NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAIHO PHARMACEUTICAL CO., LTD., *a Japanese Limited Liability Company*, *et al.*,

Plaintiffs,

v.

JOHN SQUIRES, *in his official capacity as the Director of the United States Patent and Trademark Office*, *et al.*,

Defendants.

Civil Action No. 25-17280 (ZNQ) (JBD)

OPINION

QURAISHI, District Judge

THIS MATTER comes before the Court upon two motions for summary judgment. The first motion is filed by Defendants John Squires, in his official capacity as the Director of the United States Patent and Trademark Office, the United States Patent and Trademark Office, Martin A. Makary, in his official capacity as the Commissioner of the Food and Drug Administration, the United Sates Food and Drug Administration, Robert F. Kennedy, in his official capacity as the Secretary of Health and Human Services, and the United States Department of Health and Human Services (collectively, the "Government"). ("Defs.' Mot. for Summary J.", ECF No. 17 at *1–3.) The Government's Motion was accompanied by a moving brief. ("Defs.' Moving Br.", ECF No. 17 at *4–51.[1]) Plaintiffs Taiho Pharmaceutical Company, Ltd., and Taiho Oncology, Inc.

[1] The Government filed its Notice of Motion and its moving brief in the same ECF filing. When the Court cites to pages within the Government's moving brief, the Court is referring to the page numbers found on the bottom-center of the brief and not the pages atop the ECF header. The page numbers that are preceded by an asterisk within a record cite, however, refer to the page numbers atop the ECF header.

(collectively, "Taiho") filed an opposition to the Government's Motion ("Pls.' Opp'n Br.", ECF No. 24), and the Government replied ("Defs.' Reply Br.", ECF No. 26).

The second motion is filed by Taiho. ("Pls.' Mot. for Summary J.", ECF No. 18.) Taiho's motion was accompanied by a moving brief. ("Pls.' Moving Br.", ECF No. 18-1.) The Government opposed ("Defs.' Opp'n Br.", ECF No. 23), and Taiho filed a reply ("Pls.' Reply Br.", ECF No. 27).

The Court has carefully considered the parties' submissions and decides the Motion without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court will GRANT the Government's Motion for Summary Judgment and DENY Taiho's Motion for Summary Judgment.

I. BACKGROUND AND PROCEDURAL HISTORY

A. STATUTORY AND REGULATORY BACKGROUND

A new drug requires approval from the Food and Drug Administration ("FDA") under Section 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA") before it can be commercially marketed or used. *See* 21 U.S.C. § 355(a). In its New Drug Application ("NDA"), the applicant must conduct extensive clinical studies and submit detailed information for the FDA to determine whether the drug is safe and effective for use. *See id.* §§ 355(b)(1), (d). After the filing of this application, the drug company "undergo[es] a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). "The FDA may approve an NDA only if it determines that the drug in question is 'safe for use' under 'the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.'" *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 476 (2013) (quoting 21 U.S.C. § 355(d)).

The process for submitting an NDA is time consuming, and as a result, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, now known as the "Hatch-Waxman Act," 35 U.S.C. § 156. *Id.* at 476–77. The purpose of the Hatch-Waxman Act is to "provid[e] patent holders with limited extensions of [their] patent term in order to recover a portion of the market exclusivity lost during the lengthy process of development and FDA review." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (citations omitted). The Hatch-Waxman Act, accordingly, was designed to compensate for FDA delay by permitting a patentee to apply for a patent term extension ("PTE"). *Merck & Co. v. Kessler*, 80 F.3d 1543, 1552 (Fed. Cir. 1996); *see also* 35 U.S.C. § 156(a). A PTE application must be filed with the United States Patent and Trademark Office ("USPTO") "within [a] sixty-day period beginning on the date the product received permission . . . for commercial marketing or use." 35 U.S.C. § 156(d)(1). The USPTO's determination as to whether a patent is eligible for an extension is based solely on the representations contained in the application for a PTE. 37 C.F.R. § 1.750. To that end, the USPTO must then determine whether the patent is eligible for an extension under subsection (a) of Section 156, and must assess, *inter alia*, whether the PTE application complies with the timeliness requirement under subsection (d)(1). 35 U.S.C. § 156(e)(1). The FDA shares a small role in this process—upon request from the USPTO, the FDA will confirm certain details, such as the date the NDA was initially submitted to the FDA and the date the NDA was approved. *Id.* § 156(g)(1)(B)(ii); 21 C.F.R. § 60.1(a) (describing the FDA's actions in connection with the review of PTE applications).

B. FACTUAL BACKGROUND[2]

Taiho is the assignee of U.S. Patent Nos. 9,108,973 and 10,434,103 (respectively "the '973 Patent" and "the '103 Patent," and collectively the "Patents"). (PTO at 1, 724.[3]) The '973 Patent was issued on August 18, 2015, and the '103 Patent was issued on October 8, 2019. (*Id.*) The Patents disclose various formulations of a 3,5 Disubstituted Alkynyl Benzene Compound, which Taiho describes as relevant to its cancer drug, LYTGOBI. (*Id.* at 400, 749.) Taiho sought the FDA's approval to market LYTGOBI in the United States in accordance with Section 505 of the FDCA. (FDA at 270.)

On Friday, September 30, 2022, at 12:08 P.M. Eastern Time, the FDA issued an approval letter (the "Original Approval Letter") permitting Taiho to market LYTGOBI, and sent a copy of the Original Approval Letter to Taiho by e-mail at 12:15 P.M. (*Id.*; FDA at 1555.) On the same day, Taiho alerted the FDA that the "Initial U.S. Approval" date in the Prescribing Information section of the Original Approval Letter contained a "YYYY" placeholder for the year 2022. (FDA at 1555.) A few hours later, Taiho sent another e-mail to the FDA stating that it found a minor mistake regarding the storage condition instructions on the carton label, and Taiho stated that it expected to receive a corrected version from its vendor on the following Monday, October 3, 2022. (*Id.* at 1554.) The new storage condition advised users to "[s]tore LYTGOBI tablets at room temperature 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F)." (*Id.* at 304.) Taiho represented that the storage conditions incorporated in the Original

[2] Disposition of this matter solely involves questions of law, and the essential facts are not in dispute. *See Neto v. Thomspon*, 506 F. Supp. 3d 239, 244 (D.N.J.).

[3] The record in this matter consists of the Administrative Record, which was provided to the Undersigned from the parties on a USB-drive. The Administrative Record Indices are found at ECF Nos. 14 and 15. For citation purposes, the Court refers to the PTO and FDA-affiliated Bates Numbers which correspond to the document identified by the Administrative Record Indices.

Approval Letter were "inadvertently carried over from a previous version" of the carton label. (*Id.*)

On October 3, 2022, Taiho sent the FDA a letter formalizing its noted errors and provided the FDA with: (1) a redlined version of the corrected Prescribing Information and Package Insert; (2) a clean version of the corrected Prescribing Information and Package Insert; and (3) updated Carton and Container Labeling image files. (*Id.* at 304–46.) On October 5, 2022, the FDA issued a corrected letter (the "Corrected Approval Letter"), remedying the two errors noted by Taiho. (*Id.* at 1557–89.) The Corrected Approval Letter stated that "[t]he effective action date will remain September 30, 2022, the date of the [O]riginal [Approval] [L]etter." (*Id.* at 1557.) The Corrected Approval Letter was e-mailed to Taiho on October 5, 2022, at 10:31 A.M. (*Id.* at 1553.) On October 13, 2022, Taiho submitted LYTGOBI's final carton and container label, and in the letter providing the final label, acknowledged that its NDA was approved on September 30, 2022. (*Id.* at 381.)

On November 29, 2022, Taiho submitted a PTE application for the Patents[4] to be extended until September 30, 2036. (PTO at 3, 6, 726, 737.) Taiho's PTE application stated that it received permission from the FDA for commercial marketing or use on September 30, 2022 and confirmed that the effective action date for approval is September 30, 2022, despite issuance of the Corrected Approval Letter on October 5, 2022. (*Id.* at 6.) In accordance with 37 C.F.R. § 1.740(a)(5), Taiho certified that its PTE application was submitted within the sixty-day period, which began on September 30, 2022 and ended on November 29, 2022. (*Id.* at 7.)

On September 30, 2023, the USPTO sent the FDA correspondence seeking assistance in confirming certain details of LYTGOBI's NDA application. (*Id.* at 178.) In this letter, the USPTO

[4] Although Taiho submitted a PTE application for the '973 Patent and a PTE application for the '103 Patent separately, the parties refer to it as one singular PTE application. For consistency, the Court does the same.

suggested that the PTE applications were not timely filed and, therefore, Taiho's PTE would not be eligible for an extension of the patent term under 35 U.S.C. § 156. (*Id.*) On January 24, 2024, the FDA responded to the USPTO's correspondence and confirmed that its approval was transmitted on September 30, 2022, making the submission of the PTE application on November 29, 2022 untimely under 35 U.S.C. § 156(d)(1). (FDA at 558–59.)

Taiho quickly amended its PTE application two weeks later. (PTO at 184.) The amended application revised the date on which LYTGOBI received FDA permission for commercial marketing or use from September 30, 2022 to October 5, 2022. (*Id.* at 186.) Contemporaneously, Taiho sent the FDA a letter arguing that the errors in the Original Approval Letter prevented the FDA from granting permission for commercial marketing or use because it would have constituted false or misleading branding under the FDCA's enforcement provision, 21 U.S.C. § 352(a)(1). (FDA at 560–65.) Taiho thus contended that valid FDA permission for commercial marketing or use did not exist until October 5, 2022. (*Id.* at 565.)

The USPTO issued a Notice of Final Determination on March 18, 2024, finding that Taiho's PTE application was ineligible for an extension due to Taiho's untimely submission, and the USPTO rejected October 5, 2022 as the date on which LYTGOBI received permission for commercial marketing or use by the FDA. (PTO at 226–28.) The USPTO first explained that Taiho received FDA approval on September 30, 2022 at 12:08 P.M., and that the sixty-day period to submit a PTE application commenced on that date. (*Id.* at 226–27.) As such, the USPTO determined that Taiho's PTE application should have been submitted on November 28, 2022, and Taiho's submission on November 29, 2022 was therefore untimely. (*Id.* at 227–28.) Moreover, the USPTO found that Taiho's amended PTE application containing an October 5, 2022 approval

date was "wholly uncorroborated," and as such, insufficient to overcome the USPTO's findings that Taiho's submission was untimely. (*Id.* at 228.)

Taiho sent another letter to the FDA requesting that it corroborate the October 5, 2022 approval date. (FDA at 761.) The FDA responded that it deferred to the USPTO, which was ultimately responsible for determining the timeliness of PTE applications. (*Id.* at 975–76.) The FDA also explained that the USPTO did not request the FDA's assistance with regard to the revised October 5, 2022 approval date submitted in connection with Taiho's amended PTE application. (*Id.*)

Taiho sought reconsideration of the USPTO's decision on October 3, 2024, which the USPTO denied on March 27, 2025. (PTO at 240, 698.) The USPTO asserted that the September 30, 2022 date constituted the triggering event to begin the sixty-day period under Section 156(d)(1). (*Id.* at 698.) The USPTO explained that its PTE determination was based on the representations contained in the PTE application, citing to Taiho's own admissions that its product received permission for commercial marketing use on September 30, 2022, and that the sixty-day period to file the PTE application commenced on the same date. (*Id.* at 700-01.) For those same reasons, the USPTO rejected Taiho's position that it received valid permission on October 5, 2022. (*Id.* at 702–03.) The USPTO's decision denying reconsideration constituted a final agency decision within the meaning of 5 U.S.C. § 704. (*Id.* at 704.)

Taiho initiated the present action on November 6, 2025. (*See* "Compl.", ECF No. 1.) Given that no discovery exchange was required for the present action, the parties each moved for summary judgment on April 29, 2026.

II. SUBJECT MATTER JURISDICTION

This Court has subject matter jurisdiction over this matter pursuant to 18 U.S.C. § 1331 insofar as Taiho's claims arise under federal law and has exclusive jurisdiction under 18 U.S.C. § 1338 insofar as Taiho's claims arise under statutes pertaining to patents.

III. LEGAL STANDARD

"Summary 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 [Administrative Procedures Act ("APA"), 5 U.S.C. § 551, *et seq.*,] standard of review." *Neto v. Thompson*, 506 F. Supp. 3d 239, 244 (D.N.J. 2020) (quoting *Tomasi v. Township of Long Beach*, 364 F. Supp. 3d 376, 389 (D.N.J. 2019), *aff'd*, 796 F. App'x 766 (3d Cir. 2020)). However, "'the usual summary judgment standard does not apply' in the sense that 'the district court does not need to determine whether there are disputed facts to resolve at trial' [because] 'the administrative agency is the finder of fact.'" *Id.* at 244 (quoting *Soccer Ctrs., LLC v. Zuchowski*, Civ. No. 17-1024, 2017 WL 4570290, at *4 (D.N.J. Oct. 13, 2017)). Instead, "[w]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal. The entire case on review is a question of law." *Id.* at 243–44 (quoting *Am. Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)).

Section 706 of the APA provides that reviewing courts must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706; *accord Chao v. Roy's Const., Inc.*, 517 F.3d 180, 186 (3d Cir. 2008). "An agency decision is 'arbitrary or capricious if it is not reasonable and reasonably explained.'" *In re Yellow Corp.*, 152 F.4th 491, 502 (3d Cir. 2025) (quoting *Ohio v. EPA*, 603 U.S. 279, 292 (2024)). A reviewing court must, therefore, "examine whether the agency gave 'a satisfactory explanation for its action

including a rational connection between the facts found and the choice made.'" *Id.* at 502–03 (quoting *Motor Vehicles Mrfs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Arbitrary and capricious review is narrow — a reviewing court must neither engage in de novo review nor substitute its own judgment for that of the agency. *Id.* at 503. The role of the reviewing court is simply to "ensure[] that the agency acted within the zone of reasonableness." *Id.* (alteration in original) (citation omitted).

To determine whether an agency action is in accordance with federal law or the Constitution, a reviewing court engages in de novo review. *Axalta Coating Sys. v. Fed. Aviation Admin.*, 144 F.4th 467, 472 (3d Cir. 2025) (citing *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 392 (2024) ("Under the APA, it . . . 'remains the responsibility of the court to decide whether the law means what the agency says.'" (citation omitted)). But a reviewing court "must accept an agency's factual findings as conclusive if they are supported by substantial evidence given the record as a whole." *Id.* at 472–73 (internal quotation marks and citation omitted).

IV. DISCUSSION

The parties bring two separate, yet related, motions concerning whether the Government acted contrary to law or arbitrarily or capriciously when it determined that Taiho's PTE application was untimely filed. The Court addresses the parties' motions together; however, the Court concentrates primarily on Taiho's arguments because it bears the burden in demonstrating that the Government acted contrary to law or arbitrarily or capriciously. *See Franchetti v. Cognizant Tech. Sols. Corp.*, Civ. No. 17-6317, 2025 WL 1557034, at *4 (D.N.J. May 30, 2025) (citing *Am. Farm Bureau Fed'n v. EPA*, 984 F. Supp. 2d 289, 309 (M.D. Pa. 2013), *aff'd*, 792 F.3d 281 (3d Cir. 2015)); *accord El Puente v. Army Corps of Eng'rs*, 100 F.4th 236, 246 (D.C. Cir. 2024).

This matter requires the Court to decide five separate issues. The first issue is whether the Government correctly interpreted 35 U.S.C. § 156(d)(1) ("Section 156(d)(1)") to commence the clock for the sixty-day filing period on the same date that the FDA transmitted its approval letter. The second issue is whether the Government's application of the sixty-day period under Section 156(d)(1) was arbitrary and capricious. The third issue is whether the Government acted contrary to law when it determined that the Patents received permission for commercial marketing or use on September 30, 2022. The fourth issue is whether the Government's decision to utilize September 30, 2022 as the date on which the Patents received permission for commercial marking and use was arbitrary and capricious. And the fifth issue is whether the Government acted arbitrarily and capriciously when it declined to consider Taiho's amended PTE application. The Court addresses each issue in turn.

A. THE GOVERNMENT'S INTERPRETATION OF SECTION 156(d)(1) WAS NOT CONTRARY TO LAW

When interpreting a statute, the court "must begin with the statutory text." *Khan v. Att'y Gen.*, 979 F.3d 193, 197 (3d Cir. 2020) (quoting *A.A. v. Att'y Gen.*, 973 F.3d 171, 180 (3d Cir. 2020)). Courts "do not examine [statutory] language in isolation, however." *Hayes v. Harvey*, 903 F.3d 32, 41 (3d Cir. 2018). "Rather, in examining the statutory language, '[courts] take account of the specific context in which that language is used, and the broader context of the statute as a whole.'" *Id.* (quoting *Disabled in Action of Pa. v. Se. Pa. Transp. Auth.*, 539 F.3d 199, 210 (3d Cir. 2008)). The court must "give effect, if possible, to every clause and word of the statute." *Fischer v. United States*, 603 U.S. 480, 486 (2024) (quoting *Williams v. Taylor*, 529 U.S. 362, 404 (2000)). When "the language at issue has a plain an unambiguous meaning with regard to the particular dispute in the case[,] [the] inquiry must cease[.]" *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) (citing *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240 (1989)). When

a statutory provision is ambiguous, however, courts no longer defer to the agency's interpretation of that language. *See Loper Bright*, 603 U.S. at 396. In the event of ambiguity, courts will endeavor to discern Congress's intent using canons of statutory construction. *United States v. Cooper*, 396 F.3d 308, 310 (3d Cir. 2005) (citing *Ki Se Lee v. Ashcroft*, 368 F.3d 218, 222 (3d Cir. 2004)).

As previously discussed, Section 156(d)(1) provides for the extension of patent terms. It states that:

> To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. . . . [S]uch an application may only be submitted *within the sixty-day period beginning on the date the product received permission* under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use . . . .
>
> For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term "business day" means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.

35 U.S.C. § 156(d)(1) (emphasis added).

The Government argues that this language unambiguously creates a sixty-day filing window for a PTE application which commences on, and includes, the date on which the FDA transmits its permission to commercially market or use a new drug. (Defs.' Moving Br. at 16–17.) Taiho submits that the "beginning on" language in Section 156(d)(1) triggers a period to file a PTE application and does not specify whether the date on which a product receives permission should be included or excluded from the sixty-day count. (Pls.' Moving Br. at 10–11.) Taiho thus contends that the absence of a computing methodology in Section 156(d)(1) requires application

of Rule 6(a)(1)(A) of the Federal Rule of Civil Procedure,[5] which provides that "[w]hen the period is stated in days or a longer unit of time[ ] . . . exclude the day of the event that triggers the period." (*Id.* at 9–11.) In response, the Government argues that the computation method provided in Rule 6(a)(1)(A) does not apply because the full text of Section 156(d)(1) specifies the method to calculate the sixty-day period, and the legislative history implementing Section 156(d)(1)'s business day proviso confirms that. (Defs.' Opp'n Br. at 8–13.)

Here, the Court finds that the Government's interpretation employs the most natural reading of the statute. A full reading of the plain language of Section 156(d)(1) leaves no room for equivocation. A PTE application must be submitted within a period of sixty days beginning on the date the product receives permission from the FDA for commercial or marketing use. The date on which a product receives permission must be a business day — a Monday, Tuesday, Wednesday, Thursday, or Friday — before 4:30 P.M., Eastern Time. Reading these provisions together means that the sixty-day period commences on the same date permission for commercial marketing or use is granted so long as such permission is transmitted on a business day before 4:30 P.M., Eastern Time. Conversely, if permission for commercial marketing or use is transmitted after 4:30 P.M. on a business day or on a day that is not a business day, the product is deemed to receive permission on the next business day, and the sixty-day period commences on that subsequent date.

In reaching this conclusion, the Court rejects Taiho's proposed interpretation for several reasons. *First*, Taiho's interpretation fails to read the statute as a whole. *See Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 320 (2014) (noting that a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall

[5] All references to "Rule" or "Rules" hereafter refer to the Federal Rules of Civil Procedure.

statutory scheme." (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000))). If the Court were to adopt an interpretation that excludes the date the applicant receives permission from the FDA, it would fundamentally alter the statutory definitions consistently delineating the point at which certain periods begin under Section 156. For example, while the court in *Medicines Company v. Kappos*, 699 F. Supp. 2d 804 (E.D. Va. 2010) ("*Medicines I*") and *Medicines Company v. Kappos*, 731 F. Supp. 2d 470, 474–77 (E.D. Va. 2010) ("*Medicines II*") did not squarely address the question presented here, its dicta sheds light on whether Congress intended for Section 156(d)(1)'s sixty-day period to begin on the same date the FDA concludes its regulatory review.

The court in *Medicines I* and *II* addressed whether the USPTO should adopt a business day construction in determining what date the product receives permission for commercial marketing or use. In *Medicines I*, the court explained Sections 156(d)(1) and 156(g)(1)(B)(ii) have distinct purposes: Section 156(g)(1)(B)(ii) outlines the period of time the FDA takes to review an NDA and the FDA uses a business day rule to demarcate the point at which that regulatory review period starts. 699 F. Supp. 2d at 811. Section 156(d)(1), on the other hand, "refers to the time given to an applicant to prepare and file its [PTE] application. In that context, the focus is on *when the product receives permission* [from the FDA], such that it would be *fair for the applicant's filing period to begin*." *Id.* (emphases added). When the issue came back to the court in *Medicines II*, the court explained that the USPTO's calendar day interpretation

> ignore[d] the fact that the phrase ["sixty-]day period["] does not *start until the applicants are deemed to have received notice* of the FDA's approval — which in the case of after-hours approvals, occurs on the next business day, "beginning on the date" serves the same purpose in [Section] 156(d)(1) and [Section] 156(g)(1)(B)(ii): in both instances, it *defines the start of a period in which a party is required to take some action*. . . . The logic that led the FDA to adopt for itself a business day construction — that the clock should

> not start to run before the party needing to act can reasonably be deemed to be *on notice* — applies with equal force to the construction of [Section] 156(d)(1).

31 F. Supp. 2d at 481 (emphases added). The court concluded that the proper interpretation of Section 156(d)(1) required a business day interpretation to: (1) further the statute's remedial purpose in safeguarding the applicant's sixty-day filing period; and (2) ensure the phrase "beginning on the date" is afforded the same meaning throughout Sections 156(d)(1) and 156(g)(1)(B)(ii). *Id.* at 482–83. Extrapolating from *Medicines I* and *II*, it is therefore clear that Congress intended the sixty-day period to commence on the same date the applicant received notice from the FDA that its product was approved for commercial marketing or use.

Second, while Taiho contends that Section 156(d)(1) is silent on whether it provides a means to calculate the sixty-day period, the broader legislative history confirms that the business day proviso was enacted to clarify when the sixty-day PTE filing period *starts*. *See Lundeen v. 10 W. Ferry St. Operations LLC*, 156 F.4th 332, 340 (3d Cir. 2025) (explaining that "Congress's silence does not render [a] statut[ory provision] ambiguous"). In failing to give effect to the business day proviso, Taiho's proposed interpretation neutralizes the intent Congress had when it enacted Section 37 of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 122-29, 125 Stat. 284 (2011), in light of the decisions in *Medicines I* and *II*. *See Stone v. INS*, 514 U.S. 386, 397 (1995) ("When Congress acts to amend a statute, [courts] presume it intends its amendment to have real and substantial effect."); *see also United States v. Milchin*, 128 F.4th 199, 202 (3d Cir. 2025) (explaining that the canon against surplusage applies with special force when statutory construction renders an entire subparagraph meaningless).

Several indicia of congressional intent confirm that Section 156(d)(1) provides a mechanism to calculate the sixty-day PTE filing period.[6] For example, Section 37 of the AIA is titled "Calculation of [Sixty]-Day Period for Application of Patent Term Extension." *See U.S. v. Quality Stores, Inc.*, 572 U.S. 141, 150–51 (2014) (observing that legislative titles can be useful aids in determining congressional intent). Additionally, certain legislators have expressly confirmed that Section 37 of the AIA addresses how to calculate the sixty-day filing period. *See Brock v. Pierce Cnty.*, 476 U.S. 253, 263 (1986) (explaining that, although not controlling, statements by individual legislators can provide evidence of congressional intent when those statements are consistent with the statutory language and other legislative history); *see also* 157 Cong. Rec. H4480-01, 2011 WL 2495388, at *H4489 (June 23, 2011) (Rep. John Coyners stating that Section 37 of the AIA "addresses the confusion regarding *the calculation of the filing period* for [PTE] applications under the Hatch-Waxman Act. . . ." (emphasis added)); *see also* 157 Cong. Rec. S5402-02, 2011 WL 3962364, at *S5404–05 (Sep. 8, 2011) (Sen. Chuck Grassley stating that "it is wrong . . . for a bureaucracy to have one sort of definition of when [sixty] days begins — whether it is after business hours, if something goes out, or, if something comes in . . . . *So we are talking about how we count [sixty] days*. . . ." (emphasis added)).

Third, the cases utilizing the calculation methodology provided by Rule 6(a)(1)(A) on which Taiho places its reliance are readily distinguishable. For example, Taiho cites to *American Federation of Government Employees, AFL-CIO v. Federal Labor Relations Authority*, 802 F.2d 47, 48–49 (2d Cir. 1986) to support its proposition that the date of the triggering event is excluded

[6] The Court emphasizes that it finds the plain text of Section 156(d)(1) unambiguous, and therefore, dispositive to the issue. However, by referring to the legislative history, the Court is confirming its interpretation against that intended by Congress. *Paskel v. Heckler*, 768 F.2d 540, 543 (3d Cir. 1985) (explaining that it is appropriate to give credence to legislative history when interpreting a statute to comport with its statutory purpose); *see also Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 395–96 (Fed. Cir. 1990) (permitting courts to review the legislative history to inform the court's construction of a statute).

from the period's count. (*See* Pls.' Moving Br. at 14–15.) In *American Federation of Government Employees, AFL-CIO v. Federal Labor Relations Authority*, the Second Cicuit held that Congress did not intend for the date on which the Federal Labor Relations Authority issues a final order subject to judicial review to be counted in the sixty-day period to initiate a petition for review. 802 F.2d at 48–49. In so holding, the Second Circuit found that that neither the plain language nor the legislative history of 5 U.S.C. § 7123(a)[7] resolved the question of Congress's intent. *Id.* at 48. The court, however, found it compelling that the statutory language made a distinction between the date of issuance of a final order from the date of receipt of the final order. *Id.* at 48. Here, unlike 5 U.S.C. § 7123(a), the plain language of Section 156(d)(1) hinges upon the date of receipt such that it is fair to say that an applicant received notice that its product was approved in order to begin counting the sixty-day filing period for a PTE application. *Medicines I*, 699 F. Supp. 2d at 811; *Medicines II*, 31 F. Supp. 2d at 481. Moreover, Taiho does not cite to any caselaw holding that the computation method in Rule 6(a)(1)(A) applies to statutes with no relation to court processes or adjudicatory proceedings.[8]

Fourth, although Section 156 is remedial and designed to compensate a patentee for time lost on its patent term due to FDA delay, *see Merk*, 80 F.3d at 1442, Taiho's proposed interpretation seeking to commence the sixty-day count on the day after the FDA transmitted its permission letter nudges Section 156(d)(1)'s remedial purpose past its intended bounds. *Lundeen*,

[7] The relevant portion of 5 U.S.C. § 7123(a) provides that "[a]ny person aggrieved by any final order of the [Federal Labor Relations] Authority . . . may, during the 60-day period beginning on the date on which the order was issued, institute an action for judicial review of the Authority's order . . . ."

[8] The Court does not mean to suggest that the computation methodology provided by Rule 6(a)(1)(A) would never apply to statutes beyond those relating to judicial proceedings. However, there is no textual support in the plain language of Section 156(d)(1) to indicate that PTE applications are adjudicative in nature. *See, e.g.*, *Brand v. Miller*, 487 F.3d 862, 868 (Fed. Cir. 2007) (noting that USPTO proceedings, generally, do not generally involve formal adjudications). If Congress intended for Rule 6(a)(1)(A)'s computation methodology to apply, such that the date on which a product receives FDA approval for commercial marketing or use is excluded from the sixty-day count in a manner similar to calculating a filing deadline in civil litigation, it can amend Section 156(d)(1) to explicitly say so.

156 F.4th at 340 ("Congress wrote the statute it wrote — meaning, a statute going so far and no further." (internal quotation marks and citation omitted)). Congress intended patentees to have only sixty days to file a PTE application and that count begins on the date the product receives FDA permission. Although the Court recognizes that, in this instance, a literal reading of the statutory text produces a harsh result, such an outcome "alone cannot justify setting aside a statute's natural construction, lest textualism gives way to consequentialism." *Dodd v. United States*, 545 U.S. 353, 359 (2005). Here, the Court's task is simply to construe the language Congress has enacted, not rewrite it. *Duncan v. Walker*, 533 U.S. 167, 172 (2001); *Lewis v. City of Chicago*, 560 U.S. 205, 215 (2010). Against that backdrop, there is no textual support to indicate that Congress intended for the date on which the product receives permission for commercial marketing or use to be excluded from the count.

In sum, the Court holds that Section 156(d)(1) is unambiguous. The plain text of the statute provides that a PTE application must be filed within a sixty-day period beginning on the same date the product receives permission from the FDA for commercial marketing or use. There is no textual support in the statute to exclude the date on which the product receives permission from that count. Accordingly, the Government's interpretation of Section 156(d)(1) is not contrary to law.

B. THE GOVERNMENT DID NOT ACT ARBITRARILY OR CAPRICIOUSLY WHEN IT APPLIED SECTION 156(d)(1) TO BEGIN COUNTING THE SIXTY-DAY PERIOD ON THE SAME DATE TAIHO RECEIVED FDA PERMISSION FOR COMMERCIAL MARKETING OR USE

Taiho contends that, under its interpretation of Section 156(d)(1), the Government acted arbitrarily and capriciously when it began counting the sixty-day period on the date Taiho received FDA permission for commercial marketing and use because the triggering date is excluded from the count. (Pls.' Moving Br. at 9–11.) In its reconsideration decision, the Government explained

that counting day one as the day after the triggering event would be contrary to congressional intent, and that the date the FDA issues notice of a product's approval triggers both the sixty-day filing period and is day one of the sixty-day period. (PTO at 697–703.)

As explained by the Government, its PTE eligibility determination was based solely on Taiho's representations. (*Id.* at 700-01.) Taiho admitted that it received permission from the FDA for marketing and commercial use on September 30, 2022 and that the sixty-day period to file the PTE application commenced on the same date. (*Id.*) Taiho then filed its PTE application on November 29, 2022. (*Id.* at 703.) The Government found that, because the FDA notice was transmitted at 12:08 P.M. Eastern Time, the business day proviso did not apply. (*Id.*) Therefore, the Government found that the sixty-day period commenced on September 30, 2022 and ended on November 28, 2022. (*Id.*) As a result, the Government concluded that Taiho's PTE application was one day late, and thus, untimely. (*Id.*) The Government, here, provided sufficient rationale, tied to substantial record evidence, in concluding that the sixty-day period commenced on September 30, 2022 — the same date on which Taiho received FDA permission for commercial marketing or use.

Accordingly, the Court concludes that the Government did not act arbitrarily or capriciously when it began counting the sixty-day period on the same date Taiho received FDA approval for commercial and marketing use.

C. THE GOVERNMENT DID NOT ACT CONTRARY TO LAW WHEN IT DETERMINED THAT THE PATENTS RECEIVED PERMISSION FOR COMMERCIAL MARKETING OR USE ON SEPTEMBER 30, 2022

Taiho submits that the Government acted contrary to law when it refused to regard the October 5, 2022 date as the date it received FDA permission for commercial marketing and use. (Pls.' Moving Br. at 24–32.) Taiho maintains that the FDA's September 30, 2022 approval was without effect because the FDA effectively approved a misbranded drug under Section 352(a) of

the FDCA, and therefore, Taiho did not have "actual permission" to place a misbranded drug on the market. (*Id.*) The Court finds no merit to this argument.

Under its own regulations, the FDA must approve an NDA for commercial marketing or use unless any of the reasons for refusing an NDA under Section 314.125(b) are present. 21 C.F.R. §§ 314.105(a), (c). One ground for refusing an NDA is a false or misleading label, so long as the applicant is provided notice and an opportunity to be heard.[9] *See* 21 U.S.C. § 355(d) (providing grounds for refusal of an NDA); 21 C.F.R. § 314.125(b)(6) (enumerating that a false of misleading label is a reason for refusing an NDA). Furthermore, a false or misleading label can cause the FDA to withdraw approval of an NDA, so long as there is notice and an opportunity to correct the mislabeling within a reasonable time. 21 U.S.C. § 355(e). The authority to determine whether a product is mislabeled rests with the FDA. *See Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678, 685 (E.D. Pa. 2006) (explaining that "the FDA must initiate an enforcement action in order to find a drug misbranded" (citation omitted)).

Additionally, Taiho's attempt to distinguish "permission for commercial or marketing use" and "FDA approval" of an NDA is unpersuasive. The regulations governing FDA approval under Section 505 of the FDCA provide that "[a] drug product *may be introduced or delivered for introduction into interstate commerce when the [Section] 505(b)(2) application . . . for the drug product is approved*. A [Section] 505(b)(2) application . . . for the drug product *is approved on the date FDA issues an approval letter*[.]" 21 C.F.R. § 314.107 (emphases added). Based on this language, there is no material difference between the date upon which a product receives approval and the date upon which a product receives permission for commercial marketing or use. A drug

[9] Pursuant to Section 352(a), a drug shall be deemed to be misbranded "[i]f its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1).

product may be introduced into commerce on the same date it receives approval under Section 505.

On the other hand, the USPTO is responsible for granting, issuing, or extending patent terms. *See* 35 U.S.C. § 2(a)(1). While the FDA and USPTO may communicate to confirm regulatory details, the USPTO is not congressionally authorized to determine whether the FDA's approval here was valid because of a potentially misbranded label. For the purpose of determining whether a PTE application should be granted, the USPTO's role is to base its decision solely on what information the applicant provides in its PTE application. 37 C.F.R. § 1.750 ("A determination as to whether a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for extension filed in compliance with [Section] 1.740 or [Section] 1.790."); *see also id.* at § 1.740 (providing formal requirements for PTE applications, including the date upon which an NDA was approved for commercial marketing or use). That distinction is important. Contrary to Taiho's position, the USPTO did what it was supposed to do. If the USPTO were to determine that Taiho's product was misbranded, it would be an act outside the scope of the USPTO's authority, which would have been an action that is contrary to law. *See, e.g.*, *Atlantic City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) (noting that an agency's action is contrary to law when it acts in the absence of statutory authority for its act).

Accordingly, the Court concludes that the Government did not act contrary to law when it determined that September 30, 2022 was the date upon which Taiho received FDA approval for commercial marketing or use.

D. THE GOVERNMENT DID NOT ACT ARBITRARILY OR CAPRICIOUSLY WHEN IT FOUND THAT THE PATENTS RECEIVED PERMISSION FOR COMMERCIAL MARKETING OR USE ON SEPTEMBER 30, 2022

Taiho contends that the Government's decision to recognize September 30, 2022 as the date on which LYTGOBI received permission for commercial marketing and use was arbitrary and capricious because the product was misbranded. (Pls.' Moving Br. at 30.) As the Government explained in its reconsideration letter, Taiho admitted[10] in its PTE application that September 30, 2022 was the date on which it received permission and that Taiho unilaterally amended its application to designate October 5, 2022 as the date on which it received permission. (PTO at 699–703.) The Government explained that Taiho failed to show that the FDA actually deemed LYTGOBI to be misbranded or otherwise withdrew permission for commercial marketing or use Taiho's NDA on that basis. (PTO at 699.) Nor did the FDA condition its approval for commercial marketing or use on Taiho submitting any subsequent labeling. (*See id.*) Additionally, the Government recognized that there was no evidence suggesting the minor changes to Taiho's carton and container label necessitated a change to the approval date. (*Id.* at 227.)

Taiho's attempt to distinguish FDA approval of an NDA from FDA permission to commercial market or use an NDA is again unpersuasive. Relying on Sections 156(d) and 156(i), Taiho contends that the sixty-day period for filing a PTE extension begins on the "covered date"[11] which requires both FDA approval and permission for commercial marketing use. (Pls.' Moving Br. at 20–30.) The applicability of that language to the present circumstance is overstated. The "covered date" provision only comes into effect under subsections (d) and (i) if the Secretary of

[10] Indeed, throughout the record Taiho admitted that September 30, 2022 was the date on which it received FDA permission for commercial marketing or use. (FDA at 381; PTO at 6–7.)

[11] A "covered date", under subsection (i) is the later of the date an NDA application is approved under Section 505(b) or "the date of issuance of the interim final rule controlling the drug under" the Controlled Substances Act. 35 U.S.C. § 156(i)).

Health and Human Services requests indexing of a drug product and recommends controls under the Controlled Substances Act. *See* 35 U.S.C. §§ 156(d), (i); 21 U.S.C. § 355(x). Here, there is no evidence in this record demonstrating that Taiho's NDA was recommended for indexing under the Controlled Substances Act, causing subsection (i)'s "covered date" language to apply.

Accordingly, the Court concludes that the Government did not act arbitrarily or capriciously when it determined that September 30, 2022 was the date upon which Taiho received FDA approval for commercial marketing or use.

E. THE GOVERNMENT DID NOT ACT ARBITRARILY OR CAPRICIOUSLY WHEN IT REFUSED TO CONSIDER TAIHO'S AMENDED PTE APPLICATION

Taiho argues that the Government acted arbitrarily or capriciously because it failed to explain why it refused to consider Taiho's amended PTE application. (Pls.' Moving Br. at 31.) In opposition, the Government contends that it rejected Taiho's amended PTE after fulsome consideration and with a substantial analysis. (Defs.' Opp'n Br. at 27–28.)

The Court disagrees with Taiho's contention that the Government failed to explain why it rejected Taiho's amended PTE application, changing the date on which Taiho received permission for commercial marketing or use from September 30, 2022 to October 5, 2022. Here, in the initial denial decision, the Government stated that there was no evidence in the record to corroborate Taiho's amended representation that it received FDA approval on October 5, 2022 given that the Original Approval Letter, the Corrected Approval letter, and Taiho's initial PTE application all provided September 30, 2022 as the approval date. (PTO at 228.) On reconsideration, the Government elaborated that it was required to evaluate the timeliness of Taiho's PTE application based on the representations presented in the PTE application. (*Id.* at 700 (citing 37 C.F.R. § 1.750).) The Government again found that Taiho's initial PTE application received permission for commercial marketing or use on September 30, 2022, and the FDA confirmed that fact. (*Id.* at

700–01; *accord id.* at 13, 391, 734, 558.) With respect to Taiho's amended PTE application, the Government made clear that it rejected Taiho's attempt to revise the identified date of approval from September 30, 2022 to October 5, 2022 because it considered September 30, 2022 to be the date of FDA approval, rendering Taiho's November 29, 2022 PTE application untimely. (*Id*. at 703.) The Government, therefore, did not act arbitrarily or capriciously because there is support in the record for its factual findings and, contrary to Taiho's assertion, articulated why it rejected Taiho's amended PTE application.

Accordingly, the Court concludes that the Government did not act arbitrarily or capriciously when it rejected Taiho's amended PTE application providing for an approval date of October 5, 2022.

The drastic consequences of today's decision are not lost on the Court. It is beyond unfortunate that Taiho has lost valuable patent rights to a drug product due to, what the Court infers was, a mere administrative oversight involving a single day. But the statute is clear in this case, as is the administrative record. The Court is bound by them. Had there been any discretion allotted under these circumstances, the Court would quite confidently have reached a different result. But no such discretion is given here. Whatever relief Taiho hopes to obtain must be left for appellate review or legislative intervention.

V. CONCLUSION

For the reasons stated above, the Court will GRANT the Government's Motion for Summary Judgment and DENY Taiho's Motion for Summary Judgment. An appropriate Order will follow.

Date: October 26, 2026

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE