UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANDOZ, INC, Plaintiff, v. MICHAEL LEAVITT, Secretary of Health, and Human Services, and ANDREW VON ESCHENBACK, Acting Commissioner, Food and Drug Administration, Defendants.	Civil Action No.: Document Nos.:	05-1810 (RMU) 19, 25

MEMORANDUM OPINION

GRANTING THE PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT;
DENYING THE DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Currently before the court is the plaintiff's motion for summary judgment and the defendant's[1] cross-motion for summary judgment. The plaintiff challenges the defendant's inaction in processing the plaintiff's application for a new drug application for the drug Omnitrope. The plaintiff claims that the defendant's delay in acting on the plaintiff's drug application violates a statutory requirement that the defendant act within 180 days of the drug application's submission to the FDA. The defendant does not dispute that it has failed to act within the 180-day time frame, but argues that the time frame is a congressional aspiration rather

[1] The complaint identifies both the Secretary of Health and Human Services, Michael Leavitt, and the Acting Commissioner of the Food and Drug Administration ("FDA") as defendants. For simplicity, the court refers to the defendants collectively as the FDA or as a singular defendant.

than a statutory requirement. In essence, the defendant asks the court to excuse its delay, accept governmental mediocrity and vitiate the statute's mandatory language. Because the defendant's inaction violates an express statutory provision and because the defendant has identified no compelling reason for this court to excuse its delay, the court grants the plaintiff's motion for summary judgment and denies the defendant's cross-motion for summary judgment.

II. BACKGROUND

A. Statutory Framework and Factual Background

The plaintiff, Sandoz, Inc. ("Sandoz"), is a pharmaceutical and biologic medicine manufacturer. Compl. ¶ 11. Sandoz would like to distribute Omnitrope, a growth hormone for use in pediatric patients who have growth failure and adults with growth hormone deficiency. Pl.'s Mot. ¶ 68. Before Omnitrope can enter the marketplace and be disseminated to the American public, the FDA must approve the drug. 21 U.S.C. § 355(a) & (b); Def.'s Mot. at 1. Under the Federal Food, Drug and Cosmetic Act ("FFDCA"), however, the FDA may only approve a drug after finding that the drug is "safe." 21 U.S.C. § 355(a). In determining whether a product is sufficiently safe to warrant approval, the FDA reviews a large amount of clinical data submitted by the drug applicant (through a new drug application ("NDA")), including the following: a listing of the drug's chemical or biological components; a statement of the drug's composition; a description of the drug company's manufacturing, processing, and packaging of the drug; drug samples; patent information; and proposed labeling for the drug. 21 U.S.C. § 355(b)(1). If the FDA approves an NDA, it includes the drug in a publication titled "Approved Drug Products With Therapeutic Equivalence Evaluations." Def.'s Mot. at 2.

For an NDA of a drug which closely resembles a previously approved drug (e.g., generic drugs or an identical drug with a proposed new use or delivery method), the sponsoring drug company may bypass the traditional full NDA process. 21 U.S.C. § 355(b). To do this, the drug company essentially piggybacks its drug application on the FDA's previous findings regarding the approved drug. Compl. ¶¶ 19-21; Def.'s Mot. at 2. The purpose of this abbreviated drug approval mechanism is to strike a "balance encouraging innovation in drug development with accelerating the availability of lower cost alternatives to approved brand-name drugs." *Id.* (citing H.R. Rep. No. 98-857 (Part I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647-48).

The plaintiff submitted an abbreviated NDA for Omnitrope to the FDA on July 30, 2003.[2] Pl.'s Statement. of Material Facts Not in Dispute ("Pl.'s Stmt.") ¶ 12. Sandoz's abbreviated NDA was based, in part, on the FDA's previous approval of Genotropin, a drug manufactured by Pfizer, Inc. Pl.'s Compl. ¶¶ 67, 69-70. According to Sandoz, "Omnitrope is indistinguishable from Genotropin and . . . [is] safe and effective." Pl.'s Stmt. ¶ 32. In May 2004, Pfizer Inc., the approval holder for Genotropin, urged the FDA to reject the Omnitrope NDA. Def.'s Mot. at 5. On August 31, 2004, the FDA sent a letter to the plaintiff informing it that the FDA had completed its review of Omnitrope but that because of the application's "nature and complexity . . . [the] FDA is deferring a decision on whether the data submitted in [the NDA] are adequate to support a conclusion that Omnitrope is safe and effective for the proposed indications." Def.'s Mot., Ex.1.

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[2] According to the defendant, the FDA "accepted" Sandoz's submission on July 31, 2003. Def.'s Mot. at 4.

B. Procedural Background

On September 13, 2005, the plaintiff filed the instant lawsuit. Essentially, the plaintiff argues that the FDA is currently in violation of its statutory obligation to act on the plaintiff's NDA within 180 days of its submission. *See* Compl. Before the court are the parties' cross-motions for summary judgment. These motions present two legal questions to the court. First, is the FDA statutorily required to act within 180 days of an NDA submission? Second, should the court "exercise its equitable powers in enforcing the deadline[?]" *In Re Barr Labs., Inc.*, 930 F.2d 72, 74 (D.C. Cir. 1991). The court turns now to the parties' summary judgment motions.

III. ANALYSIS

A. Legal Standard for a Motion for Summary Judgment

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a court must look to the substantive law on which each claim rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248.

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true.

Anderson, 477 U.S. at 255. A nonmoving party, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252. To prevail on a motion for summary judgment, the moving party must show that the nonmoving party "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322. By pointing to the absence of evidence proffered by the nonmoving party, a moving party may succeed on summary judgment. *Id.*

In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999); *Harding v. Gray*, 9 F.3d 150, 154 (D.C. Cir. 1993). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Greene*, 164 F.3d at 675. If the evidence "is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (internal citations omitted).

B. The Plaintiff is Entitled to Summary Judgment

This case raises two basic questions regarding the FDA's statutory requirements under the FFDCA: (1) whether the FFDCA requires the FDA to take action on an NDA within 180 days of its submission, Pl.'s Mot. at 25; Def.'s Mot. at 11, and (2) the court's role in ensuring the FDA's compliance with the statutory provision. Pl.'s Reply at 11; Def.'s Mot. at 14. The court rules that the 180-day statutory provision imposes a mandatory obligation on the FDA and that the FDA failed to so act. The court also rules that equitable relief is appropriate in this case.

1. Legal Standard for Judicial Review of Agency Actions

The APA entitles "a person suffering legal wrong because of agency action, or adversely

affected or aggrieved by agency action . . . to judicial review thereof." 5 U.S.C. § 702. Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706; *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotations omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986); *Tourus Records*, 259 F.3d at 736. An agency action usually is arbitrary or capricious if

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also County of L.A. v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action").

As the Supreme Court has explained, however, "the 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 Veh. Mfrs. Ass'n*, 463 U.S. at 43. Rather, the agency action under review is "entitled to a presumption of regularity." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S.

402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

The court's jurisdiction to entertain the plaintiff's challenge to the FDA's inaction falls under section 706(1) of the Administrative Procedures Act ("APA"). 5 U.S.C. § 706(1). Although civil litigants are typically able to bring suit only for *final* agency action, "agency action" includes, *inter alia*, agency "failure to act." 5 U.S.C. § 551(13). In instances in which a litigant is challenging an agency failure to act, the APA provides relief under section 706. *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004) (quoting section 706 for the proposition that "[t]he reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed"). The court may act under the APA if an agency fails to act by not making "some decision by a statutory deadline." *Id.*, 542 U.S. at 63. The court's authority to act under the APA is limited to compelling the agency "to take a *discrete* agency action that it is *required to take*." *Id.*, 542 U.S. at 64 (emphasis in original). And when the court is justified in acting, its order must be limited to directing the agency to "perform a ministerial or non-discretionary act, or to take action upon a matter, without directing *how* it shall act. *Id*. (emphasis in original).

2. The FFDCA Requires the FDA to Take Action within 180 Days of an NDA

Here, the legal dispute between the parties concerns a single statutory provision, 21 U.S.C. § 355(c). That provision states, *inter alia*, that "[w]ithin one hundred and eighty days after the filing of an [NDA] or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either . . . approve the application" if he doesn't find any grounds for its denial under the statute or "[g]ive the applicant notice of an opportunity for a hearing before the Secretary." 21 U.S.C. § 355(c). The defendant does not dispute the fact that

the agency has not acted in accordance with this statutory provision. Def.'s Mot. at 11. Instead, the defendant argues that the 180-day "time frame" is "aspirational rather than mandatory." *Id.* The defendant's argument is based on its reading of the Prescription Drug User Fee Act of 1992 ("PDUFA"). *Id.*

The PDUFA was enacted by Congress to address the FDA's historic inability to complete NDA reviews within the statutorily proscribed time frame. *Id.* at 11-12. It creates a user-fee program providing the FDA with additional resources to review NDAs. 21 U.S.C. § 379g note. Under the PDUFA, a drug applicant must pay a fee to the FDA which "will be dedicated toward expediting the review of human drug applications." 21 U.S.C. § 379g note.

In establishing the PDUFA, Congress referenced a June 4, 2002 letter from Health and Human Services ("HHS") then-Secretary Tommy Thompson to Senator Edward Kennedy, the Chairman of the Committee on Health, Education, Labor, and Pensions. *Id.* This letter, in turn, references an executive branch document titled the PDUFA Reauthorization Performance Goals and Procedures ("Performance Goals").[3] 148 Cong. Rec. S5195-04 (stating that the "performance goals referenced in [21 U.S.C. § 379g note] are specified in the enclosure to this letter, entitled 'PDUFA Reauthorization Performance Goals and Procedures'").

The defendant argues that then-HHS Secretary Thompson's letter and the referenced Performance Goals modify 21 U.S.C. § 355(c), changing its 180-day time frame from a mandatory deadline to a "performance goal that FDA strives to meet in the large majority of cases but with which FDA is not required to comply as to all drug applications." Def.'s Mot. at

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[3] Senator Kennedy incorporated the letter and the attached PDUFA Reauthorization Performance Goals and Procedures into the congressional record. 148 Cong. Rec. S5195-04.

11. Without saying so, the defendant is actually arguing that the PDUFA, through its circuitous reference to the Performance Goals, repeals by implication 21 U.S.C. § 355(c). *See infra* at n.3. The court cannot agree.

a. Congress' Power to Repeal by Implication

Congress has the authority to suspend or repeal its previous acts. *United States v. Dickerson*, 310 U.S. 554, 555 (1940) (stating that "[t]here can be no doubt that Congress could suspend or repeal (its own acts); and it could accomplish its purpose by an amendment to an appropriations bill, or otherwise"). "The cardinal rule is that repeals by implication are not favored." *Posadas v. Nat'l City Bank of N.Y.*, 296 U.S. 497, 503 (1936); *Bd. of Supervisors of Wood County v. Lackawana Iron and Coal Co.*, 93 U.S. 619 (1876) (stating that courts' disfavor of repeals by implication "is so well settled, that discussion and the citation of authorities are unnecessary"). In determining whether Congress has repealed or suspended a provision through implication, the court first must consider "the plain language of the laws alleged to be in conflict." *Demby v. Schweiker*, 671 F.2d 507, 510 (D.C. Cir. 1981). "Only when the language of two statutes leaves [the court] in doubt as to whether they represent truly irreconcilable intentions [does the court] resort to such legislative history as may bear credibly upon the issue at hand." *Id.* In assessing the two statutory provisions, [t]he courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton v. Mancari*, 417 U.S. 535, 551 (1974).

b. Congress Did Not Repeal[4] or Otherwise Modify[5] 21 U.S.C. § 355(c)

The first step in assessing whether Congress has repealed a statute absent explicitly doing so is to determine whether the two statutory provisions are irreconcilable. *Branch v. Smith*, 538 U.S. 254, 273 (2003) (stating that "[a]n implied repeal will only be found where provisions in two statutes are in 'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and "is clearly intended as a substitute"). In addressing this question, the court turns to the specific statutory provisions in dispute.[6]

The time-frame provision at issue in this case reads as follows:

> Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either--

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[4] The defendant does not argue specifically that 21 U.S.C. § 379g actually repealed 21 U.S.C. § 355(c) but that it "clarified . . . that the time frames specified in 21 U.S.C. § 355(c) are meant to be aspirational rather than mandatory." Def.'s Mot. at 11. Section 355(c) states that the "[w]ithin one hundred and eighty days after the filing of an [NDA], the Secretary *shall*" take one of two specific actions. 21 U.S.C. § 355(c) (emphasis added). This provision is both unambiguous and mandatory. *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) (stating that the mandatory term "shall" normally creates an obligation impervious to judicial discretion"). In essence, therefore, the defendant is asking the court to excise the "shall" from Section 355(c) due to 21 U.S.C. § 379g.

[5] Presumably, the defendant's argument could otherwise be construed as an advocacy for the court to interpret 21 U.S.C. § 379g as a gloss to place over 21 U.S.C. § 355(c). This argument would quickly fail, however, because the court will not engage in an analysis of legislative intent or employ any other cannons of statutory construction when the statute itself is unambiguous. *In re England*, 375 F.3d 1169 (D.C. Cir. 2004); *Guam Indus. Services, Inc. v. Rumsfeld*, 383 F. Supp. 2d 112 (D.D.C. 2005). Section 355(c) is not ambiguous, and the defendant does not advance any argument to the contrary.

[6] The defendant's assertion that Section 355(c) is aspirational comes not from a statute, not from the congressional note to that statute, not to the referenced letter in the congressional note to that statute, but in a document attached to a letter referenced in a note to the statute. *See* "PDUFA Reauthorization Performace Goals and Procedures," *attached to* June 4, 2002 Letter from then-HHS Secretary Thompson to Senator Edward Kennedy, *referenced in* 21 U.S.C. § 379g note.

> (A) Approve the application if he then finds that none of the grounds for denying approval specified in subsection (d)[7] of this section applies, or
> (B) Give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

21 U.S.C. § 355(c). Of particular importance to the discussion herein is the mandatory nature of this statute – that the Secretary of the FDA "shall" take one of two required steps. *Id.* According to the FDA's Performance Goals, this statute requires that the FDA, within 180 days, "review and act on" the NDA, which "is understood to mean the issuance of a complete action letter after the complete review of filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval." 148 Cong. Rec. S5195-04 at XIV.A.

Assuming the referenced document to the letter attached to the note in 21 U.S.C. § 379g could, through some miraculous feat of congressional-referencing-interpretive-gloss osmosis, effectively alter the mandatory nature of Section 355(c), the court considers the referenced

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[7] Sub-section (d) identifies seven criterion the Secretary may use in denying approval of an NDA. 21 U.S.C. § 355(d). The defendant indicates that it is not yet prepared to render any findings regarding Omnitrope. Def.'s Mot. at 16-18. In so stating, the defendant in essence concedes that it has not yet found grounds for denying approval of Omnitrope as specified in section 355(d). Under sub-section (c), the FDA's statutory obligation seems clear. 21 U.S.C. § 355(c) (stating that the Secretary "shall . . . [a]pprove the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies"). The Secretary's other statutory option is to afford the applicant "notice of an opportunity for a hearing." *Id.*

document head on.[8] That document concerns "performance goals and procedures of the FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation." 148 Cong. Rec. S5195-04. The relevant portions of the document, as summed up by the defendant, indicate that the "FDA aspires to act on ninety percent of standard original NDA submissions within ten months and to act on ninety percent of priority original NDA submissions within six months." Def.'s Mot. at 13 n.6 (citing 148 Cong. Rec. S5195-04). The court finds nothing in this statement, or in the document itself, which is irreconcilable with the express provisions of section 355(c). *Demby*, 671 F.2d at 510. The referenced document concerns the FDA's goals, not the FDA's statutory obligations.[9] And the mere fact that the FDA sets its aspirations somewhere below what the statute requires is not reason enough to ease the statutory provision. The FDA must comply with the statute, not visa-versa.

The context in which Congress incorporated this letter into the congressional record is also detrimental to the defendant's argument. True, Congress recognized the FDA's inability to meet the statutory deadline. *See* 21 U.S.C. § 379g note. But in response, Congress took no direct action to modify the 180-day action window but instead created a program, the PDUFA, to

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[8] The court must note that the congressional reference to the letter is not for the express purpose of congressional codification as law, but solely within the context of specifying the agency's "drug development process and the process for the review of human drug applications." 21 U.S.C. § 379g note. Thus, even if the letter (actually, the document attached to the letter) speaks specifically to the mandatory as opposed to the aspirational nature of section 355(c), the court has serious reservations as to its legal affect on section 355(c). The defendant's lack of briefing on this point certainly doesn't help.

[9] The court typically affords "considerable weight . . . to an executive department's construction of a statutory scheme." *Chevron,* 467 U.S. 837, 844 (1984). Such deference is only appropriate, however, when Congress delegated authority to the agency. *U.S. v. Mead Corp.*, 533 U.S. 218, 232 (2001) (ruling that deference was not appropriate because the statute on its face gave "no indication that Congress meant to delegate authority to the executive").

boost the FDA's resources. 21 U.S.C. § 379g. Had Congress meant to transmogrify section 355(c) from a mandatory statutory requirement to a non-mandatory goal, it most likely would have acted directly on the statute, changing for example "shall" to "may." Absent this type of express congressional action, the court is unwilling to alter the 180-day action requirement simply because the FDA cannot cope. *Gemsco v. Walling*, 324 U.S. 244, 260 (1945) (stating that the "plain words and meaning of a statute cannot be overcome by a legislative history which through strained processes of deduction from events of wholly ambiguous significance, may furnish dubious bases for inference in every direction"). Whether the 180-day action requirement is realistic, whether it should be aspirational, and whether the FDA's performance goals should be the standard by which the legal requirements imposed upon it are questions better left to Congress. The court is the steward, not the craftsman, of the law, and the defendant's remonstrations to section 355(c) have already been heard, and addressed, by Congress. *See e.g.*, 21 U.S.C. § 379.

3. The Defendant's Violation of 21 U.S.C. § 355(c) is Judicially Cognizable and Merits Equitable Relief

Having ruled that the defendant is required to take action on the plaintiff's NDA within 180 days of its filing, and the defendant's failure to dispute that such action never took place, the court now considers what it must do in response. The defendant says that the court should do nothing, citing *In Re Barr* for the proposition that "[e]quitable relief . . . does not necessarily follow a finding of a violation: respect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities." Def.'s Mot. at 14 (quoting *In Re Barr*, 930 F.2d at 74). *In Re Barr* involves facts substantially similar to those presented in this case. In that case, drug manufacturers sued to

compel the FDA to expedite its processing of NDAs under 21 U.S.C. § 355(c). *In Re Barr*, 930 F.2d 72.

In assessing whether an agency's statutory violation necessitates the court's exercise of its equitable powers, the court must weigh six factors (the "TRAC factors"):

> (1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

Telecomm. Research and Action Ctr. [TRAC] *v. F.C.C.*, 750 F.2d 70 (D.C. Cir. 1984) (internal citations and quotations omitted). In assessing the TRAC Factors, the court closely models its analysis after the D.C. Circuit's analysis in *In Re Barr.*

As in *In Re Barr*, the court "assume[s] that Congress's 180-day deadline indeed supplies content for item one's 'rule of reason', but a finding that delay is unreasonable does not, alone justify judicial intervention." *In Re Barr*, 930 F.2d at 75. After dispensing with TRAC factors one and two, the circuit court next considered prongs three and four, which consider whether the delay involves "human health and welfare" or "economic regulation," and whether the effects of judicial intervention on agency activities are of a higher or competing priority. *Id.* For these factors, the circuit court concluded that swift approval of new drugs certainly benefits the public health and welfare. But, when juxtaposed against the concomitant delay that expedited review for this drug manufacturer would have on other drug manufacturers' NDAs, the D.C. Circuit found no net benefit to the public welfare. *Id.* This court is bound by that analysis.

Although the court in *In Re Barr* did not explicitly tackle the sixth TRAC factor, this factor is particularly compelling in this case, and is substantially at odds with the facts presented to the D.C. Circuit in *In Re Barr*. In considering TRAC factor six, the court "need not 'find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'" *Id.*, 930 F.2d at 74 (quoting *TRAC*, 750 F.2d at 80). In *In Re Barr*, the circuit court did not find the FDA's inaction to be "egregious" for two principal reasons, both of which differ from this case. *Id.* at 75 (indicating that a common practice in the circuit is to consider whether the delay is "egregious") (citing *In Re Monroe Commc'ns Corp.*, 840 F.2d 942, 946 (D.C. Cir. 1988)). First, the plaintiff in *In Re Barr* had not shown that the FDA "singled it out for mistreatment" and the circuit refused to consider this claim because the plaintiff first raised the issue in its reply brief. *Id.*, 930 F.2d at 75 (stating that because "Barr raised the issue only in its reply, respect for the adversary process makes it inappropriate to address the claim at all"). In contrast, the plaintiff here claims that the FDA is treating it disparately. Pl.'s Mot. at 35. The plaintiff supports this claim, for example, by representing to the court that the FDA has recently approved NDAs for "recombinant hyaluronidase, calcitonin, and glucagon, as well as other approved 505(b)(2) NDAs for naturally-sourced products such as hyaluronidase and menotropins, and other biologic drugs." Pl.'s Mot. at 35. The defendant does not dispute this fact, Def.'s Mot. at 24, rather, it contends that "given the complexity of scientific and regulatory issues to be reviewed in a drug application" they are "*sui generis*."[10] *Id.* While the defendant has a point – that drug applications are inherently complex – the defendant's position seeks to place

[10] "*Sui generis*" is defined as: "Of its own kind or class; unique or peculiar." BLACK'S LAW DICTIONARY 1448 (7th ed. 1999).

the plaintiff in an untenable position: maintaining the position that the plaintiff must prove disparate treatment while arguing that a showing of disparate treatment is not feasible because of legitimate scientific differences between the drugs.

Although the plaintiff's reference to other recent drug approvals does not necessarily prove that it is being singled out, it does demonstrate that the FDA's drug approval process does not take the form of a first in, first out operation. *See Summers v. Dept. of Justice*, 925 F.2d 450, 452 n.2 (D.C. Cir. 1991) (citing *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976) for the proposition that an agency exercised due diligence, in part, because it processed document requests under the Freedom of Information Act on a "first in, first out basis"). As such, an order expediting the plaintiff's NDA would not directly bottleneck other NDAs. The proper focus when considering delay is not whether other NDAs would be delayed by the prompt completion of this plaintiff's NDA, but whether the completion of this plaintiff's NDA has languished while other NDAs have been processed.[11] *In re Am. Rivers and Idaho Rivers United*, 372 F.3d 413 (D.C. Cir. 2004) (finding a lengthy agency delay unreasonable in part because of the delay was "uncharacteristic of the relatively swift treatment it routinely gives similar petitions"). For this reason, the FDA's approval of other drugs, while this plaintiff's NDA remains stuck in the ether, constitutes a factor that this court considers in determining the reasonableness of the FDA's delay in processing or completing its review of the plaintiff's NDA and whether that delay is "egregious." *See In Re Monroe*, 840 F.2d at 945 (stating its

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[11] Section 355(c) does not necessarily require that the agency formulate its final decision as to the safety of Omnitrope within 180 days of its submission. 21 U.S.C. § 355(c). Rather, the agency may first offer the plaintiff notice of an opportunity for a hearing. *Id.* In light of this fact, an order directing the FDA to comply with the statute does not necessarily equate with putting the plaintiff at the head of the queue, a primary concern to the circuit court in *In Re Barr*. *Cf. In Re Barr*, 930 F.2d 72, 75 (D.C. Cir. 1991).

consideration of whether the agency's inaction is "unreasonably slow").

Second, presumably responding to the D.C. Circuit's suggestion that "[p]erhaps Congress should earmark more funds," *In Re Barr*, 930 F.2d at 75, Congress created the PDUFA as a mechanism for "making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of human drug applications and the assurance of drug safety." 21 U.S.C. § 379g. With additional funds now available to the FDA for its processing of NDAs, unreasonableness in agency's delay comes sooner than it did prior to the PDUFA. In short, with higher funds comes higher expectations. Thus, unlike in *In Re Barr*, in which a driving force behind the FDA's delay was its lack of funding, here, the funding drought has been ameliorated. Perhaps the circuit court in *In Re Barr* would have considered the FDA's delay of roughly 489 days as sufficiently egregious to warrant judicial intervention if a funding shortage were not at issue.[12] In this case, however, the court is presented with an agency delay almost double that faced by the court in *In Re Barr*, and roughly a quintuplicate to the time permitted by Congress. If egregiousness is to have any meaning, it must include those instances in which an agency fails to act within five times that required by Congress, particularly after the agency's prayers for additional funds have been answered. And though the agency's decision of how to allocate its resources is entitled to deference, *In Re Barr*, 930 F.2d at 76, such deference yields when the statutory violation (here an excruciatingly long delay) is egregious and ceases to be reasonable. *In Re Monroe*, 840 F.2d at 945.

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[12] The D.C. Circuit, in dismissing *In Re Barr* and finding no point in "maintaining constant supervision over the FDA's progress," invited the plaintiff to "refile should circumstances arise that would change the outcome" of the court's analysis. *Id.* at 76. This court believes that the current case presents exactly those changed circumstances which justify judicial intervention.

In tracking the TRAC factors as discussed *supra*, the court concludes as follows. First, Congress' 180-day action requirement provides a strong indication that the FDA's nearing 1000-day response time is unreasonable. Second, the delay at work here is less tolerable than in other instances because the FDA has prioritized other NDA applications over the plaintiff's. Third, given Congress' grant to the FDA of additional funds to process NDAs, (via the PDUFA program), the FDA's nearing 1000 days in processing the plaintiff's NDA, or otherwise complying with the statute, is egregious.[13] *See In re Am. Rivers and Idaho Rivers United*, 372 F.3d at 419 (stating that "a reasonable time for agency action is typically counted in weeks or months, not years").

In light of the egregiousness of the FDA's delay in addressing the plaintiff's NDA, the court rules that relief is justified in this case. The court's ruling does not necessarily require the agency to adopt its final conclusion to the plaintiff's NDA, but merely to comply with the statutory requirements. *Norton*, 542 U.S. at 64. Among them, the Secretary may give the applicant notice of a hearing before the Secretary on the question of whether the plaintiff's application is approvable. 21 U.S.C. § 355(c). The plaintiff is entitled to an end to this

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[13] The defendant's briefing is particularly troubling in that it seems to take *TRAC* and *In Re Barr* as *de facto* invitations for the FDA to not comply with Congress' mandates. In essence, by failing to interject when an agency has unequivocally violated a statute, a court sacrifices the legislature's prerogatives at the altar of the executive agency's prerogatives. When the agency presents to the court a significant justification for the delay, or where the delay is not, itself, egregious, the court will extend the agency leniency in its diligent attempts to comply with the statute. *See In Re Barr*, 930 F.2d at 76 (stating that the court, given the facts presented, has "no basis for reordering agency priorities"). However, when the agency's shortcomings are egregious, the court will take action. *In re Am. Rivers and Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004) (quoting *TRAC* and indicating the appropriateness of court interference "with the normal progression of agency proceedings to correct transparent violations of a clear duty to act . . . because [i]t is obvious that the benefits of agency expertise and creation of a record will not be realized if the agency never takes action") (internal citations omitted).

"marathon round" of "keep-away and soon." *In re Am. Rivers and Idaho Rivers United*, 372 F.3d at 420.

IV. CONCLUSION

For the foregoing reasons, the court grants the plaintiff's motion for summary judgment and denies the defendant's motion for summary judgment. An order consistent with this Memorandum Opinion is issued contemporaneously this 10th day of April, 2006.

RICARDO M. URBINA
United States District Judge