidance on this specific issue, sufficient legal authority supports the Court's conclusion. As previously noted, for an agency action to be final, it must first "mark the consummation of the agency's decisionmaking process." Sw. Airlines Co. v. U.S. Dep't of Transp., 832 F.3d 270, 275 (D.C. Cir. 2016) (quoting Bennett, 520 U.S. at 178). To demonstrate that the FDA's rescission action satisfies this first prong of the finality doctrine, Lannett argues that the FDA's action resulted in the "consummation of the agency's decision-making process to revoke the approval" of its ANDA for Temozolomide. Pls.' Reply at 27 n.16. However, Lannett's position is too narrow for the Court to accept, primarily because Lannett's position focuses solely on the rescission of the approval, which Lannett equates as a final agency action. See id. But, "[i]n assessing whether a particular agency action qualifies as final for purposes of judicial review, [this Circuit] and the Supreme Court have looked to the way in which the agency subsequently treats the challenged action." Sw. Airlines Co., 832 F.3d at 275 (citing cases). Applying that principle to what occurred in this case, although the FDA did rescind Lannett's ANDA approval, the FDA expressly advised Lannett that its ANDA was "now in pending status." A.R. FDA822. The FDA also informed Lannett that if it "submit[ed] an amendment to [its] ANDA, as [Lannett's April 21, 2016] letter suggest[ed it was] considering, to substitute an alternative supplier for Lummy, [the FDA] w[ould] give that amendment . . . prompt attention." Id. In addition, the FDA's cGMP Complete Response letter submitted along with the rescission letter specifically outlined the regulatory options available to Lannett and the procedures that Lannett was required

to satisfy to reacquire approval of its ANDA. See A.R. FDA826 ("Within one year after the date of this letter, you are required to respond by taking one of the actions available under 21 C.F.R. § 314.110(b)). Thus, the FDA's rescission action did not represent the conclusion of its decision-making process regarding the review process for Lannett's ANDA or its ultimate decision to either approve or deny Lannett's ANDA. See Rhea Lana, Inc. v. U.S. Dep't of Labor, 824 F.3d 1023, 1032 (D.C. Cir. 2016) ("[This Circuit has] repeatedly held that agency action is not final if the adverse effects of the action depend 'on the contingency of future administrative action.'" (quoting DRG Funding Corp. v. Sec'y of Hous. & Urban Dev., 76 F.3d 1212, 1214 (D.C. Cir. 1996))).

Nonetheless, even if the FDA's rescission action could be perceived as the consummation of its decision-making process, the Court is not convinced that this action satisfies the second prong of the finality doctrine, i.e., an action "by which [Lannett's] rights or obligations have been determined." Id. at 1026 (quoting Bennett, 520 U.S. at 178). As support for its position that the second prong is satisfied, Lannett argues that the FDA "definitively adjudicated and revoked Lannett's legal right to market Temozolomide capsules." Pls.' Reply at 27 n.16. However, Lannett "pictures itself, quite incorrectly, as having been deprived of a vested right. [Rather, i]t had no right to put on the market a drug when facts were available indicating that the public health might be injured." Am. Therapeutics, Inc. v. Sullivan, 755 F. Supp. 1, 2 (D.D.C. 1990) (denying the plaintiff's motion for judgment on the pleadings because the FDA, which had rescinded its approval of the plaintiff's new drug application, was "entitled to some deference," as it made "a good faith mistake [that was] promptly discovered and corrected, nothing more"). Additionally, the FDCA expressly precludes the FDA from approving an ANDA if it finds that "the methods used in, or the facilities and controls used for, the manufacture, processing, and

packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity." See 21 U.S.C. § 355(j)(4)(A). Therefore, based on the facts available to the FDA at the time it mistakenly approved Lannett's ANDA, the FDA expeditiously rescinded Lannett's authorization to market the Temozolomide capsules because that authorization was not legally valid, a conclusion that Lannett does not challenge. See Pls.' Mem. at 21–41 (primarily arguing that the FDA was required under § 355(e) to provide Lannett with notice and a pre-rescission hearing because the information regarding Lummy's failure to comply with cGMP requirements were not before the FDA personnel who actually made the approval decision). Thus, as Lannett did not have a validly vested legal right given the incomplete information that had been made available to the FDA, it appears that Lannett "seeks only to profit from [the] FDA's inadvertent and quickly corrected mistake." Am. Therapeutics, Inc., 755 F. Supp. at 2.[3]

Furthermore, the FDA's rescission action cannot be considered final because Lannett has yet to exhaust all of its available administrative remedies. See Woodford v. Ngo, 548 U.S. 81, 88–89 ("The doctrine [of exhaustion of administrative remedies] provides 'that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.'" (quoting McKart v. United States, 395 U.S. 185, 193 (1969))). As explained in the FDA's cGMP Complete Response Letter, Lannett was obligated to comply with the procedures provided in the FDA's regulations by either resubmitting or supplementing its ANDA, withdrawing its ANDA, or requesting an opportunity for a hearing. See A.R. FDA826; see also 21 C.F.R. § 314.110(b). Instead of pursuing one of these administrative remedies, Lannett opted to file this action seeking judicial review. See generally Compl.; Pls.' Mem. However, Lannett "must exhaust [all available administrative remedies] before proceeding to

[3] But, even if Lannett did have "a right [that] had vested, [Lannett] was not deprived of a factual hearing to prove its qualifications to make and sell the [Temozolomide capsules], and, given the circumstances, the post-denial hearing offered easily met due process requirements." Am. Therapeutics, Inc., 755 F. Supp. at 2.

federal court." Conservation Force, 919 F. Supp. 2d at 90 (granting summary judgment because the plaintiffs failed to exhaust the administrative remedies available to them under the agency's regulations).

Moreover, the Court agrees with the FDA that requiring Lannett to exhaust the agency's administrative remedies fulfills the purposes of the exhaustion doctrine. See Defs.' Mem. at 44–45. As the Supreme Court observed, "[e]xhaustion gives an agency 'an opportunity to correct its own mistakes with respect to the programs it administers before it is haled into federal court,' and it discourages 'disregard of [the agency's] procedures.'" Woodford, 548 U.S. at 89 (second alteration in original) (quoting McCarthy v. Madigan, 503 U.S. 140, 145 (1992)) In addition, "exhaustion promotes efficiency." Id.; see also id. ("Claims generally can be resolved much more quickly and economically in proceedings before an agency than in litigation in federal court. In some cases, claims are settled at the administrative level, and in others, the proceedings before the agency convince the losing party not to pursue the matter in federal court. And even where a controversy survives administrative review, exhaustion of the administrative procedure may produce a useful record for subsequent judicial consideration." (internal quotation marks and citation omitted)). In this case, permitting Lannett to proceed with this litigation in its current posture would disregard the procedures provided by the FDA in 21 C.F.R. § 314.110(b) and undermine the FDA's ability to correct, if appropriate, the mistakes alleged by Lannett. See Garlic v. FDA, 783 F. Supp. 4, 5 (1992) ("[B]ypass[ing] the administrative remedies would undermine the entire regulatory process.").

Also, requiring Lannett to exhaust the available administrative remedies would aid judicial review in several respects. For example, Lannett could persuade the FDA that its ANDA should be approved through its anticipated supplement to its ANDA, wherein it intimates that

another manufacturer may be substituted to supply the Temozolomide capsules, and this could possibly eliminate the need for judicial review. See Defs.' Mem. at 45. Alternatively, Lannett could request a hearing on "whether there are grounds for denying approval of . . . [its ANDA]." 21 C.F.R. § 314.110(b)(3). The FDA would then be required to either approve or deny Lannett's ANDA and provide Lannett with a hearing. See id. And, this would amount to a final agency action that would be subject to review by the Circuit. See 21 U.S.C. § 355(h) (granting the Circuit exclusive jurisdiction over appeals of an order refusing or withdrawing approval of an ANDA application). Consequently, judicial review would benefit from Lannett exhausting the administrative remedies available to it under 21 C.F.R. § 314.110(b).

## V. CONCLUSION

For the foregoing reasons, the Court concludes that the FDA's rescission action is not a final agency action subject to judicial review under the APA. Furthermore, Lannett failed to exhaust all of its available administrative remedies pursuant to 21 C.F.R. § 314.110(b) prior to bringing this case to federal court. Accordingly, the Court must grant summary judgment in favor of the defendants.[4]

**SO ORDERED** this 25th day of October, 2017.[5]

REGGIE B. WALTON
United States District Judge

[4] Having concluded that the FDA's rescission action is not a final agency action within the meaning of the APA and that Lannett failed to exhaust all of its available administrative remedies, the Court need not address the merits of Lannett's claims under the APA. Additionally, the Court's conclusion is applicable to Lannett's constitutional claim, which, as Lannett asserts, "should be adjudicated . . . with the other four integrally-related [APA] claims." Pls.' Reply at 27 n.16 (noting that Darby and the exhaustion doctrine explained therein should apply to its constitutional claim). Moreover, given that the Court finds it unnecessary to address the merits of Lannett's claims, the Court will also deny as moot the defendants' motion to strike extra-record documents.

[5] The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.