IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

OTSUKA PHARMACEUTICAL CO., LTD.,	*	
Plaintiff,	*	
v.		**Case No.: GJH-15-852**
SYLVIA MATHEWS BURWELL, ET AL.,	*	
Defendants.	*	

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MEMORANDUM OPINION

On March 24, 2015, Plaintiffs Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka America Pharmaceutical Inc., (collectively, "Otsuka") filed a two count complaint against Defendants U.S. Food and Drug Administration, Sylvia Mathews Burwell, Dr. Margaret Hamburg, and Dr. Stephen Ostroff (collectively, "FDA") challenging various actions it took concerning its approval of a supplemental new drug application ("sNDA") for Otsuka's drug aripiprazole, which Otsuka markets under the name Abilify. See ECF No. 1. Contemporaneous with the filing of its complaint, Otsuka filed a motion for summary judgment (see ECF No. 2), as well as a motion to expedite proceedings. See ECF No. 3.

On March 25, 2015, the Court conducted a teleconference during which the parties presented arguments concerning Otsuka's motion to expedite. After considering the parties' respective positions, the Court granted Otsuka's motion to expedite (see ECF No. 7) and issued a Scheduling Order. See ECF No. 6. The Scheduling Order required that FDA file a full and complete administrative record by March 31, 2015. See id. Thus, on March 31, 2015, FDA filed

its "administrative record to date," which consisted of seven documents comprising 288 pages. Believing FDA's administrative record to be incomplete, Otsuka filed an Emergency Motion to Compel Immediate Filing of the Complete Administrative Record. See ECF No. 38. That motion to compel, which is now fully briefed, is presently before the Court on a shortened briefing schedule given the expedited nature of this case. See ECF No. 40; see also ECF No. 7. For the reasons discussed more fully below, Otsuka's motion to compel is GRANTED.

I. BACKGROUND

Count one of Otsuka's complaint challenges FDA's approval of Abilify for the treatment of Tourette's Disorder in the general population as arbitrary and capricious under the Administrative Procedure Act ("APA"). See ECF No. 1 at ¶¶ 1, 58-63.[1] According to Otsuka, in 2014, following the conclusion of clinical trials establishing the safety and efficacy of the use of Abilify in the pediatric population, Otsuka submitted a sNDA to FDA. See id. at ¶ 38. Otsuka's sNDA sought approval for the new indication of the treatment of Tourette's Disorder in pediatric patients which, according to Otsuka, was the only population group in which Otsuka had conducted safety and efficacy studies. See id.

On December 12, 2014, FDA sent a letter to Otsuka notifying it that FDA was granting marketing approval for Abilify "based upon two adequate and well-controlled trials that demonstrate the efficacy for the new indication in pediatric patients with Tourette's Disorder." Id. at ¶ 46. Counsel for Otsuka thereafter wrote to FDA's Chief Counsel setting forth the company's understanding that FDA's approval of Abilify of an orphan indication for treatment of pediatric patients with Tourette's Disorder meant that FDA was precluded from approving an

[1] Count two of Otsuka's complaint, which seeks a declaration barring FDA from approving any generic versions of Abilify pending the expiration of Otsuka's seven-year period of orphan drug market exclusivity, is not at issue here as there is no apparent dispute concerning the adequacy of the administrative record as it pertains to this count.

abbreviated new drug application ("ANDA") for a generic version of Abilify for any indication pending the expiration of Otsuka's statutory seven-year period of orphan drug market exclusivity for the new indication. See id. at ¶ 22.

Shortly after receiving Otsuka's letter, FDA sent Otsuka a letter on February 24, 2015, informing the company that "as the first sponsor of [aripiprazole] to obtain marketing approval for this indication, [Otsuka] is entitled to seven years of orphan-drug exclusive approval . . . for treatment of Tourette's disorder." Id. ¶ 23. Later that day, FDA sent Otsuka a "corrected" approval letter in which FDA advised Otsuka that its earlier December 12, 2014, approval letter "contained an error in the 'indications' section." Id. According to Otsuka, FDA attempted to correct this error by broadening the approved indication from treatment "in pediatric patients with Tourette's Disorder" to treatment of "patients with Tourette's Disorder." Id. Otsuka maintains that by taking such action FDA approved Abilify for the treatment of Tourette's Disorder in a population that was larger than that for which Otsuka had demonstrated the drug's safety and efficacy. Accordingly, Otsuka filed the instant complaint contending the FDA's approval of its sNDA was arbitrary, capricious, and in violation of the law.

II. STANDARD OF REVIEW

"Judicial review of an agency action must be premised on the complete administrative record." Novartis Pharm. v. Shalala, No. 99-323, 2000 WL 1769589, at *2 (D.D.C. Nov. 27, 2000) (citing Serono Lab. v. Shalala, 35 F.Supp.2d 1, 2 (D.D.C. 1999)). Section 706 of the APA directs a court evaluating an agency action to "review the whole record or those parts of it cited by a party." 5 U.S.C. § 706. "[A]n agency is entitled to a strong presumption of regularity that it properly designated the administrative record." Pac. Shores Subdivision, Cal. Water Dist. v. U.S. Army Corps of Eng'rs, 448 F.Supp.2d 1, 5 (D.D.C. 2006). Thus, "[s]upplementation of the

administrative record is the exception, not the rule." Id. Nonetheless, an "agency may not skew the record by excluding unfavorable information but must produce the full record that was before the agency at the time the decision was made." Blue Ocean Inst. v. Gutierrez, 503 F.Supp.2d 366, 369 (D.D.C. 2007). Nor may an agency exclude information simply because it did not rely on it for its final decision. See Banner Health v. Sebelius, 945 F. Supp. 2d 1, 16 (D.D.C. 2013). Rather, "a complete administrative record should include all materials that might have influenced the agency's decision, and not merely those on which the agency relied in its final decision." Amfac Resorts, L.L.C. v. U.S. Dep't of the Interior, 143 F. Supp. 2d 7, 12 (D.D.C. 2001) (internal quotations omitted). "[I]f the agency decisionmaker based his decision on the work and recommendations of subordinates, those materials should be included as well." Id. Thus, "a court reviewing an administrative tribunal's decision on the record 'should have before it neither more nor less information than did the agency when it made its decision.'" Washington Metro. Area Transit Auth. v. Local 689, Amalgamated Transit Union, 818 F. Supp. 2d 888, 907 (D. Md. 2011) (quoting IMS, P.C. v. Alvarez, 129 F.3d 618, 623 (D.C. Cir. 1997) (internal citations and quotation marks omitted)).

If an agency fails to produce a complete administrative record, a party may request that the record be supplemented. "An administrative record may be 'supplemented' in one of two ways – either by (1) including evidence that should have been properly a part of the administrative record but was excluded by the agency, or (2) adding extrajudicial evidence that was not initially before the agency but the party believes should nonetheless be included in the administrative record." WildEarth Guardians v. Salazar, 670 F.Supp.2d 1, 5 n. 4 (D.D.C. 2009). Here, Otsuka seeks supplementation on the first ground – that evidence before the decision-maker at the time of the decisions has been excluded from the record. See ECF No. 38 at 9-13.

Supplementation on this ground is appropriate only under three "unusual circumstances": "(1) if the agency deliberately or negligently excluded documents that may have been adverse to its decision, (2) if background information was needed to determine whether the agency considered all the relevant factors, or (3) if the agency failed to explain administrative action so as to frustrate judicial review." See City of Dania Beach v. F.A.A., 628 F.3d 581, 590 (D.C. Cir. 2010) (internal quotation marks and citations omitted). Here, it appears that FDA has, at the very least, negligently excluded documents relevant to its December 12, 2014 decision to approve Otsuka's sNDA.

III. DISCUSSION

The fundamental question the Court must answer in resolving Otsuka's motion to compel is whether Otsuka's complaint challenges FDA's December 12, 2014 approval of Otsuka's sNDA or whether it challenges FDA's February 24, 2015 corrected approval letter. For if Otsuka is challenging the former, FDA effectively concedes that the administrative record is incomplete and must therefore be supplemented. See ECF No. 47 at 2 ("Because plaintiffs' Complaint does not challenge FDA's December 12, 2014 final agency action approving plaintiffs' sNDA, there is no need for FDA to produce the voluminous administrative record supporting that unchallenged action."). In resolving this threshold question, the Court need not look any further than the first sentence of the first substantive paragraph of Otsuka's complaint. There, Otsuka states unequivocally that:

> In count one of this complaint, Otsuka challenges FDA's arbitrary, capricious, and unlawful abuse of its authority in approving a [sNDA]. FDA unlawfully broadened the scope of Otsuka's approved 'indication for use' of its prescription brand drug aripiprazole, which Otsuka markets under the name Abilify®.

ECF No. 1 at ¶ 1. Thus, it is clear from the very first paragraph of the complaint that Otsuka challenges FDA's approval of Abilify for the treatment of Tourette's Disorder in the general population – a population that, Otsuka maintains, is larger than the pediatric population for which Otsuka demonstrated the drug's safety and efficacy. See also at ¶¶ 4, 18-21, 46-54, 58-63; see also ECF No. 2 at 3, 4. Indeed, as Otsuka points out, each of the defendant-intervenors similarly understand Otsuka to be challenging FDA's original approval decision and not just the February 24, 2015 "clarification" letter. See e.g., ECF No. 9-1 at 2, 8; ECF No. 29-1 at 3; ECF No. 41-1 at 2. By misconstruing the obvious thrust of Otsuka's complaint, the FDA excluded documents, either purposely or inadvertently, that were plainly relevant to its December 12, 2014 approval of Otuska's sNDA. Otsuka has therefore overcome the strong presumption of regularity concerning the administrative record and has satisfied the standard for requiring FDA to supplement the administrative record. See City of Dania Beach, 628 F.3d at 590.[2]

FDA discusses various practical problems it would face if it were forced to supplement the administrative record – namely, the need for a protective order, the need to conduct additional document review and redactions, and the need for supplemental briefing. See ECF No. 47 at 12, 15. The Court notes, however, that these problems are entirely self-inflicted wounds. FDA had every opportunity to voice these concerns to the Court during the March 25, 2015 teleconference. Indeed, the Court specifically asked FDA if there was anything that made it impossible or impracticable for it to assemble a complete administrative record. Aside from its

[2] The Court also notes that if it is true, as FDA contends, that the February 24, 2015 letter did not broaden the Abilify indication, and that the December 12, 2014 approval of Abilify was always for the treatment of Tourette's in the general population, then it is inconsequential whether Otsuka challenges the February letter or the December decision, as they are, in effect, the same decision. And that is the decision that Otsuka challenges - the decision to approve a drug for an indication that Otsuka contends has not been proven safe or effective.

jurisdictional concern, FDA voiced no such concerns. The Court therefore does not take kindly to FDA's belated arguments or its apparent dilatory tactics. The Court will simply not permit FDA to run-the-clock on this litigation.[3] Accordingly, the Court grants Otsuka's motion and ORDERS FDA to supplement the administrative record by Monday, April 13, 2015 at 9:00 am. At that time, the administrative record will be closed and FDA will be precluded from relying upon any evidence or materials not included in the record for the remainder of this litigation.

IV. CONCLUSION

For the reasons stated above, the Court will GRANT Otsuka's motion to compel.

Dated: April 8, 2015

/S/
George J. Hazel
United States District Judge

[3] The Court also notes that it is not persuaded by FDA's vague and hypothetical invocation of the deliberative process and/or attorney-client privilege as shield to supplementing the record. See ECF No. 47 at 8-10. FDA has not identified any specific documents, or categories of documents, that it believes are covered by an applicable privilege. Thus, any assertion of privilege is, at this point, premature and not a basis upon which to deny Otsuka's motion.