IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Otsuka Pharmaceutical Co., Ltd., et al.,	*	
	*	
Plaintiffs,	*	
	*	
v.	*	
	*	
Sylvia Mathews Burwell, Secretary	*	Civil No. 15-CV-0852-GJH
U.S. Department of Health and Human	*	
Services, et al.,	*	
	*	
Defendants.	*	
	*****	

FEDERAL DEFENDANTS' MEMORANDUM
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

This case reflects the efforts of plaintiffs Otsuka Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Development & Commercialization, Inc., and Otsuka American Pharmaceutical, Inc. ("Otsuka" or "plaintiffs") to maintain their monopoly for Abilify (aripiprazole), a blockbuster antipsychotic drug. Otsuka contends that, based on a novel interpretation of 21 U.S.C. § 355a(o), its orphan drug exclusivity for ***one*** pediatric indication should block generic approvals of Abilify for ***all*** indications, including those without any patent or exclusivity protection. The United States Food and Drug Administration ("FDA") fully considered Otsuka's arguments and rejected them, explaining that this statutory provision provides additional authority for FDA to approve generic applications with pediatric information, and does not limit FDA's authority to carve-out pediatric labeling when a carve-out is appropriate.

Otsuka filed a motion for a temporary restraining order and/or preliminary injunction, which this Court denied, finding that Otsuka was unlikely to succeed on the merits of its claims, and that Otsuka additionally failed to demonstrate any of the other factors for such relief. The Court rejected Otsuka's arguments about the plain meaning of the statute, and upheld FDA's interpretation as reasonable under *Chevron* step two. This Court's decision was correct, and its thorough analysis should apply to the merits. Accordingly, this Court should grant the Federal Defendants' Motion for Summary Judgment, and deny Otsuka's motion.

II. STATUTORY AND REGULATORY BACKGROUND

A. New Drug Applications and Supplemental New Drug Applications

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), pharmaceutical companies seeking to market the initial version of a drug (also known as the "innovator" or "pioneer" drug) must first obtain FDA approval by filing a new drug application ("NDA") containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. § 355(a)-(d). A

sponsor may thereafter submit a supplemental new drug application ("sNDA") seeking FDA's approval of a new indication of an already approved drug. 21 C.F.R. § 314.70(b). Drug sponsors must justify the labeling change proposed in the supplement by submitting data supporting the safety and effectiveness of the drug for the new indication. 21 U.S.C. § 355(a)-(d); 21 C.F.R. § 314.70(b)(3)(iv)-(v). FDA will refuse to approve the supplement if, *inter alia*, the sponsor's investigations do not show that the drug is safe or effective for "the conditions of use prescribed, recommended, or suggested in the proposed labeling."[1] 21 U.S.C. § 355(d)(1), (2), (5).

B. Abbreviated New Drug Applications

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282, permits a manufacturer to submit an abbreviated new drug application ("ANDA") requesting approval of a generic version of an approved drug product. 21 U.S.C. § 355(j). ANDA applicants need not submit clinical data to demonstrate the safety and efficacy of the generic product, as with an NDA. *See id*. Rather, an ANDA relies on FDA's previous findings that the product approved under the NDA is safe and effective. Among other information, an ANDA must include data showing that the generic drug product is bioequivalent[2] to the innovator product. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.127(a)(6)(i), 314.94(a)(7).

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[1] The FDCA defines "labeling" as "all labels and other written, printed or graphic matter (1) upon any article or any of its components or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). "Label," a narrow category of "labeling," is defined as a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k).

[2] Two drugs are considered bioequivalent if, in general, the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug. 21 U.S.C. § 355(j)(8)(B).

C. Marketing Exclusivity

The timing for approval of ANDAs may depend, in part, on some form of marketing exclusivity afforded to the innovator drug.

1. Three-Year Hatch-Waxman Exclusivity

For instance, pioneer drugs may be eligible for three years of exclusivity under the Hatch-Waxman Amendments ("three-year Hatch-Waxman exclusivity") "for a change approved in the supplement" if that sNDA "contains reports of new clinical investigations (other than bioavailability studies)[3] essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement." 21 U.S.C. § 355(j)(5)(F)(iv). Three-year Hatch-Waxman exclusivity for a supplement does not prevent the submission or approval of every application that references the product with the exclusivity protection. Instead, it protects against the approval of an ANDA that includes the "change approved in the supplement." *Id.*

2. Orphan Drug Exclusivity

In addition, pioneer drugs may be eligible for seven years of exclusivity under the Orphan Drug Act for approval of an orphan-designated indication. Congress enacted the Orphan Drug Act (Public Law 97-414) in 1983, to provide incentives to develop drugs to treat rare diseases and conditions. *See* 21 U.S.C. § 360aa *et seq*. As defined in 21 U.S.C. § 360bb, a rare disease or condition includes any disease or condition that affects fewer than 200,000 people in the United States. To obtain orphan exclusivity, a sponsor must first request and obtain from FDA orphan designation for the drug for the proposed orphan indication. 21 U.S.C. § 360bb. The statute generally grants seven-year orphan exclusivity to designated drugs for the specified

[3] FDA's implementing regulation (21 C.F.R. § 314.108(a)) defines "new clinical investigation" as "an investigation in humans the results of which have not been relied on by FDA to demonstrate substantial evidence of effectiveness of a previously approved drug product for any indication or of safety for a new patient population and do not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness or safety in a new patient population of a previously approved drug product."

indication upon approval of that indication. 21 U.S.C. § 360cc (providing that FDA "may not approve another application . . . *for such drug for such disease or condition* . . . until the expiration of seven years") (emphasis added). Orphan exclusivity does not attach to the product as a whole, only to the indication for which orphan designation was obtained and for which the drug was subsequently approved. 21 C.F.R. § 316.31(b) ("Orphan-drug exclusive approval protects only the approved indication or use of a designated drug."). Thus, like three-year Hatch-Waxman exclusivity, orphan drug exclusivity is limited in its scope and does not preclude approval of the same drug for a different, unprotected indication.

D. Same Labeling Requirements for Products Approved in ANDAs

Although the FDCA generally mandates that generic drug labeling be the same as the reference listed drug's labeling, *see* 21 U.S.C. § 355(j)(2)(A)(v),[4] it does not require that a generic drug's labeling be identical to that of the listed drug it references in every respect. Instead, the FDCA reflects Congress' intent that the generic drug be safe and effective for each condition of use prescribed, recommended, or suggested in the generic drug labeling but does not require that an ANDA be approved for each condition of use for which the listed drug is approved. In describing the Hatch-Waxman amendments, Congress explicitly acknowledged that, "the bill permits an ANDA to be approved for less than all of the indications for which the listed drug has been approved." H.R. REP. NO. 98-857, pt.1, at 2; *see also id*. at 21 ("The [ANDA] applicant need not seek approval for all of the indications for which the listed drug has been approved.").

[4] Section § 355(j)(2)(A)(v) requires that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed drug."

Specifically, the FDCA allows for exceptions to the same labeling requirement if "the new [ANDA] drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v); *see also* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.92(a)(1), 314.127(a)(7). In such cases, ANDA applicants may, for example, "carve-out" indications protected by patent or exclusivity in certain circumstances. The implementing FDA regulation, 21 C.F.R. § 314.94(a)(8)(iv), provides examples of permissible labeling differences that may result because the generic drug product and reference listed drug are produced or distributed by different manufacturers. These permissible differences include an omission of an indication or other aspect of labeling protected by exclusivity. *Id.*; see also 21 C.F.R. § 314.127(a)(7). In order to approve an ANDA containing proposed labeling that omits such protected information, FDA must find that the "differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, non-protected conditions of use." 21 C.F.R. § 314.127(a)(7).

Courts have confirmed an ANDA applicant's ability to carve-out labeling protected by exclusivity. *See, e.g.*, *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 147-48 (4th Cir. 2002) (upholding ANDA applicant's ability to carve-out an indication protected by orphan exclusivity and noting dangers of expanding exclusivity beyond Congressional intent); *Bristol-Myers Squibb v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (noting that the FDCA "expresses the legislature's concern that the new generic be safe and effective for each indication that will appear on its label; whether the label for the new generic lists every indication approved for use of the pioneer is a matter of indifference"); *cf. Hospira, Inc. v. Burwell*, No.14-02662, 2014 WL 4406901, at *17 (D. Md. Sept. 5, 2014) (upholding FDA's carve-out of information protected by patent).

III. CASE-SPECIFIC BACKGROUND

A. Otsuka's NDA for Abilify

Otsuka holds several NDAs (Nos. 21436, 21713, 21729, 21866) for various dosage forms and strengths of aripiprazole, which the company markets under the proprietary name Abilify.[5] Abilify currently has six different approved indications for use, all psychiatric in nature.[6] FDA first approved Abilify on November 15, 2002.[7] Many of Abilify's indications do not have any current exclusivity protection.[8]

B. Otsuka's sNDA for a Tourette's Disorder Indication for Abilify

On December 12, 2014, FDA's Center for Drug Evaluation and Research, Division of Psychiatry Products approved Otsuka's sNDA for Abilify for a new indication, treatment of

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[5] *See* AR 1010-31; *see also* drugs@fda, *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (search for "Abilify") (last accessed Apr. 18, 2015).

[6] *Id*.

[7] *See* AR 1030; *see also* Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, *available at* http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_ No=021436&TABLE1=OB_Rx (search for "Abilify") (last accessed Apr. 18, 2015).

[8] In addition to the current three-year Hatch-Waxman exclusivities for "Treatment of pediatric patients with Tourette's Disorder (6-18 years)," and "Labeling Revisions Resulting from a Maintenance Trial in Pediatric Patients with Irritability Associated with Autistic Disorder," Abilify has already received three-year exclusivity for each of the following indications: "Longer-Term Efficacy of Aripiprazole in the Treatment of Schizophrenia" (Orange Book at ADA 6 (24th ed. 2004)); "Treatment of Acute Manic and Mixed Episodes Associated with Bipolar Disorder" (Orange Book at ADA 11 (25th ed. 2005)); "Maintenance Therapy in Bipolar I Disorder" (Orange Book at ADA 11 (27th ed. 2007)); "Adjunctive Treatment to Treat Patients with Major Depressive Disorder" (Orange Book at ADA 13 (28th ed. 2008)); "Treatment of Acute Manic or Mixed Episodes Associated with Bipolar I Disorder in Pediatric Patients Aged 10-17 Years" (Orange Book at ADA 13 (29th ed. 2009)); "Adjunctive Therapy Added to Lithium or Valproate in Short Term Treatment Bipolar Disorder Manic or Mixed" (Orange Book at ADA 13 (29th ed. 2009); "Treatment of Irritability Associated with Autistic Disorder in Pediatric Patients Ages 6-17 Years of Age" (Orange Book at ADA 15 (30th ed. 2010); and "Maintenance Treatment of Bipolar I Disorder as an Adjunct to Lithium or Valproate" (Orange Book at ADA 14 (32d ed. 2012)), all of which have since expired.

Tourette's Disorder.[9] AR 170-265. The approved labeling for the Tourette's Disorder indication has a concise description in the Indication and Usage statement portion of the labeling (*i.e.*, Treatment of Tourette's Disorder), but the dosage and administration and clinical studies sections, among others, pertain only to pediatric patients. *See, e.g.*, AR 176, 179, 248-50. Thus, FDA considers the approval of Abilify for Tourette's Disorder to be for the pediatric population only. *See, e.g.*, AR 468-70.

Upon approval, Otsuka's sNDA received three years of Hatch-Waxman exclusivity and was assigned the Orange Book code I-700, "treatment of pediatric patients with Tourette's Disorder (6-18 years)."[10] Otsuka also received seven years of orphan drug exclusivity for the "Treatment of Tourette's Disorder."[11]

C. FDA's Determination Regarding ANDA Applicants' Ability to Carve-Out the Tourette's Disorder Indication

In a letter dated January 21, 2015, from Otsuka's counsel to Elizabeth H. Dickinson, FDA's Chief Counsel, Otsuka argued that section 505A(o) of the FDCA (21 U.S.C. § 355a(o)) prohibited FDA from approving generic versions of Abilify for any indication, including those without any remaining patent or exclusivity protection, until the expiration of Otsuka's orphan

[9] For ease of reference, this brief refers to Otsuka's sNDA for the Tourette's Disorder indication in the singular. To add the Tourette's Disorder indication, FDA actually approved four sNDAs, one for each of the four NDAs for different dosage forms of Abilify (*i.e.*, Supplement No. 038 to NDA 021436, Supplement No. 030 to NDA 021713, Supplement No. 022 to NDA 021729, and Supplement No. 023 to NDA 021866). *See, e.g.*, AR 170.

[10] *See* AR 1091; *see also* Orange Book at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl _No=021436&Product_No=001&table1=OB_Rx (accessed April 25, 2015).

[11] *See* AR 1093; *see also* AR 453-54, Letter from Gayatri R. Rao, M.D. to Otsuka Pharmaceutical Development & Commercialization, Inc., re: Orphan-drug designation 05-2079 (Feb. 24, 2015). As noted in FDA's General Advice letters to Otsuka dated March 27, 2015, and April 10, 2015, the scope of approval for an indication is reflected by the approved labeling, not the Hatch-Waxman or orphan drug exclusivity codes or approval letters. *See* AR 465-67; AR 468-70.

drug exclusivity period for its Tourette's Disorder indication in December 2021. AR 275-76. Otsuka contended that because § 355a(o) does not address orphan exclusivity a carve-out of pediatric information protected by orphan exclusivity is prohibited by that provision. AR 275.

FDA responded on April 28, 2015, issuing a letter setting forth its determination that ANDA applicants seeking to market generic versions of Abilify could carve-out from their labeling the Tourette's Disorder indication and related information. AR 488. The agency determined that, contrary to Otsuka's contentions, 21 U.S.C. § 355a(o) did not prohibit a labeling carve-out for the Tourette's Disorder indication. *Id.* FDA based its determination on an in-depth analysis of the relevant statutory provisions, regulations, and past agency precedent. AR 490-502. FDA also concluded, based on its scientific review, that "omission of the protected Tourette's Disorder indication and related information does not render the generic drug less safe or effective than Abilify for the remaining non-protected conditions of use" and, thus, "permitted [] ANDAs to omit from their labeling all information related to treatment of Tourette's Disorder." AR 502.

1. Pediatric Labeling Requirements

In its response, FDA began by describing the concerns and rationale that led Congress to enact certain statutory provisions regarding drugs approved for pediatric populations. AR 496-99. FDA explained that "[w]hen a product is approved for use in adults for an indication that also occurs in pediatric populations, FDA generally presumes, based on experience, that the product will be used in the pediatric population for that adult-approved indication regardless of whether it is labeled for that use." AR 496. This experience led to FDA's promulgation of the Pediatric Rule and its later codification in the Pediatric Research Equity Act ("PREA"), which requires studies of drugs in pediatric populations for indications approved in adults. *Id.* (citing 21 U.S.C. § 355c); *see also* 21 C.F.R. § 201.57(c)(9)(iv)(C) ("If there are specific statements on

pediatric use of the drug *for an indication also approved for adults* that are based on adequate and well-controlled studies in the pediatric population, they must be summarized in the 'Pediatric use' subsection.") (emphasis added).

In addition, "[b]ecause pediatric patients and adults metabolize drugs differently, are susceptible to different safety risks, and often require different dosing instructions, Congress gave FDA explicit authority to find a drug misbranded when it is approved for adults for an indication that occurs in pediatric patients but does not include adequate information regarding the use of the drug in pediatric populations for that approved indication." AR 496-97 (citing 21 U.S.C. § 355c(a)(2)(A)(i) (requiring submission of pediatric studies "*for the claimed indications* in all relevant pediatric subpopulations") (emphasis added), and 21 U.S.C. § 355c(d)(2) (noting that if a drug fails to comply with provisions of PREA for submission of pediatric studies for the claimed indications, it "may be considered misbranded solely because of that failure")).[12]

FDA explained that "where a drug is approved in adults and pediatric patients for the same indication but the pediatric information is protected by exclusivity and is significantly different from the information regarding use in adults for the same indication, a carve-out of pediatric information while adult information is retained in the ANDA labeling may result in a potential safety risk to pediatric patients." AR 497. This safety risk may arise "because pediatric patients may be given the drug without adequate safety or dosing information and with the unsubstantiated expectation that it will behave in the same way it does in adults." *Id.* In such

[12] The requirement that pediatric information be included in labeling and the possibility of being found misbranded for failure to include such information only arises for indications for which a drug is approved in adults. AR 497 n.26 (citing 21 U.S.C. §§ 355c(a) and 355c(b) (limiting pediatric study requirement for marketed drugs to the "labeled indications")). As FDA noted in its determination, "PREA does not require that sponsors provide pediatric information for indications for which they do not have (or seek) adult approval." *Id*.

cases, "FDA might consider a generic drug misbranded for failing to include the pediatric information that corresponds to the approved adult indication and will not approve it for the adult indication with the corresponding pediatric information omitted." *Id.*

2. 21 U.S.C. § 355a(o) Provides FDA with Additional Authority to Retain Protected Pediatric Information in ANDA Labeling

These requirements for pediatric labeling, however, resulted in a potential exclusivity loophole—one that Congress sought to close by enacting 21 U.S.C. § 355a(o). As FDA explained (and as the legislative history makes clear) this provision was enacted in response to the example of Glucophage, whose sponsor conducted pediatric studies of the drug for an indication which had previously been approved in adults and, as a result, earned three years of Hatch-Waxman exclusivity after the pediatric-use information was added to the labeling. AR 497 n.27 (citing 147 CONG. REC. H10209 (Dec. 18, 2001)). FDA would not approve an ANDA for Glucophage, even for the adult indication, until after the expiration of the three-year exclusivity because the agency concluded that, given that the drug was approved for the same indication in adults, the protected pediatric information was necessary for the safe use of the drug and therefore could not be carved out. *Id.* As a result, the exclusivity awarded for the pediatric information provided a de facto exclusivity for use of the drug in all populations. *Id.*

FDA explained in its response to Otsuka that 21 U.S.C. § 355a(o), entitled "Prompt Approval of Drugs under Section 505(j) [21 U.S.C. § 355(j)] When Pediatric Information Is Added To Labeling," was enacted "[t]o ensure that ANDA approval is not delayed . . . where a listed drug is approved in adults and pediatric patients for the same indication but protected by [Hatch-Waxman] exclusivity for that use in pediatric patients only." AR 497 (citing 147 CONG. REC. H8105 (Nov. 13, 2001) (noting that § 355a(o) was intended to close the potential

Glucophage exclusivity "loophole")).[13] Indeed, § 355a(o) states that, for pediatric labeling protected by three-year Hatch-Waxman exclusivity, an ANDA "shall *not be considered ineligible for approval* under [section 355(j)] *or misbranded*[14] under section 352 of this title on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use." 21 U.S.C. § 355a(o)(1)) (emphasis added). To this end, 21 U.S.C. § 355a(o) "provides FDA with additional authority to retain [Hatch-Waxman]-protected pediatric information in ANDA labeling where a carve-out would not be appropriate (because such information is necessary for safe use of the product)." AR 498 (citing 21 U.S.C. § 355a(o)(2)(B)).[15]

3. 21 U.S.C. § 355a(o) Does Not Limit FDA's Authority to Permit Labeling Carve-Outs of Protected Pediatric Information

FDA also explained that, contrary to Otsuka's assertions, 21 U.S.C. § 355a(o) "does not limit FDA's authority to carve-out pediatric labeling where a carve-out would otherwise be

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[13] *See also* AR at 498 (citing Best Pharmaceuticals for Children Act ("BPCA") House Report 107-277 (Nov. 9, 2001) at 30 ("[355a(o)]would require prompt approval of a generic drug that otherwise meets all other applicable requirements even when its labeling omits pediatric information that is protected by patent or other market exclusivity provisions"); *id*. at 38 ("[355a(o)] does make clear that if a manufacturer does claim supplemental exclusivity under section [355(j)], the terms of that exclusivity *will not prevent generic competition for the indications or aspects of labeling which are not protected*.") (emphasis added); Letter from Janet Woodcock to Terry G. Mahn (May 21, 2003), Dkt. No. 02P-0469/CP1 at 12 (noting that § 355a(o) was designed to ensure that protection of pediatric labeling for a reference listed drug will not block generics from entering the market)).

[14] FDA noted "that the misbranding that is referred to in this context is the misbranding that occurs when a drug product is approved in adults for an indication that also occurs in pediatric patients but is not fully labeled for the relevant pediatric populations in which it occurs." AR 498 n.29.

[15] Section 355a(o)(2) provides that, notwithstanding Hatch-Waxman exclusivity, FDA may require a drug that omits protected pediatric labeling to include "(A) a statement that, because of marketing exclusivity for a manufacturer – (i) the drug is not labeled for pediatric use; or (ii) . . . the drug is not labeled for pediatric use [due to Hatch-Waxman exclusivity]; and (B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use."

appropriate." AR 498. Indeed, FDA noted that § 355a(o) "was not intended to speak directly to, and leaves unchanged other situations where carve-outs are permissible and would not misbrand the drug." AR 499 (citing 21 U.S.C. § 355a(o)(3)(D) (stating that "except as expressly provided in [section 355a(o)(1) and (2)]" section 355a(o) does not affect "the operation of section 355"). Accordingly, § 355a(o) "does not limit but, in fact, is complementary to FDA's longstanding approach to labeling carve-outs under section [355(j)]." *Id.* As detailed in FDA's decisional letter, "under that longstanding approach, 'conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted.'" *Id.* (quoting 21 C.F.R. § 314.92(a)(1)). The agency explained that under section 355(j) and FDA regulations, "FDA has long carved out from ANDA labeling information protected by [orphan drug exclusivity], consistent with the Orphan Drug Act and FDA's implementing regulations which, as described above, provide that [orphan drug exclusivity] only protects against approval of the same drug for the same indication or use." *Id.*; *see also* AR 499-500 (discussing meloxicam precedent). FDA also considered case law upholding its carve-out authority, noting that courts have held that "carve-out of an orphan-protected indication is permissible provided that the drug without the protected indication will remain safe and effective for the remaining, non-protected conditions of use." AR 499.

D. FDA's Approval of Generic Versions of Abilify

Consistent with its response to Otsuka, on April 28, 2015, FDA issued approvals for multiple ANDAs referencing Abilify. AR 502; *see also* AR 643-45; AR 660-62; AR 678-80; AR 696-98; AR 714-16; AR 733-35; AR 750-52. All of these generic versions carved out protected labeling relating to Tourette's Disorder in pediatric patients. *Id.* In accordance with this Court's schedule, FDA submitted the record of its decision on May 4, 2015.

IV. ARGUMENT

A. The Federal Defendants Are Entitled to Summary Judgment

On summary judgment, the moving party must demonstrate that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). As this Court correctly explained in *Hospira, Inc.*, "[i]n a case involving review of a final agency action under the APA, however, the standard set forth in Rule 56(a) does not apply because of the limited role of a court in reviewing the administrative record." 2014 WL 4406901 at *9 (citing *Roberts v. United States*, 883 F. Supp. 2d 56, 62-63 (D.D.C. 2012); *Kaiser Found. Hosps. v. Sebelius*, 828 F. Supp. 2d 193, 197-98 (D.D.C. 2011)).

In APA actions such as this, "[s]ummary judgment thus serves as a mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review." *Id.* (citing *Richard v. INS*, 554 F.2d 1173, 1177, n.28 (D.C. Cir. 1977)). "Thus, 'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" *Id*. (quoting *Kaiser Found. Hosps.*, 828 F. Supp. 2d at 198).

Here, the administrative record demonstrates that, consistent with past agency precedent and case law, FDA reasonably applied the relevant statutory and regulatory provisions to allow ANDA applicants to carve-out the pediatric Tourette's Disorder indication, which is protected by orphan drug exclusivity, from their labeling because the omission of such information does not render the generic Abilify less safe or effective than the innovator's product for the remaining, nonprotected conditions of use. Accordingly, summary judgment for the Federal Defendants is appropriate.

B. FDA's Interpretations Are Entitled to Deference

The Supreme Court's decision in *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), and its progeny set forth a two-step framework for reviewing an administrative agency's interpretation of its statute. Under *Chevron* step one: "First, always, is the question whether Congress has directly spoken to the precise question at issue. 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. Here, the plain language of the statutory provision supports FDA's position, and certainly does not prohibit it, *see infra* section IV.D.1. And under *Chevron* step two, well-established precedent establishes that this Court must defer to FDA's interpretation of the statutory and regulatory provisions that FDA is charged with implementing. *Chevron* step two applies when Congress has not directly addressed the issue or has done so ambiguously. In that event, the Court may not "simply impose its own construction on the statute," but rather must determine whether the agency's construction is based on a permissible interpretation of the statute. *See id*. at 843, 843-44 n.11 (in case of ambiguity, the court must uphold the agency's interpretation if construction is permissible under the statute; a court need not conclude that agency construction was the only one it permissibly could have adopted or even the reading the court would have reached); *see also Barnhart v. Walton*, 535 U.S. 212, 218 (2002) (reviewing court must decide: (1) whether the statute unambiguously forbids agency interpretation, and (2) whether the agency interpretation exceeds the bounds of the permissible).

Courts have repeatedly given *Chevron* deference to FDA's interpretation of the FDCA, as well as the agency's own implementing regulations. *See, e.g.*, *Sigma-Tau Pharm.*, 288 F.3d at 146; *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 238 (4th Cir. 2002); *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 764 (D.C. Cir. 2010); *Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 349

(D.C. Cir. 2006); *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1281 (D.C. Cir. 2004); *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 883 (D.C. Cir. 2004); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319, 1320 (D.C. Cir. 1998) (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)). Indeed, when a court is evaluating an agency's interpretation of its own regulations, the agency is entitled to "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *see also Fed. Express Corp. v. Holowecki*, 552 U.S. 389, 397 (2008) (courts accept an agency's interpretation of its regulations unless the agency's position is "plainly erroneous or inconsistent with the regulation") (internal quotations omitted) (citing *Auer*, 519 U.S. at 461).

Chevron deference extends to administrative determinations that are not embodied in rulemaking or formal adjudication. As the Supreme Court made clear in *Barnhart*:

> [T]he fact that the Agency previously reached its interpretation through means less formal than "notice and comment" rulemaking . . . does not automatically deprive that interpretation of the judicial deference otherwise its due. . . . If this Court's opinion in [*Christensen v. Harris Cnty.*, 529 U.S. 576 (2000))] suggested an absolute rule to the contrary, our later opinion in [*United States v. Mead Corp.*, 533 U.S. 218 (2001)] denied the suggestion. Indeed, *Mead* pointed to instances in which the Court has applied *Chevron* deference to agency interpretations that did not emerge out of notice-and comment rulemaking.

535 U.S. at 221-22 (citations omitted).

In *Mylan Labs.*, 389 F.3d at 1279-80, for example, the D.C. Circuit extended *Chevron* deference to the agency's interpretation of ANDA exclusivity provisions that was expressed in a letter decision. The court explained that deference was appropriate because of "the complexity of the statutory regime . . . the [presence of] FDA's expertise or the careful craft of the scheme it devised to reconcile the various statutory provisions." *See also Novartis*, 435 F.3d at 351-52 (deferring to FDA's interpretation of a statute without notice-and-comment rulemaking).

C. FDA's Administrative Decisions Are Entitled to Deference

Moreover, under the APA, FDA's administrative decisions may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). As recently explained by this Court:

> In evaluating agency decision making under the APA, the Court's only role is to determine whether "the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens of Overton Park v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds, Califano v. Sanders*, 430 U.S. 99 (1977). 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 Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983). Furthermore, administrative actions are presumed valid; thus, a "court will not second guess an agency decision or question whether the decision made was the best one." *C & W Fish Co. v. Fox*, 931 F.2d 1556, 1565 (D.C. Cir. 1991). The APA only requires the Court to decide whether the agency "articulated a rational connection between the facts found and the choice made." *Baltimore Gas & Elec. Co. v. Natural Res. Def. Council*, 462 U.S. 87, 105 (1983) (citations omitted).

Hospira, Inc., 2014 WL 4406901 at *10.

D. FDA's Decision Should Be Upheld

1. The Plain Language of 21 U.S.C. § 355a(o) Does Not Bar ANDA Approvals Under *Chevron* Step One

Here, the language of 21 U.S.C. § 355a(o) itself (*i.e.*, setting forth circumstances where an ANDA "*shall not be considered ineligible for approval*"), as this Court found, does not "proscribe[] FDA's ability to omit from a generic's label information pertaining to pediatric orphan drug exclusivity." Mem. Op. at 16 (Dkt. No. 100). Section 355a(o) provides:

> A drug for which an application has been submitted or approved under section 355(j) of this title shall not be considered ineligible for approval under that section or misbranded under section 352 of this title on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by three-year exclusivity under [Section 505(j)(5)(F)(iii) or (iv)].

21 U.S.C. § 355a(o)(1).

Otsuka contends that 21 U.S.C. § 355a(o) permits a labeling carve-out only of pediatric information protected by Hatch-Waxman exclusivity, not information protected by orphan drug exclusivity, because orphan drug exclusivity is not expressly enumerated as a basis for a labeling carve-out under that section. *See* Pls.' TRO Mot. (Dkt. No. 77), at 13-15 (relying on the canon of *expressio unius*). Accordingly, Otsuka argues that because Abilify's Tourette's Disorder indication contains pediatric information that is protected by orphan exclusivity, all ANDAs referencing Abilify must await the expiration of that exclusivity period in December 2021, before they will be eligible for approval, even if they seek approval for only unprotected indications. *Id.*

But, as this Court recognized in denying Otsuka's motion for a temporary restraining order and/or preliminary injunction, Otsuka's purported plain language arguments "ignore[] the critical fact that section 505A(o) sets forth circumstances where FDA cannot *deny* approval for a labeling carve-out; it does not, as Otsuka contends, address situations where FDA can or cannot *grant* approval." Mem. Op. at 11 (Dkt. No. 100) (emphasis in original); *see also* AR 502 ("[s]ection [355a(o)] did not purport to describe what can be omitted from ANDA labeling; it described information that can be retained."). Nor is there any basis to Otsuka's contention that the statute addresses or precludes carve-outs of orphan drug exclusivity, as this Court stated:

> Here, Otsuka cites no evidence that Congress even contemplated orphan drug exclusivity at the time section 505A(o) was proposed and enacted, much less that Congress expressly considered orphan drug exclusivity and purposefully excluded it. . . . In the absence of such evidence, Otsuka cannot rely on the *expressio unius* canon to turn section 505A(o) into a restriction on FDA's carve-out authority.

Mem. Op. at 12-13 (Dkt. No. 100).

In addition, as this Court noted, the Orphan Drug Act "confirms FDA's authority to approve ANDAs carving out an orphan drug exclusivity." *Id.* at 15. This Court stated that

"Otsuka's reading of section 505A(o) would nullify the limitation expressly written into section 360cc – that the exclusivity is given to a drug 'for [the orphan] disease or condition' – and instead treat the orphan drug exclusivity as extending to the drug for any and all diseases and conditions, directly contradicting that provision's text and the Fourth Circuit's holding in *Sigma-Tau*." *Id.* at 17-18.

Looking at the statutory framework as a whole, and not just section 505A(o) in isolation, this Court properly concluded that the plain language of the statute did not clearly foreclose ANDA approvals with labeling omitting the orphan indication. Accordingly, Otsuka's arguments under *Chevron* step one should be rejected.

2. FDA's Interpretation Is Permissible and Should Be Upheld Under *Chevron* Step Two

Congress did not address orphan drug exclusivity carve-outs in section 355a(o), and FDA's interpretation of 21 U.S.C. § 355a(o) should be upheld under *Chevron* step two. Under *Barnhart*, 535 U.S. at 218, if the statute does not "unambiguously forbid" the agency interpretation, the agency's interpretation must be upheld unless it "exceeds the bounds of the permissible." FDA's interpretation is entirely reasonable and fully within permissible bounds, particularly in view of the statute's language, the overall statutory and regulatory scheme, and FDA's longstanding approach to labeling carve-outs under section 355(j). FDA's approach also furthers the goals of the Hatch-Waxman Amendments to facilitate generic drug entry, and is entitled to "substantial deference." *See Thomas Jefferson Univ.*, 512 U.S. at 512, *see also Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008) ("The Hatch-Waxman Amendments help to expedite the marketing of generic drugs.") (citing Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585 (1984)).

Indeed, this Court has already found "that the statute, case law, and FDA regulations all support the FDA's construction of the statute that allows it to carve-out an indication or other information from ANDA labeling when that indication or information is protected by orphan drug exclusivity as long as the ANDA with that carved out label remains safe and effective for the remaining non-protected conditions of use." Mem. Op. at 17 (Dkt. No. 100). Furthermore, this Court noted that "[b]ecause 'FDA has been consistent in how it has interpreted' the carve-out provisions over an extended period of time [on multiple occasions over the past decade], the deference afforded to FDA's interpretation of its statute is particularly high. *Id*. at 18 (quoting *Hospira, Inc.*, 2014 WL 4406901, at *13); *see also Kasten v. Saint-Gobain Performance Plastics Corp.*, 131 S. Ct. 1325, 1336 (2011) (noting that the "length of the time the agencies have held" their position "suggests that [the position] reflect[s] careful consideration" and is entitled to deference).

This deference is particularly appropriate because Otsuka's challenge concerns the interplay of different statutory and regulatory provisions relating to orphan drug exclusivity, pediatric use, and ANDA approvals in a complex regulatory scheme. *See Mylan Labs.*, 389 F.3d at 1279-80 (granting Chevron deference to FDA's decision, noting "the complexity of the statutory regime . . . the [presence of] FDA's expertise or the careful craft of the scheme it devised to reconcile the various statutory provisions"). FDA has been charged with implementing this complex scheme. Moreover, as FDA observed, "Otsuka's arguments regarding the meaning of section [355a(o)] turn section [355a(o)] on its head." AR 502. Specifically, "Otsuka seeks to use a provision designed to ensure that ANDA approval would not be delayed in certain circumstances to support its arguments to delay approval for any ANDA

referencing Abilify, including those ANDAs seeking approval only for the non-protected indications." *Id.* FDA correctly rejected such a contorted reading of the statutory scheme.

As explained in its decisional letter, FDA has "long interpreted" the differences due to differences in manufacturer exception to the "same labeling" requirement in 21 U.S.C. § 355(j)(2)(A)(v) and 21 C.F.R. §§ 314.92(a)(1), 314.94(a)(8)(iv), and 314.127(a)(7), to allow carve-outs of labeling protected by orphan drug exclusivity, as well as by Hatch-Waxman exclusivity, "as long as FDA determines that the drug with the information carved out remains safe and effective for the remaining non-protected conditions of use." AR 500-01.

In order "[t]o determine if the carve out of the Tourette's Disorder information would leave the ANDAs safe and effective for the remaining non-protected conditions of use, [the agency] must consider both the information that will be carved out and the information that will remain in the labeling once the carve out is implemented." AR 501. As noted, "FDA has determined in certain instances that ANDA applicants needed to retain pediatric information related to an indication protected by exclusivity where carving it out would present a safety risk to pediatric patients using the drug for its approved (non-protected adult) indication." *Id.*; *see also* AR 595-628 (ANDA labeling approval for sildenafil tablets); and AR 528-554 (ANDA labeling approval for zolpidem tartrate tablets). However, as FDA noted in its letter, "under PREA, pediatric information is only required (and lack of pediatric information will only misbrand the drug) when the indication for which pediatric information is being omitted is one that is approved for use in adults." AR 501.

FDA explained that, here, the agency "determined that it was not necessary to retain in the generic drug labeling any protected Tourette's Disorder information to assure safe use." *Id.*; *see also* AR 471-87. The agency "also determined that aripiprazole with the protected Tourette's

Disorder information carved out remains safe and effective for all of the remaining non-protected conditions of use." *Id.* Indeed, "there will be no information remaining in the aripiprazole labeling describing the use of generic aripiprazole in adults that would lead to an unsupported use of generic aripiprazole in pediatric patients with Tourette's Disorder." *Id.* "As Otsuka has so strenuously argued and as FDA has confirmed, Abilify's labeling includes no dosing or administration information for Tourette's Disorder in adults."[16] *Id.* Thus, "if pediatric information related to Tourette's Disorder is carved out for generic aripiprazole labeling, the remaining labeling would not include any information on use of the drug for adults with Tourette's Disorder because no such information exists in Abilify's labeling." *Id.* Accordingly, as set forth in FDA's decision, "[i]n this case, the harm that section [355a(o)] sought to address, use for an adult indication in pediatric patients without adequate pediatric safety or dosing information, will not be implicated" and there is no basis for finding a carve-out of pediatric information to be unsafe. AR 501-02.

For all of these reasons, this Court should reject Otsuka's misguided construction, which is not grounded in the text of the statute or case law and would grant brand-name companies a windfall of exclusivity for unprotected indications. FDA's interpretation should be upheld under *Chevron* step two.

[16] *See, e.g.*, Pls.' Mot. for TRO and/or PI (Dkt. No. 77) at 4 ("The narrow pediatric indication is made clear by Otsuka's label."); AR 468-70, FDA General Advice Letter (April 10, 2015) ("The labeling describes only pediatric clinical trials, provides instructions only for pediatric dosing in Tourette's Disorder, and describes warnings and adverse reactions only for pediatric patients with Tourette's Disorder. Thus, the approval of Abilify for Tourette's Disorder is only for the pediatric population.").

3. FDA's Administrative Decision Is Not Arbitrary and Capricious

FDA properly determined that ANDA applicants seeking to market generic versions of Abilify could carve-out from their labeling the Tourette's Disorder indication and related information. FDA's application of the statute and regulations to this set of facts easily passes muster under the deferential standard of review in the APA. *See* 5 U.S.C. § 706(2)(A) (court may "set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"). FDA considered the relevant factors, including, but not limited to, the text of the relevant statutory and regulatory provisions, Otsuka's arguments concerning 21 U.S.C. § 355a(o), the labeling at issue, FDA's past precedent in similar circumstances, and case law.[17] FDA explained its consideration of all of these factors, and its decision is presumptively valid. *See Fla. Power & Light*, 470 U.S. at 743. FDA's decision deserves this Court's full deference as a rational exercise of the agency's authority to approve generic drugs under 21 U.S.C. § 355(j).

4. FDA's Decision Is Consistent with Agency Precedent and Case Law

As detailed in the agency's decisional letter, FDA's decision with respect to the carve-out of information related to Abilify's Tourette's Disorder indication is entirely consistent with, and flows directly from, FDA precedent relating to orphan drug exclusivity and carve-outs. Specifically, FDA explained that it had previously considered a labeling carve-out of pediatric information protected both by three-year Hatch-Waxman exclusivity and orphan drug exclusivity for ANDAs referencing Mobic (meloxicam tablets) NDA 20938. AR 499-500. Mobic's sponsor

[17] Otsuka has not challenged FDA's scientific conclusions, which are entitled to considerable deference. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973) (The FDA is "peculiarly suited" to evaluate conflicting scientific reports, a matter "not . . . well left to a court without chemical or medical background," because it "necessarily implicates complex chemical and pharmacological considerations.").

had obtained FDA approval of two supplements to its NDA, on August 11, 2005.[18] AR 499. Upon approval, FDA determined that one of these supplements satisfied the criteria for three-year Hatch-Waxman exclusivity. *Id.* This Hatch-Waxman exclusivity expired on August 11, 2008, but a six-month period of pediatric exclusivity attached to extend the period until February 11, 2009.[19] *Id.* FDA also awarded Mobic orphan drug exclusivity upon approval for "Treatment of Juvenile Rheumatoid Arthritis." *Id.* The orphan drug exclusivity expired on August 11, 2012, but, again, an additional six months of pediatric exclusivity attached, expiring February 11, 2013.[20] AR 499-500. FDA approved multiple ANDAs referencing Mobic between July 19, 2006 and July 31, 2006 (*i.e.*, before the expiration of the Hatch-Waxman and orphan drug exclusivity periods). AR 500. In order to gain approval, each of these ANDAs employed a carve-out of labeling associated with the orphan drug exclusivity and the Hatch-Waxman exclusivity. *Id.*[21]

In addition, as FDA noted in its decisional letter "[r]elevant case law affirms an ANDA applicant's ability to carve-out protected labeling without violating the 'same labeling' requirement." AR 496. For example, in *Bristol Myers Squibb v. Shalala*, the D.C. Circuit ruled that "the statute expresses the legislature's concern that the new generic be safe and effective for each indication that will appear on its label; whether the label for the new generic lists every

[18] One supplement (S-013) was the efficacy supplement, which, upon approval, resulted in three-year Hatch-Waxman and seven-year orphan drug exclusivity, while the other supplement (S-015) was a labeling supplement. AR 499 n.31.

[19] *See* AR 1037 (Orange Book at ADA 87 (27th ed. 2007)).

[20] *See id.*

[21] FDA has consistently permitted labeling carve-outs based on orphan drug exclusivity protection. AR 495 n.25; *see also* AR 629-42 (ANDA labeling approvals for levoleucovorin carving out labeling protected by both Hatch-Waxman exclusivity and orphan drug exclusivity); AR 555-83 (carving out labeling for temozolomide protected by both Hatch-Waxman exclusivity and orphan drug exclusivity); and AR 584-94 (carving out labeling for tacrolimus protected by orphan drug exclusivity).

indication approved for use of the pioneer is a matter of indifference." 91 F.3d at 1500. Similarly, in *Sigma-Tau Pharmaceuticals, Inc. v. Schwetz*, the Fourth Circuit upheld the right of an ANDA applicant to carve-out an indication protected by orphan drug exclusivity as a permissible difference due to a difference in manufacturer. *See* 288 F.3d at 148, n.3. The Fourth Circuit observed that orphan exclusivity was "disease-specific, not drug-specific," and noted that if it adopted Sigma Tau's argument this could mean that once FDA approves an orphan drug for a protected indication, "generic competitors might be prohibited from entering the market for almost any use." *Id.* at 147. The Fourth Circuit asserted that "[Sigma Tau's theory] to bar the approval of generic drugs, even for unprotected indications . . . [would add] a huge evidentiary hurdle to the generic drug approval process [and] would be profoundly anti-competitive." *Id*. Accordingly, the court rejected Sigma Tau's argument and concluded that the statutory scheme permitted an ANDA applicant to carve-out the orphan-protected indication at issue. *Id.*

Accordingly, FDA precedent and case law fully support FDA's decision for Abilify.

V. CONCLUSION

For the foregoing reasons, the Federal Defendants' Motion for Summary Judgment should be granted, and Otsuka's motion denied.[22]

[22] Otsuka seeks a permanent injunction, Am. Compl. (Dkt. No. 76-1), Prayers for Relief ¶ (g), but fails to establish any of the prerequisites for such relief. *See, e.g.*, Mem. Op. at 18-24 (Dkt. No. 100) (finding that Otsuka failed to show irreparable harm, and that the balance of harms and the public interest weigh against granting a preliminary injunction). We will not re-argue the other injunction factors here, but instead refer the Court to federal defendants' previously filed brief in opposition to Otsuka's motion for a temporary restraining order and preliminary injunction. *See* Defs.' Resp. in Opp'n to Mot. for Temp. Restraining Order and/or Prelim. Inj. (Dkt. No. 81).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 11th day of May 2015, FEDERAL DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT was served on the following individuals through ECF who are counsel for the Plaintiffs, as well as all other attorneys of record registered with ECF:

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