UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STAT-TRADE INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 11-1789 (ABJ)
FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiff Stat-Trade, Inc. ("Stat-Trade") brings this action against the United States Food and Drug Administration ("FDA"), its commissioner Margaret Hamburg, and the Secretary of the Department of Health and Human Services, Kathleen Sebelius, for declaratory, mandamus, and injunctive relief. Stat-Trade is a small pharmaceutical company subject to fees under the Prescription Drug User Fee Act of 1992, as amended ("PDUFA"). It has filed a motion for summary judgment, [Dkt. # 19], and defendants have moved to dismiss or, in the alternative, for summary judgment, [Dkt. # 20].

Stat-Trade asserts two claims: first, it argues that since fiscal year 2009, FDA has required Stat-Trade to pay yearly fees for two pharmaceutical products that should have been exempt under the statute. The Court finds that the two products do fall under the statutory exception. However, since Stat-Trade failed to contest the charges from fiscal years 2009–2011 within the statutorily mandated time, it is barred from asserting the exception for those fees now. Accordingly, the Court will grant Stat-Trade's motion for summary judgment on Count I as to the fiscal year 2012 fees, but will deny it as to the fiscal year 2009–2011 fees.

Second, Stat-Trade argues that FDA has unreasonably delayed reviewing certain of its requests for waivers from fiscal years 2009–2011. Because the Court finds that Stat-Trade's claim is moot as to the 2009 and 2010 waiver applications, and that Stat-Trade has failed to show that FDA unreasonably delayed reviewing the 2011 waiver application, the Court will grant summary judgment for defendants and deny Stat-Trade's motion on Count II.

STATUTORY BACKGROUND

The PDUFA governs FDA's assessment of fees for prescription drug applicants and application holders. 21 U.S.C. §§ 379g, 379h. The fees at issue here are annual product fees, which FDA assesses separately for each "prescription drug product." The statute defines a "prescription drug product" as "a specific strength or potency of a drug in final dosage form" that has been approved by FDA, that may be dispensed only by prescription, and that is included on the FDA's list of approved drug products that are being actively marketed that year. 21 U.S.C. §§ 379g(3), 379h(a)(3)(A). This definition reflects amendments made by Congress in 2002 and 2007.

It was in 2002 that Congress amended the definition of "prescription drug product" to include reference to the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, informally known as the "Orange Book." *See* 21 U.S.C. § 379g(3) (2002). The Orange Book is divided into the "active" section, which lists approved drug products that are in commercial production, and the "discontinued" section, which lists those that are not. Administrative Record ("AR") 265. The 2002 Amendments clarified that a "prescription drug product" must be "on the list of products described in section 505(j)(7)(A) or [] on a list created and maintained by the Secretary of products approved under human drug applications under

section 351 of the Public Health Service Act." H.R. Rep. No. 107-481, at 95 (2002). The accompanying Conference Report stated:

> The term "prescription drug product" is modified to allow the Secretary to use the Prescription Drug Product List (the active portion) in the "approved Drug Products with Therapeutic Equivalence Evaluations," (the Orange Book) as the basis for identifying which products should be considered to be prescription drug products for fee assessment purposes.

Id. at 149, *reproduced at* AR 149. In 2007, Congress further amended the PDUFA definition of "prescription drug product" to expressly clarify that fees should be assessed for a drug on the list, but "not including the discontinued section of such list." 21 U.S.C. § 379g(3)(C) (2007).

FDA typically sends out invoices in August for fees assessed for the upcoming fiscal year. AR 226. Fees are due on October 1, and failure to pay in full by October 31 subjects a company to financial penalties, interest, and administrative fees as well as arrearage, meaning that FDA will not accept any application or supplement filing from that company until all owed fees are paid. 21 U.S.C. §§ 379h(a)(3)(A), (e).

The PDUFA also contains a product fee exception and two waiver provisions that are relevant to this case:

- Section 379h(a)(3)(B) excepts a "prescription drug product" from product fees if "such product is the same product as another product approved under an application [for generic drug approval] under … 355(j) of this title."[1] 21 U.S.C. § 379h(a)(3)(B). The parties dispute whether this exception applies in any situation where an equivalent generic has been approved by FDA or whether it applies only when the generic is being actively marketed.

1 The Court will refer to this provision as the "generic exception."

- Section 379h(d)(1)(B) requires FDA to grant a partial or complete waiver of fees to any company that can demonstrate that "the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances."[2] 21 U.S.C. § 379h(d)(1)(B). Plaintiff has asserted this waiver.
- Section 379h(d)(1)(C) requires a fee waiver if the fees "will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person."[3] 21 U.S.C. § 379h(d)(1)(C). Plaintiff has also asserted this waiver.[4]

FACTUAL BACKGROUND

Stat-Trade is a small pharmaceutical company that currently owns and holds FDA approval for the prescription anti-inflammatory drug Naprelan in three different dosage

2 The Court will refer to this provision as the "barrier-to-innovation waiver" or "BTI waiver."

3 The Court will refer to this provision as the "fees-exceed-the-costs waiver" or "FEC waiver."

4 FDA uses cumulative fees and costs, beginning in September 1, 1992 – when the PDUFA program was inaugurated – and ending in the year for which the waiver is requested. Defs.' Mem. in Support of Mot. for Summ. J. ("Defs.' MSJ") [Dkt. # 20-2] at 8–9. In other words, FDA adds all of the fees that the company and its affiliates have paid since September 1, 1992, and then subtracts the total costs that FDA has expended on reviewing their applications and supplements since the same date. The difference is the waiver amount. Important to this case, however, is a provision of the PDUFA that authorizes FDA to use "standard costs" in assessing FEC waivers. 21 U.S.C. § 379h(d)(3). Citing this provision, FDA has adopted a complicated method of calculating a company's "standard costs." *See* AR 184–89. In simplified form, FDA first determines the average cost of processing each type of application and supplement that was submitted during that year, and then adds up the standard costs for each application and supplement that the company and its affiliates have submitted since 1992. The sum is the "standard cost" for that company, which is subtracted from the fee amount in order to determine the amount of the waiver.

strengths. *See* AR 6, 150. In 2002 and 2003, FDA approved a competitor's applications for generic versions of Naprelan in two of the three strengths (375 mg and 500 mg), and the generic drugs went into commercial production. AR 257. However, in 2009, after an adverse decision in a patent infringement lawsuit, the generic manufacturer discontinued its sales of the generics. AR 77–78.[5] When the generics went off the market, FDA began assessing Stat-Trade product fees for all three strengths of Naprelan, including the two with approved generic counterparts, and it has continued to do so for fiscal years 2009–2012.[6] AR 1–2, 5, 16, 65–68.

The fiscal year 2010 invoice was the first to assess product fees for all three dosage strengths of Naprelan. AR 1. It was issued by FDA on August 14, 2009. *Id.* Nearly four months later, FDA issued Stat-Trade a second invoice for Naprelan PDUFA fees – this one for fiscal year 2009. AR 2, 5.

On April 6, 2011, Stat-Trade wrote FDA and requested an exception. AR 22–24. It asserted that the 375 mg and 500 mg strengths of Naprelan should be exempt from product fees under the generic exception, and it asked FDA to apply the exception to its invoices for fiscal years 2009–2011. *Id.* The letter also requested that FDA apply the exception to all future PDUFA invoices. AR 23. In support of its request, Stat-Trade took the position that the PDUFA exception covers product fees for all prescription drug products with approved generic counterparts, regardless of the generic drug's market status. AR 22–23. Since FDA had

5 Neither the manufacturer nor FDA withdrew approval of the generic products or withdrew the abbreviated new drug application ("ANDA") under which they were approved. AR 78, 263.

6 FDA actually issues Stat-Trade's product fee invoices to the company's affiliate, STI Pharma LLC, *see, e.g.*, AR 1, 2, 16, 66, but for the sake of convenience, the Court will refer to both STI Pharma LLC and Stat-Trade, Inc. as "Stat-Trade."

approved generic versions of two strengths of Naprelan, Stat-Trade argued, that exception applied to those two products. *Id.*

FDA did not respond to Stat-Trade's request at that time. Instead, it sent Stat-Trade a draft invoice for fiscal year 2012. AR 25–32. This invoice again assessed product fees for all three strengths of Naprelan. AR 31. Stat-Trade contacted FDA on three occasions to assert that the two strengths of Naprelan should be exempt from product fees under the PDUFA generic exception, and to request that FDA apply the generic exception to the final 2012 invoice. AR 35–37, 38–39, 57–59. Without responding to any of Stat-Trade's requests, FDA issued a final invoice on August 15, 2011, assessing product fees for all three versions of Naprelan. AR 65–68. Payment was due October 1, 2011.[7] AR 65–68.

Meanwhile, in February 2010, Stat-Trade submitted barrier-to-innovation and fees-exceed-the-costs waiver requests for fiscal years 2009 and 2010. AR 4–8. Six months later, FDA denied Stat-Trade's BTI waiver request and notified Stat-Trade of its appeal rights. AR 9–15. In the same letter, FDA stated that it had not yet considered Stat-Trade's FEC waiver request, and explained that it planned to defer consideration until after the appeal was completed or after it received notification that Stat-Trade had decided not to appeal. AR 14. Stat-Trade appealed the decision by letter in September 2010. AR 17. In the same letter, it also requested BTI and FEC waivers for fiscal year 2011. *Id.*

While Stat-Trade's generic exception and waiver requests were pending, its 2009 to 2011 invoices became overdue. AR 54. As a result, Stat-Trade sat in arrears for over a year and a half

7 After the final invoice was issued, Stat-Trade challenged it again by formally requesting that the 375 mg and 500 mg strengths of Naprelan be excepted from product fees, AR 69–74, but it later withdrew the request, AR 148.

and accumulated $234,831 in penalties and interest, until one of its affiliates agreed to pay the total amount as part of a transfer of rights to market Naprelan. AR 54–56.

Stat-Trade filed this suit, along with a motion for preliminary injunction on October 7, 2011, in an attempt to force FDA to review its generic exception and waiver requests before the next installment of PDUFA fees would become due. [Dkt. # 1, 5]. As of that date, FDA had not ruled on any of the outstanding disputes: the 2009 and 2010 BTI waiver appeals, the BTI waiver request for fiscal year 2011, the FEC waiver requests for 2009–2011, or the generic exception requests for 2009–2012 and thereafter. The Court held several conferences with the parties, and ultimately, in return for Stat-Trade's agreement to withdraw its motion for preliminary injunction, FDA agreed to rule on Stat-Trade's BTI and FEC waiver requests as well as its generic exception request. *See* Minute Order (Oct. 18, 2011); Minute Order (Oct. 25, 2011); Minute Order (Oct. 27, 2011).

On October 21, FDA issued a decision denying all three of Stat-Trade's BTI waiver requests. AR 150–63. On October 27, FDA issued a decision partially granting Stat-Trade's FEC waiver requests for fiscal years 2009 and 2010, and agreeing to refund Stat-Trade $299,367. AR 178–180. However, it refused to decide Stat-Trade's fiscal year 2011 waiver request on the grounds that it could not issue its final determination until it had calculated its standard costs for fiscal year 2011, which, it estimated, would not occur until June 2012 at the earliest. AR 192 n.7.

Finally, on October 31, FDA took a formal position on the availability of the generic exception. It issued a letter of determination denying Stat-Trade's request for correction of its fiscal year 2012 invoice on the merits, and denying requests for corrections of the fiscal year 2009–2011 invoices as time barred. AR 234–38.

Stat-Trade filed a second amended complaint on November 10, 2011. [Dkt. # 15]. Count I deals with the generic exception and alleges that FDA's assessment of product fees for the two strengths of Naprelan for which generics have been approved violates the PDUFA and exceeds FDA's authority, in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 706(2)(A), (C). Second Am. Compl. ¶¶ 64–67. Count II alleges that FDA's delay in acting upon Stat-Trade's fiscal year 2011 FEC waiver request for at least twenty-one months in order to calculate standard costs constitutes agency action unreasonably delayed and is arbitrary and capricious, in violation of the APA, 5 U.S.C. §§ 706(1), (2)(A). *Id.* ¶ 69. Count II also alleges that FDA's refusal to consider Stat-Trade's 2009 and 2010 FEC waiver requests until after Stat-Trade either exhausted or abandoned its appeal rights for the BTI waiver requests was agency action unreasonably delayed and arbitrary and capricious, in violation of the APA. *Id*. It further claims that FDA's final action imposing penalties, interest, and administrative charges on the portion of Stat-Trade's unpaid fees that should have been waived was arbitrary and capricious with respect to the period during which FDA unlawfully withheld action on those waiver requests. *Id.* ¶ 70. The parties have cross-moved for summary judgment on both counts. [Dkt. # 19, 20].

STANDARD OF REVIEW

The APA establishes the scope of judicial review of agency action, *see Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc*., 435 U.S. 519, 545–549 (1978), and the standard of review under the APA is quite narrow.

Courts are required to analyze an agency's interpretation of a statute by following the two-step procedure set forth in *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc*., 467 U.S. 837 (1984). First, the court must determine "whether Congress has directly spoken to the precise

question at issue." *Id*. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. Courts "use 'traditional tools of statutory construction' to determine whether Congress has unambiguously expressed its intent," *Serono Labs., Inc., v. Shalala*, 158 F.3d 1313, 1319 (D.C. Cir. 1998), including an examination of the statute's text, structure, purpose, and legislative history. *Bell Atl. Tel. Co. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997). If the court concludes that the statute is either silent or ambiguous, the second step of the court's review process is to determine whether the interpretation proffered by the agency is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843.

Once a reviewing court reaches the second step, it must accord "considerable weight" to an executive agency's construction of a statutory scheme it has been "entrusted to administer." *Id.* at 844. Indeed, "under *Chevron*, courts are bound to uphold an agency interpretation as long as it is reasonable – regardless whether there may be other reasonable or, even more reasonable, views." *Serono*, 158 F.3d at 1321. And the court must defer to an agency's reading of its own regulations unless it is "plainly erroneous or inconsistent with the regulation." *Id*. at 1320 (internal quotation marks omitted).

ANALYSIS

The Court agrees with the parties that this case presents pure questions of law that should be decided on summary judgment.[8] Count I of the second amended complaint asks the Court to determine whether Stat-Trade is entitled to reimbursement of product fees it paid for the 375 and 500 mg strengths of Naprelan for fiscal years 2009–2012 as well as the amounts it paid to FDA

8 FDA has alternatively moved to dismiss the two counts under Federal Rule of Civil Procedure 12(b)(6), but since the Court relies on parts of the Administrative Record in ruling on the merits of this case, it will deny the motion to dismiss and proceed to review the merits of FDA's arguments under its motion for summary judgment.

in penalties, interest, and administrative charges for its late payment of product fees for fiscal years 2009–2011. This presents two distinct legal questions:

1) Whether FDA exceeded its authority under the PDUFA by interpreting the generic exception provision to be limited to situations where the generic is not only "approved," but also in active production; and

2) If the Court finds that the exception should have applied, whether FDA abused its discretion and acted in excess of statutory authority by denying Stat-Trade's request to correct the FY 2009–2011 invoices on the grounds that they were time barred by 21 U.S.C. § 379h(i).

Count II of the complaint asks the Court to determine whether Stat-Trade is entitled to reimbursement for the penalties, interest, and administrative fees that it paid to FDA for the late payment of fees that were eventually waived under the FEC waiver provision of PDUFA. This count also presents two distinct legal questions:

1) Whether FDA's decision to defer processing Stat-Trade's 2011 FEC waiver request until it can determine standard costs for that year constitutes unreasonable delay and is arbitrary and capricious; and

2) Whether it was arbitrary and capricious for FDA to refuse to review Stat-Trade's 2009–2010 FEC waiver requests until Stat-Trade had abandoned or exhausted its appeals for its BTI waiver requests.

The Court will address each issue in turn.

I. Count I: Assessment of product fees for Naprelan 375 mg and 500 mg strengths

A. FDA's consideration of marketing status under the generic exception provision

The exception at issue in this case reads: "A prescription drug product shall not be assessed a fee under subparagraph (A) . . . if such product is the same product as another product approved under an application filed under section 355(b) or 355(j) ["abbreviated new drug applications"] . . . ." 21 U.S.C.A. § 379h(a)(3)(B). Plaintiff contends that since generic versions of the 375 and 500 mg strength Naprelan tablets were "approved" under an abbreviated new drug application ("ANDA") in 2002 and 2003, those products should be exempt from the assessment

of fees under the plain terms of the statute, notwithstanding the fact that in 2009, the manufacturer of the generics ceased their production.

Essentially, according to plaintiff, "approved" means "approved." Plaintiff points to the fact that the exception contains no express requirement that the equivalent generic product be available on the market – the applicability of the exception is triggered simply by the action of FDA in approving the generic product. In addition, under the FDA regulations that govern generic drug applications, "approval" is a specific event, *see* 21 C.F.R. § 314.105(d) (2008) ("The approval becomes effective on the date of the issuance of the agency's approval letter unless the approval letter provides for a delayed effective date."), and approval remains effective whether or not the product is commercially marketed.[9] *Id.*

Plaintiff notes that dating back to 1994, the agency itself read the statute as Stat-Trade seeks to do now. It directs the Court to the first page of a December 16, 1994 publication entitled: *Application, Product, and Establishment Fees: Common Issues and Their Resolution*:

> The marketing status of the 505(b)(2) or 505(j) application [an application under 21 U.S.C. §355(b) or (j)] . . . is not a determining factor. If the 505(b)(2) or (j) application has been approved and not withdrawn, the first approved product is excluded from fees even if the generic product is not presently marketed.

AR 247–52. Plaintiff argues that FDA was right in 1994, and that since the language of the exception itself has not changed since the issuance of this policy guidance, the Court can decide at the *Chevron* step one stage that the exception still applies.

FDA cannot fairly dispute that the statute calls for the generic that triggers applicability of the exception to be "approved" and no more, so it attempts to shift the focus from the word

9 These provisions were first published in the Federal Register as part of a proposed rule in 1989, *see* 54 Fed. Reg. 28872, 28928 (July 10, 1989) – well before 1992 when the PDUFA was first enacted. They were published in final form in 1992. *See* 57 Fed. Reg. 17950, 17989 (Apr. 28, 1992).

"approved" to the phrase "same product." It claims that Congress left a gap or ambiguity in the text when it failed to define the phrase "same product" in section 379h(a)(3)(B) – "if such product is the same product as another product approved under [an ANDA application]" – and therefore, the question before the Court is whether the agency has advanced a reasonable interpretation under *Chevron* step two. FDA asserts that the ambiguous phrase "same product" can be reasonably interpreted to require that the generic products have not only the same active ingredients and dosage, but also the same marketing status and location within the Orange Book as the original drug.

FDA points out that in 2002, Congress modified the definition of the term "prescription drug product" under PDUFA to expressly refer to the Orange Book. *See* 21 U.S.C. § 379g(3)(C) (2002) ("[a drug] which is on the list of products described in section 355(j)(7)(A) of this title [(the Orange Book)] . . . ."). The House Conference Report to the Prescription Drug User Fee Amendments of 2002 (PDUFA III) explains that the modification was made specifically "to allow the Secretary [of FDA] to use the Prescription Drug Product List (the active portion) in [the Orange Book] as the basis for identifying which products should be considered to be prescription drug products for fee assessment purposes." H.R. Rep. No. 107-481, at 149 (2002) at 149, reproduced at AR 255. This change was implemented to make the billing process more efficient and less burdensome on the agency as "[d]etermining eligibility for listing is administratively complex and sometimes resource intensive." *Id.* In 2007, Congress clarified the matter further by specifying that a "prescription drug product" for which fees would be assessed is a drug on the list, but "not including the discontinued section of such list." 21 U.S.C. § 379g(3)(C) (2007).

In light of these changes, which directed FDA to look to the Orange Book in its assessment of fees in one context – the definition of prescription drug product – FDA argues that it was reasonable for it to decide to refer to the Orange Book in connection with the assessment of fees in another context: the generic exception. In other words, FDA felt free to define "same product" to incorporate market status through reference to the Orange Book after 2002, and it attests that it has consistently interpreted the statute in this manner since 2002. *See* Letter from Jane A. Axelrad, Assoc. Dir. For Policy, Ctr. for Drug Evaluation and Research, FDA to David Jesperson, Vice President of Regulatory Affairs, KV Pharmaceutical Co. (July 10, 2008) ("the KV Letter") at 4, reproduced at AR 258–62 ("We have consistently interpreted the statute, since 2002, when PDUFA III changed the method of identifying fee-eligible prescription drug products, to mean that the product in the Prescription Drug Product List has to be the same as another product on the Prescription Drug Product List."). FDA also advances reasons why it considers its interpretation to be reasonable.

While the Court accepts FDA's representation that this has been the agency's consistent interpretation since 2002, that is not the predicate issue to be decided. At the outset, the fundamental issue presented by Count I is whether the Court can make its decision based solely upon "the unambiguously expressed intent of Congress," or whether it must defer to the FDA interpretation. *Chevron,* 467 U.S. at 842–43. The resolution of this question – the threshold *Chevron* determination – depends upon "whether Congress has directly spoken to the precise question at issue." *Id.* at 842.

The D.C. Circuit has explained:

> Under the first step of *Chevron,* the reviewing court must first exhaust the traditional tools of statutory construction to determine whether Congress has spoken to the precise question at issue. The traditional tools include examination of the statute's text, legislative history, and structure; as well as its purpose. This

> inquiry using the traditional tools of construction may be characterized as a search for the plain meaning of the statute. If this search yields a clear result, then Congress has expressed its intention as to the question, and deference is not appropriate. If, however, the statute is silent or ambiguous with respect to the specific issue, Congress has not spoken clearly, and a permissible agency interpretation of the statute merits judicial deference.

Bell Atl. Tel. Co., 131 F.3d at 1047 (internal citations and quotation marks omitted). Thus, the evaluation of whether Congress's intent has been made clear is based not just on the text of the exception, but also the structure of the statute, its purpose, and the legislative history.

Stat-Trade takes the position that the statute is unambiguous and so the obligation to defer to the department is not triggered in this case. Looking at the text of the provision, the Court agrees; the exception plainly applies when there is an approved generic without further limitation.[10]

Furthermore, when looking at the statute, one observes that while Congress expressly altered the language defining the category of brand-name drugs that were subject to fees, it did not alter the language defining the category of generic drugs that trigger the exception. It is a well-recognized canon of statutory interpretation that "[where] Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983); *see also Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even

10 This is borne out by the fact that the FDA has announced its intention to ask Congress to *amend* the statute to explicitly incorporate the agency's interpretation. *See* 76 Fed. Reg. 56,204 (Sept. 12, 2011).

greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").[11]

Moreover, the House Conference Report to which the FDA directs the Court's attention specifically indicates that the amendment was needed to facilitate the agency's assessment of fees, but it says nothing about easing the administration of the exception. Indeed, a candid sentence in a letter from FDA responding to the only other challenge to FDA's interpretation of the generic exception acknowledged that while it may have found keeping track of approved generics as difficult as cataloguing those "prescription drug products" on which fees could be assessed, Congress did not expressly address that concern. *See* KV Letter at 3 ("*Although not noted in the Conference Report,* one of the resource intensive, administratively complex issues included the determination of whether a product was the same as another product that was withdrawn from marketing.") (emphasis added). In other words, since 2002, the FDA has *interpreted* the generic exception provision to incorporate Congress's recognition of the usefulness of the Orange Book, but Congress did not expressly direct it to do that.

In *Serono*, the D.C. Circuit provided additional guidance on how to determine whether the statute is sufficiently clear, and one factor it considered was the fact that the statute did not specifically define the term at issue in the case. 158 F.3d at 1319. That is the situation in this case as well. Congress defined "prescription drug product," for fee-eligibility purposes but it did

11 In fact, Congress directed FDA to consider the Orange Book in several places in the statute, including in the definition of "prescription drug product," 21 U.S.C. § 379g(3)(C) (2002), and in a different exception to product fees contained in the exact same section of PDUFA as the provision at issue here, 21 U.S.C. § 379h(a)(3)(B) (2002). This provides further proof that Congress knew how to direct FDA to consult the Orange Book, but chose not to do so in the generic exception provision. Furthermore, at the time PDUFA was enacted, a provision of the Federal Food Drug & Cosmetic Act expressly referred to the "commercial marketing" of a generic drug, as distinct from approval. *See* 21 U.S.C. § 355(j)(4)(B)(iv)(I) (1992). So not only did Congress know how to refer to the Orange Book, it also recognized a distinction between approval and commercial marketing.

not define the terms "approved product" or "same product" that trigger the availability of the exception. Lacking a definition in the statute, the *Serono* court went on to consider "what the terms mean in context." *Id.*

Context is important in this case because while Congress did not expressly define "same product" in the PDUFA, that phrase already had a distinct meaning in the pharmaceutical context. *See United States v. Wilson*, 290 F.3d 347, 356 (D.C. Cir. 2002) ("Congress is presumed to preserve, not abrogate, the background understandings against which it legislates."). The Federal Food Drug and Cosmetic Act ("FDCA"), which predates the PDUFA, defines a generic drug, in its ANDA section, as a drug with certain properties that are the "same as" a brand-name drug. *See, e.g.*, 21 U.S.C. §§ 355(j)(2)(A)(ii), (iii), (v). So it is notable that the PDUFA generic exception provision at issue here expressly invokes the ANDA section of the FDCA – it excepts from fees a prescription drug product that is the same product as a product *approved under 21 U.S.C. section 355(j)*. Furthermore, FDA's own regulations, in effect at the time the PDUFA was enacted, use the term "same" to tie a generic drug to its brand-name counterpart. FDA regulations from 1983 declare that "[a] finding by the [FDA] that an abbreviated new drug application is suitable for a drug product applies only to a product that is the same in active ingredient dosage form and strength, route of administration, and conditions of use as the drug product that was the subject of the finding." Abbreviated New Drug Applications, 48 Fed. Reg. 2751, 2755 (Jan. 21, 1983).[12] So a consideration of context here

12 The use of the term "same" to describe the relationship between a generic drug and its brand-name counterpart in FDA's regulations has only solidified since then. In 1999 – before the 2002 amendments to the PDUFA – FDA amended its regulations to provide that "[a]bbreviated applications" are suitable for "drug products that are the same as a listed drug," and it defines "same as" as "identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use . . . ." 21 C.F.R. § 314.92(a)(1) (1999).

suggests that the phrase "same product" simply incorporates the ANDA sameness requirement, and it has nothing to do with whether the generic is in the same section of the Orange Book – that is, the active list versus the discontinued list – as the original.

Another appropriate consideration under *Chevron* step I is the legislative history. There appears to be only one mention of the exception provision in the entire legislative history of the PDUFA, and that comes from the report of the House Committee on Energy and Commerce. H.R. Rep. 102-895 (Sept. 22, 1992).[13] The report states that under the generic exception provision, "only products not subject to competition from generic drug products will be subject to the product fee." *Id.* at 16. This statement indicates that a concern underlying the provision was the loss of revenue that the brand name drug faces through competition with generics, and it may bear on the reasonableness of FDA's interpretation. But the Court finds that this isolated comment is not enough to render the plain language of the provision to be ambiguous. While market status may be one indication of active competition, it is not the indication that Congress chose to write into law. Rather, it expressly chose to measure competition by the approval status of the generic. *See also Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342–43 (S.D.N.Y. 2006) (finding irreparable harm based in part on evidence that introduction of a generic on the market can have irreparable impact on pricing of brand-name drug, even if generic is later discontinued), *aff'd by* 470 F.3d 1368, 1382–83 (Fed. Cir. 2006). And where Congress has chosen particular means of carrying out its policy objectives, FDA may not disregard that

13 The Congressional Record establishes that H.R. 5952 was passed in the House of Representatives on September 22, 1992. However, due to a filibuster in the Senate, the sponsors of the PDUFA reintroduced the bill – which was ultimately enacted – as H.R. 6181. H.R. 6181 was identical to H.R. 5952 except for minor Senate amendments, which did not affect the provision at issue here. In addition, the Committee Report to H.R. 5952, cited above, was adopted to apply "with equal force to H.R. 6181, as if the House had passed H.R. 5952 with the Senate amendments." 138 Cong. Rec. 32,406 (Oct. 5, 1992) (statement of Rep. Waxman).

choice for its own, regardless of whether its preferred choice would also satisfy those objectives. *See Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1364 (D.C. Cir. 1990) ("Where Congress prescribes the form in which an agency may exercise its authority, however, [the court] cannot elevate the goals of an agency's action, however reasonable, over that prescribed form.").

Accordingly, based on an examination of the text, structure, purpose, and legislative history of the PDUFA, the Court finds that the case must be resolved at *Chevron* step one. The generic exception provision contains no gap for FDA to interpret, and applying the plain terms of the statute, Stat-Trade is entitled to the exception.[14]

B. Stat-Trade's entitlement to reimbursement of penalties and interest paid for its failure to pay 2009–2011 product fees that should have been excepted

Since the Court has now determined that the 375 and 500 mg strengths of Naprelan are exempt from product fees, and have been exempt since the generic versions were approved in

14 Even if the Court were to reach *Chevron* step two and give FDA the deference to which it is entitled, the Court would reject FDA's interpretation. While it might be a reasonable policy choice to limit the availability of the exception to manufacturers facing active competition in the marketplace, and that might be consistent with the policy underlying the exception, it is not reasonable to suggest that somehow the term "same product" can be interpreted to include consideration of that circumstance. Furthermore, FDA's rationale for the abandonment of its original interpretation of the provision – that Congress had amended the definition of the term "prescription drug product" – does not logically lead to the change in policy. The Orange Book was in publication and contained "active" and "discontinued" sections at the time that the PDUFA was first enacted, AR 264, and FDA concluded then that the determination of whether a brand name drug and a generic were the "same product" depends only on whether they share the "same active ingredient, strength potency, dosage form, and route of administration . . . . The marketing status of the [generic drug] . . . is not a determining factor. If the [ANDA] has been approved and not withdrawn, the first approved product [*i.e.* the brand name drug] is excluded from fees even if the generic product is not presently marketed." AR 247. The mere fact that in 2002 Congress decided to allow FDA to look to the Orange Book in a completely different context cannot reasonably justify FDA's decision to insert the consideration of market status into the sameness determination. In addition, since the change was not conducted by notice and comment rulemaking, but was merely asserted in letters to individual companies, the Court would not be required to accord FDA full *Chevron* deference, but only the weaker *Skidmore* deference. *United States v. Mead Corp.*, 533 U.S. 218, 234–35 (2001).

2002 and 2003 respectively, the next question is whether Stat-Trade is therefore entitled to reimbursement of the product fees it paid for fiscal years 2009–2012.

The first time Stat-Trade contested the assessment of product fees for those two drugs was in a letter dated April 6, 2011. AR 22–24. FDA views this fact as critical and points the Court to section 379h(i), which it argues acts as a statute of repose. AR 234–38. That provision states:

> To qualify for consideration for a waiver or reduction under subsection (d) of this section, or for a refund of any fee collected in accordance with subsection (a) of this section, a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

21 U.S.C. § 379h(i). Since the contested fees were assessed as product fees under subsection (a) of section 379h, the Court agrees that Stat-Trade's failure to submit a written request for a refund of the fiscal year 2009–2011 product fees within 180 days after the fees were due (March 30, 2010; July 7, 2010; and March 30, 2011 respectively), bars it from reimbursement now.

Stat-Trade asks the Court to find that the time bar does not apply in this case because: (1) the product fees were not assessed "in accordance with" subsection (a), but rather, were assessed in contravention of it, and (2) Stat-Trade could not have sought a "refund" of a fee "collected" until May 29, 2011, when it actually paid the amount due.[15] But that reading is not compelled by the text or structure of the statute. First, the Court agrees with defendants that FDA assessed the fees "in accordance with" subsection (a): FDA derived its authority for assessing the product fees from that provision, even though this Court has now found its interpretation to be in error.

15 Stat-Trade also argues that the Court should interpret the April 2011 letter as a supplement to its earlier FEC and BTI waiver requests and on that basis, should find that Stat-Trade in effect satisfied the statute of repose. But since Stat-Trade did not raise the generic exception issue in those letters, it cannot claim that those letters satisfy the statute of repose. The exception request was a new request – not only did it seek a different adjustment amount, but it was raised under a completely different section of PDUFA than the waiver requests. FDA was not put on notice of Stat-Trade's claim to the generic exception until the April 2011 letter.

If this Court were to accept Stat-Trade's interpretation, then individuals would have an indefinite period of time to contest any billing mistake, and FDA would never be able to calculate the amount it collected in fees for any given year with certainty. This would make it nearly impossible for FDA to assess the balance of fees, costs, and expenses, as it is required to do by the statute. *See* 21 U.S.C. §§ 379h(g).[16]

The Court also declines to excuse Stat-Trade from the requirements of the provision merely because Stat-Trade failed to pay its fees on time. The provision requires that a request – whether for a waiver or a refund – must be submitted within 180 days of when the fee is due, not when it is due or paid, whichever comes later. So, Stat-Trade was required to request the exception within 180 days after the fees were due. Since it failed to do so for fiscal years 2009–2011, it is not entitled to a refund of those fees now. Similarly, because Stat-Trade failed to contest those fees within the statutory time limit, it essentially waived its generic exception claim, and is therefore not entitled to a refund of the penalties, interest, or administrative fees that arose out of its failure to make timely payments. *See United States v. Kubrick*, 444 U.S. 111, 117 (1979) (explaining that the elapse of a statute of repose bars the assertion of "stale claims").

16 For example, subsection (g)(4) provides:

> If the sum of the cumulative amount of fees collected under this section for the fiscal years 2008 through 2010 and the amount of fees estimated to be collected under this section for fiscal year 2011 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2008 through 2011, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.

Accordingly, Stat-Trade is entitled to a refund of the fiscal year 2012 product fees that it paid for the 375 and 500 mg strengths of Naprelan, but not of the fiscal year 2009–2011 product fees or the penalties, interest, and administrative fees on the unpaid 2009–2011 fees.

II. Count II: FDA's delay in considering Stat-Trade's 2009–2011 FEC waiver requests

Stat-Trade next claims that FDA's delay in considering the 2009–2011 FEC waiver requests was arbitrary and capricious in violation of the APA. This claim requires the Court to consider two distinct questions: First, was it reasonable for FDA to refuse to review Stat-Trade's 2009 and 2010 FEC waiver requests until Stat-Trade either exhausted or abandoned the appeals of its BTI waiver request? Second, is it reasonable for FDA to delay its review of Stat-Trade's 2011 FEC waiver until it can calculate standard costs for that year?

A. 2009 & 2010 FEC requests: Penalties and interest Stat-Trade paid on fees that would have been waived under the FEC waiver had FDA not refused to consider the FEC request until Stat-Trade exhausted its appeals on the BTI waiver request

Stat-Trade claims that it is entitled to a refund of the penalties and interest that accrued on the fees that would have been waived under the FEC waiver much earlier if FDA had not conditioned its review of Stat-Trade's FEC waiver request on Stat-Trade's exhaustion or abandonment of its BTI waiver request and appeals. Notably, Stat-Trade's original complaint and accompanying motion for preliminary injunction were filed while its requests for a final determination on its BTI waiver request and all of its original FEC waiver requests were still pending. *See* [Dkt. # 1]. At that time, FDA had refused to consider the FEC waiver requests until Stat-Trade either exhausted or abandoned its appeals of its BTI waiver requests. Its rationale for this policy was based on efficiency: since the BTI determination would affect the amount of the FEC waiver, FDA claimed that it would be inefficient to process the FEC waiver before there was a final determination on the BTI waiver. Stat-Trade's original pleadings asked

the Court to find FDA's delay arbitrary and capricious and to compel FDA to rule. *Id*. Before the Court could rule on those motions, however, FDA issued its ruling on the pending FEC waiver requests for 2009–2010,[17] and granted an FEC waiver of nearly $300,000. [Dkt. # 11].

Now, Stat-Trade has amended its complaint, and asks this Court to require FDA to refund the penalties and fees that accrued on the portion of the late FY 2009–2010 payments that should have been waived under the FEC waivers, and which Stat-Trade finally paid on May 29, 2011. [Dkt. # 15]. It argues that FDA's delay in considering those waiver requests was arbitrary and capricious. *Id.*

But Stat-Trade's claim fails to pinpoint the reason why the penalties and interest were assessed in the first place: because Stat-Trade did not pay its fees on time. The statute expressly requires a company to pay its fees within thirty days of the payment deadline, in order to avoid the fee being "treated as a claim of the United States Government subject to subchapter II of chapter 37 of Title 31." 21 U.S.C. § 379h(h). The referenced section of Title 31, in turn, allows the government to charge penalties and interest on the claim. 31 U.S.C. § 3717. Waiver requests, by comparison, are not due until 180 days after the fee is due. 21 U.S.C. § 379h(i). So the statute is structured so that companies must pay the full amount of the fees within 30 days of the deadline, but may be reimbursed for any waived portion of the fees later, once FDA receives and processes the waiver request.[18] Regardless of how long FDA takes to process the waiver requests, the only way that the company avoids penalties is by paying the full amount of its fees

17 FDA declined to rule on the 2011 request because it had not yet calculated standard costs for the 2011 fiscal year.

18 FDA does have a process for companies to receive some waivers before fees are due if the company submits its request far in advance of the payment deadline. *See* AR 226. However, FDA does not guarantee that it will consider waiver requests before payment is due. *Id.* Moreover, the statute does not require FDA to adopt or maintain this policy.

on time. So, the reason that Stat-Trade accrued penalties and interest was not FDA's delay in processing its waiver requests.

Since there are no damages attributable to FDA's delay now that FDA voluntarily reviewed the waiver requests, this issue is moot and the Court has no jurisdiction to consider the reasonableness of the delay on the merits. *Powell v. McCormack*, 395 U.S. 486, 496 n.7 (1969) ("The rule that this Court lacks jurisdiction to consider the merits of a moot case is a branch of the constitutional command that the judicial power extends only to cases or controversies.").

B. FY 2011 FEC request: FDA's policy of waiting to consider an FEC waiver request until it can calculate standard costs for the applicable fiscal year

Stat-Trade's 2011 FEC waiver request, however, is still pending before FDA, so Stat-Trade's claim that FDA has unreasonably delayed responding to that request is not moot. Stat-Trade submitted its 2011 FEC waiver request on September 9, 2010. AR 50. The PDUFA requires FDA to grant a waiver where "the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person." 21 U.S.C. § 379h(d)(1)(C). FDA stated that it would not begin to process the waiver until it had sufficient information to calculate standard costs for fiscal year 2011, which it predicted would be in June 2012 at the earliest. AR 193.

The statute expressly grants FDA the authority to use "standard costs" in making waiver determinations. 21 U.S.C. § 379h(d)(3). But since it does not contain a definition of "standard costs," FDA has supplied its own consistent interpretation since 1993. AR 185. According to FDA, it uses a complicated system whereby costs are accumulated in cost centers corresponding to various organizational components. AR 202. Importantly, its calculation is based in part on its average costs for the actual fiscal year of the waiver request. AR 202–03. This requires FDA

to wait until the close of the fiscal year before it begins to calculate standard costs for that year. Since waiver applications are submitted before the beginning of the fiscal year, this system results in a delay of up to two years between when the applicant submits the application and when FDA processes it. Accordingly, Stat-Trade submitted its 2011 FEC request in September 2010, and as of the time the parties filed their memoranda regarding the cross-motions at issue here, FDA had not yet processed the request. This, Stat-Trade argues, constitutes "agency action unlawfully withheld or unreasonably delayed" and is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law" in violation of the APA. Second Am. Compl. ¶¶ 68–70.

The Court's role in evaluating a claim of unreasonable delay is to determine "whether the agency's delay is so egregious as to warrant mandamus." *Telecomm. Research & Action Ctr. v. FCC*, 750 F.2d 70, 79 (D.C. Cir. 1984) ("TRAC"). In *TRAC*, the Court set out six factors that govern this analysis. *Id.* at 80. The factors are not "ironclad," but provide "useful guidance in assessing claims of agency delay." *Id.*; *see also In re Core Comms., Inc.*, 531 F.3d 849, 855 (2009) (explaining the *TRAC* standard). The first and most important factor is that "the time agencies take to make decisions must be governed by a 'rule of reason.'" *Core Comms.*, 531 F.3d at 855, citing *TRAC*, 750 F.2d at 80. The other five factors are:

> (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.

TRAC, 750 F.2d at 80 (internal citations and quotation marks omitted).

There is no question that FDA has applied a rule of reason here. FDA maintains a consistent timetable for processing FEC waiver requests, which is based on its method of calculating standard costs. There is no indication that the processing of Stat-Trade's 2011 FEC waiver request will exceed FDA's regular timetable.

But Stat-Trade argues that FDA's method of calculating standard costs, which requires it to wait until the end of the applicable fiscal year, is inconsistent with the language of the statute. The statute requires FDA to grant a waiver if it finds that "the fees *to be paid* by such person *will exceed* the *anticipated* present and *future* costs incurred by the Secretary . . . ." 21 U.S.C. § 379h(d)(1)(C) (emphasis added). Stat-Trade claims that this use of the future tense means that the agency must make its determination in advance. But the waiver provision also uses the past tense: section 379h(d)(1) states that the Secretary shall grant a waiver from *or* a reduction of the fees "*assessed*" if it makes the necessary finding under section 379h(d)(1)(c). In any event, FDA explains that its method of calculating standard costs does require it to anticipate the present and future costs; FDA applies the standard costs for all human drug applications submitted in the fiscal year, regardless of whether its review of the application is actually completed within that fiscal year or whether it will be completed in the future. AR 187. And, the statute also expressly permits the agency to utilize standard costs in making the waiver finding.[19]

Although Stat-Trade offers several alternative methods of calculating standard costs that could be utilized before the end of the fiscal year, the inquiry for the Court is not whether there are *better* systems for processing FEC waivers, but whether FDA's chosen method of responding to plaintiff's waiver request is reasonable. Since it is the statute, and not FDA policy, that

19 In its opposition brief, Stat Trade does not actually address FDA's arguments for why this claim should be dismissed. But since Stat-Trade does address this issue in its motion for summary judgment, the Court will incorporate that argument into its opposition and will not treat the issue as abandoned.

requires waiver applicants to pay their fees before they receive the waiver, the Court cannot find FDA's timetable to be unreasonable merely because the upfront payment imposes a burden on some companies. Furthermore, FDA offers a reasonable justification for its method of calculating standard costs. It explains that the main reason it waits until the end of the fiscal year is so that it knows how many human drug applications each company and its affiliates have submitted during that year. This allows it to easily multiply the number of applications submitted by the standard cost for each kind of application. Accordingly, the Court finds that FDA's delay in processing Stat-Trade's fiscal year 2012 waiver request is not unreasonable, arbitrary, or capricious.

CONCLUSION

For the foregoing reasons, the Court will: (1) deny defendants' motion to dismiss under Rule 12(b)(6), [Dkt. # 20]; (2) grant in part plaintiff's motion for summary judgment [Dkt. # 19] and deny in part defendants' cross-motion for summary judgment [Dkt. # 20] as to the part of Count I that relates to product fees for fiscal year 2012; and (3) deny plaintiff's motion for summary judgment and grant defendants' cross-motion for summary judgment as to the remaining claims. A separate order will issue.

//s//

AMY BERMAN JACKSON
United States District Judge

DATE: June 25, 2012