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.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

This is an action brought by Plaintiffs Otsuka America Pharmaceutical, Inc., Otsuka Pharmaceutical Development and Commercialization, Inc., and Otsuka America Pharmaceutical Inc. (collectively, "Otsuka") pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 701, *et seq.*, challenging various actions taken by Defendant Food and Drug Administration ("FDA").[1] Specifically, Otsuka challenges FDA's approval of the sale of four generic versions of the prescription brand drug aripiprazole, which is marketed and sold under the brand name of Abilify® by Otsuka. After the Court denied Otsuka's motion for temporary restraining order and/or preliminary injunction on April 29, 2015 (*see* ECF No. 100), FDA, Otsuka, and the Defendant-Intervenors[2] filed cross-motions for summary judgment. *See* ECF Nos. 107-09. On

[1] In addition to naming FDA as a defendant, Otsuka has also named Sylvia Mathews Burwell, Secretary of the U.S. Department of Health and Human Services, and Drs. Margaret Hamburg and Stephen Ostroff as defendants. Because the allegations against these four defendants are the same, the Court will refer to them collectively as the "FDA."

[2] Defendant-Intervenors include Apotex Inc., Apotex Corp., Teva Pharmaceuticals USA, Inc., Alembic Pharmaceuticals Ltd., Alembic Ltd., Alembic Global Holdings S.A., Alembic Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA) Inc., Torrent Pharma Inc., Torrent Pharmaceuticals Ltd., and Sandoz, Inc.

May 20, 2015, the Court held a hearing on these fully briefed motions. For the reasons discussed more fully below, the Court will DENY Otsuka's motion for summary judgment, and will GRANT FDA's and Defendant-Intervenors' motions for summary judgment.

I. BACKGROUND

This case involves the interplay between statutory exclusivities, particularly orphan drug exclusivity, statutory and regulatory mandates that require labels of generic drugs to contain the same information as their brand counterpart, and requirements that pediatric information be included on drug labels. Specifically, Otsuka, the new drug application holder for Abilify®, contends that, as a result of FDA's recent approval of a pediatric indication for Abilify® that is protected by orphan drug exclusivity, FDA is precluded from approving generic versions of Abilify® until its orphan drug exclusivity expires in December 2021 because 21 U.S.C. § 355a(o) does not permit this type of pediatric information to be omitted from a generic's label.[3]

A. Statutory and Regulatory Framework

1. New Drug Applications and Supplemental New Drug Applications

Under the 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. *See* 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. *See* 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

[3] In its April 29, 2015 Memorandum Opinion, the Court referred to 21 U.S.C. § 355a(o) as section 505A(o), which is a reference to the corresponding section of the Federal Food, Drug, and Cosmetic Act ("FDCA"). For purposes of this Memorandum Opinion, the Court will use the citation from the United States Code.

the drug for the new indication. *See* 21 U.S.C. § 355(a) and (d); *see also* 21 C.F.R. § 314.70(b)(3)(iv)-(v). FDA will refuse to approve the sNDA if, among other reasons, 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." 21 U.S.C. § 355(d)(1), (2), (5).

2. 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, & 282, permits a drug manufacturer to submit an abbreviated new drug application ("ANDA") requesting approval of a generic version of an already approved drug product. *See* 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 to the innovator product. *See* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); *see also* 21 C.F.R. § 314.127(a)(6)(i), 314.94(a)(7).

3. Orphan Drug Exclusivity

To justify the costly and risky investment of time and money in preparing and submitting NDAs and sNDAs, Congress has provided these applicants with certain periods of statutory exclusivity during which they can sell their product without generic competition. One of these periods of statutory exclusivity is found in the Orphan Drug Act provisions of the FDCA, Pub. L. 97-414, 96 Stat. 2049. There, Congress encouraged drug manufacturers to develop drugs for the treatment of rare diseases or disorders affecting small patient populations. One of the incentives

that Congress provided in the Orphan Drug Act is a seven-year period of market exclusivity for approved orphan drugs. *See* 21 U.S.C. § 360cc(a). FDA's regulations provide that, when a drug receives orphan exclusivity, "no approval will be given to a subsequent sponsor of the same drug for the same use or indication for 7 years." 21 C.F.R. § 316.3(b)(12).

4. Labeling Requirements

FDA has promulgated regulations requiring certain pediatric information to be included on a prescription drug's label.[4] For example, in the "Indications and Usage" section of the Full Prescribing Information portion, "[i]f evidence is available to support the safety and effectiveness of the drug or biological product only in selected subgroups of the larger population (*e.g., . . . patients in a special age group*) . . . a succinct description of the limitations or usefulness of the drug and any uncertainty about anticipated clinical benefits," must be included. 21 C.F.R. § 201.57(c)(2)(i)(B) (emphasis added). Elsewhere the regulations explain that, "[i]f there is a specific pediatric indication different from those approved for adults that is supported by adequate and well-controlled studies in the pediatric population, it must be described under the 'Indications and Usage' section." § 201.57(c)(9)(iv)(B).

Likewise, the "Dosage and Administration" section "must state the recommended dose and, as appropriate," among other things, "[d]osages for each indication and *subpopulation*." § 201.57(c)(3)(C) (emphasis added). This section must include appropriate pediatric dosage information "[i]f there is a specific pediatric indication different from those approved for adults

[4] A drug's labeling includes "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." 21 U.S.C. § 321(m)(1)-(2). The labeling must "contain [a]dequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented." 21 C.F.R. § 201.100(d)(1).

that is supported by adequate and well-controlled studies in the pediatric population." § 201.57(c)(9)(iv)(B).

The regulations require that the labeling also includes other specific pediatric information. Where a specific pediatric indication has been demonstrated by adequate and well-controlled studies, the pediatric use section "must cite any limitations on the pediatric indication," among other things. *Id*. "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 . . . ." § 201.57(c)(9)(iv)(C).

5. The "Same Labeling" Requirement

Generally, generic drugs must contain the same information on their labels as the label of their respective brand-name predicate drug. *See* 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. § 314.94(a)(8)(iv). Nonetheless, there are situations where ANDA applicants may carve out from proposed labeling patent or exclusivity-protected conditions of use and obtain approval for the remaining non-protected conditions of use. For example, the FDCA allows for exceptions 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.

Additionally, Congress enacted 21 U.S.C. § 355a(o) which identifies certain situations where the FDA cannot deny approval based on the omission of pediatric information on a brand's label from the generic's label. 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 [21 U.S.C. § 355(j)(5)(F)(iii) or (iv)].

21 U.S.C. § 355a(o)(1). According to Otsuka, "the statute defines FDA's approval authority by expressly limiting the agency's authority to disapprove a generic drug based on specific pediatric labeling omissions." ECF No. 107 at 20.[5] Because the only labeling omissions the statute allows are for pediatric indications or information pertaining to pediatric use protected by patent or by three-year exclusivity under § 355(j)(5)(F), Otsuka argues that FDA cannot omit pediatric labeling information that is protected by orphan drug exclusivity. *See id*. at 19-20. FDA, on the other hand, contends that section 355a(o) "does not limit [its] authority to carve-out pediatric labeling where a carve-out would otherwise be appropriate"; instead, section 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)." ECF No. 109 at 15 (citing Administrative Record ("AR") 498).

B. Case-Specific Background

Otsuka is the NDA holder for Abilify®. *See* AR 1010-31. FDA first approved Abilify® on November 15, 2002, then for schizophrenia, and FDA has since approved it for schizophrenia in adolescents, acute treatment of manic and mixed episodes associated with Bipolar I Disorder in both adult and pediatric patients, irritability associated with autistic disorder in pediatric patients, and as an add-on treatment for depression in adults. *See id*. In 2005, Otsuka submitted

[5] For the citations to page numbers in this Memorandum Opinion, the Court uses the page numbers assigned to the document from CM/ECF or PACER.

an application to FDA requesting orphan drug designation for Abilify® "for the treatment of Tourette Syndrome in children and adolescents." ECF No. 77-2 at ¶ 10.

In 2006, FDA granted Otsuka orphan drug designation for the use of Abilify® for the treatment of Tourette's Disorder. *See id.* at ¶ 11. This designation meant, among other things, that Otsuka would be entitled to a seven-year period of market exclusivity running from the date of FDA's approval of the use of Abilify® for the treatment of Tourette's Disorder. *See id*. During that seven-year period, FDA would be precluded from approving a drug for the same use or indication. *Id*. When the FDA awarded Abilify® orphan designation for the treatment of Tourette's Disorder, no sNDA had been submitted and no safety and efficacy studies had been conducted in any population group. As such, Otsuka initiated clinical trials which ultimately demonstrated the safety and efficacy of Abilify® to treat Tourette's Disorder in the pediatric population. *See id*. at ¶¶ 14-15, 24. Following the conclusion of these trials, Otsuka submitted a sNDA to FDA seeking approval for the new indication of the treatment of Tourette's Disorder in pediatric patients. *See id*. at ¶ 16. FDA ultimately approved Otsuka's sNDA for Abilify® for treatment of Tourette's Disorder in the pediatric population. *See* AR 468-69. As a result of FDA's decision, Otsuka obtained approval for a pediatric Tourette's Disorder indication for Abilify® that is protected by orphan drug exclusivity.

Otsuka contends that by receiving this pediatric approval, which is protected by orphan drug exclusivity, it is entitled to a seven-year period of total market exclusivity (until December 2021). During that time, Otsuka argues that the law precludes FDA from approving any generic version of Abilify® for *any* of its FDA-approved indications (absent a license from Otsuka). It is against this backdrop that Otsuka filed a complaint, along with a motion for a temporary restraining order and/or preliminary injunction, against FDA seeking to stay the effect of FDA's

approvals of generic versions of Abilify® that occurred on April 28, 2015, to prevent FDA from issuing any further approvals prior to the expiration of Otsuka's seven year period of orphan drug exclusivity, and to prohibit the recipients of generic approvals from distributing their respective versions of generic Abilify®.

Specifically, on April 28, 2015, FDA issued a letter decision to Otsuka 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. *See* AR 488-502. FDA determined that, contrary to Otsuka's contentions, section 355a(o) did not prohibit a labeling carve-out for the Tourette's Disorder indication. *See id.* FDA based its determination on an in-depth analysis of the relevant statutory provisions, regulations, past agency precedent, and case-law. *See* 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. As such, FDA approved four generic version of Abilify®. *See* 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. *See id.*

Just hours after FDA's approval, the Court held a hearing on April 28, 2015 to address Otsuka's motion for temporary restraining order and/or preliminary injunction. *See* ECF No. 94. The following day, the Court issued its Memorandum Opinion and accompanying Order denying Otsuka's motion ("April 29 Opinion"). *See* ECF Nos. 100 & 101. After the Court set an expedited briefing schedule, Otsuka, FDA, and Defendant-Intervenors all filed cross-motions for

summary judgment on May 11, 2015. *See* ECF Nos. 107-109. A hearing on the cross-motions was held on May 20, 2015. Having considered the arguments of the parties, the Court will deny Otsuka's motion for summary judgment and grant the FDA's and Defendant-Intervenors' motions for summary judgment.

II. STANDARD OF REVIEW

Under Fed.R.Civ.P. 56(a), summary judgment is appropriate when the pleadings and the evidence demonstrate that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). In 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. *See Roberts v. United States*, 883 F.Supp.2d 56, 62-63 (D.D.C. Mar. 23, 2012); *see also Kaiser Found. Hosps. v. Sebelius*, 828 F.Supp.2d 193, 197-98 (D.D.C. 2011). Summary 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. *See 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." *Kaiser Found. Hosps.*, 828 F.Supp .2d at 198 (internal quotations and citations omitted).

Under the APA, the Court shall "hold unlawful and set aside agency action, findings and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). 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).

III. DISCUSSION

Otsuka claims that 21 U.S.C. § 355a(o) directly addresses the question of when generics can omit from their labels the pediatric information that is included in the brand's label. *See* ECF No. 107 at 15. According to Otsuka, section 355a(o) permits FDA to approve generic drugs that omit pediatric labeling in only two circumstances – (1) when that information is protected by patent; and (2) when that information is protected by three-year new clinical study exclusivity. Section 355a(o) does not, according to Otsuka, allow for the omission of labeling information protected by pediatric orphan drug exclusivity. *See id* at 19. By approving Otsuka's sNDA for Abilify® to treat Tourette's Disorder in pediatric patients – an indication which is indisputably covered by orphan drug exclusivity – Otsuka argues that FDA was precluded from approving an ANDA for a generic version of Abilify® for any of its approved indications because section 355a(o) does not allow for the omission of this type of pediatric information from the generic's label. Thus, when FDA *did* approve generic versions of Abilify® on April 28, 2015, Otsuka argues it did so in contravention of section 355a(o). FDA and Defendant-Intervenors, on the

other hand, contend that while section 355a(o) limits FDA's ability to deny approvals in two specified circumstances, it does not limit its ability to grant approvals in others. The Court must therefore address the scope of 21 U.S.C. § 355a(o).

A. Applicable Level of Deference

Ordinarily, a court reviews "an agency's construction of the statute which it administers" under the familiar two-step process of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). Despite arguing in its motion for temporary restraining order and/or preliminary injunction that the two-step *Chevron* process was, in fact, the appropriate analysis, Otsuka now contends (for the first time) that *Skidmore* deference – a less stringent form of deference – applies. *See Skidmore v. Swift & Co.*, 323 U.S. 134 (1944); *see also Christensen v. Harris* County, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters – like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law – do not warrant *Chevron* like deference.").[6] According to Otsuka, *Chevron* deference is not appropriate here because FDA's interpretation was not the subject of notice and comment rulemaking. *See* ECF No. 107 at 16-18. The Court disagrees.

The Supreme Court has made clear that "'[t]he want of' notice and comment 'does not decide'" whether *Chevron* applies. *Barnhart v. Walton*, 535 U.S. 212, 222 (2002) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001)). The relevant question is whether "it is 'apparent from the agency's generally conferred authority and other statutory circumstances

[6] Under *Skidmore* deference, an agency interpretation "receives weight in proportion to its 'power to persuade,' as measured by factors like 'the thoroughness evident in its consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements.'" *Shipbuilders Council of Am., Inc. v. U.S. Dep't of Homeland Security*, 673 F. Supp. 2d 438, 453 (E.D. Va. 2009).

that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law.'" *Patel v. Napolitano*, 706 F.3d 370, 376 (4th Cir. 2013) (quoting *Mead*, 533 U.S. at 229)). Several factors are relevant to resolving the issue, including "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time." *Barnhart*, 535 U.S. at 222.

As Defendant-Intervenors rightly point out, Courts applying these factors have routinely held that FDA letter decisions like the one at issue here are entitled to *Chevron* deference. For example, in *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004), the D.C. Circuit rejected the argument that FDA's interpretation of the pediatric exclusivity provision contained in 21 U.S.C. § 355a was not entitled to deference because it was "expressed in letters to the parties" rather than in a regulation. 389 F.3d at 1279. Given "the complexity of the statutory regime under which the FDA operates, the FDA's expertise [and] the careful craft of the scheme it devised to reconcile the various statutory provisions" and that "FDA's decision made no great legal leap but relied in large part on its previous determination of the same or similar issues," the D.C. Circuit concluded that *Chevron* deference was appropriate. *Id.* at 1280.

Likewise, in *AstraZeneca Pharm. LP v. FDA*, 713 F.3d 1134 (D.C. Cir. 2013), the D.C. Circuit applied *Chevron* deference under circumstances similar to those presented here. In that case, AstraZeneca filed suit against FDA seeking an injunction to prevent the agency from approving ANDAs that AstraZeneca claimed were barred by a change to its labeling (the addition of a table) that was protected by pediatric exclusivity. *See id.* at 1136. The district court dismissed AstraZeneca's initial suit as unripe because FDA had not yet decided whether to

approve any ANDAs with the new labeling. *See id*. at 1137. Four days later, FDA approved ANDAs with the new labeling and "issued a letter to AstraZeneca on the same day explaining its decision that [the table] was not entitled to a period of exclusivity." *Id*. The district court granted summary judgment to FDA, concluding that the statute was "ambiguous" and that FDA's interpretation in its letter decision was "reasonable." *Id*. at 1138. In affirming the district court's decision under the two-step *Chevron* test, the D.C. Circuit specifically recognized that *Chevron* deference applied to "FDA decision letters." *Id*. at 1139.

The Court sees no reason to depart from the approach taken by the D.C. Circuit in *Mylan Labs* and *AstraZeneca*, especially given the complexity of the statutory regime at issue, FDA's expertise in regards to this complex scheme, and the fact that FDA's decision on the scope of Otsuka's exclusivity under the FDCA was based on its longstanding understanding of its general carve-out authority (embodied in several regulations) and its precedent addressing the specific question of whether to approve ANDAs that carve out pediatric information protected by orphan drug exclusivity. *See* AR 499-500; *see also Mylan Labs., Inc.*, 389 F.3d 1280. While Otsuka correctly observes that these cases are not binding on this Court, decisions from the D.C. Circuit "are afforded particular weight in the area of administrative law." *Ohio Valley Envt'l Coal. v. U.S. Army Corps of Eng'rs*, 674 F. Supp. 2d 783, 800 (S.D. W. Va. 2009). Furthermore, the only case involving the FDA cited by Otsuka to support the notion that *Skidmore* deference applies was *United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692 (D. Md. 2001), which predated the Supreme Court's decisions of *Mead* and *Barnhard*, and, in any event, involved a non-binding FDA policy statement that lacked the force of law. The Court therefore concludes that the appropriate level of deference afforded to FDA in this case is that provided by the two-step *Chevron* framework.

B. Chevron—Step One[7]

Having decided that *Chevron* deference applies here, the Court begins with the first step of the analysis which asks whether "Congress has directly spoken to the precise question at issue," such that "the intent of Congress is clear." *Nat'l Elec. Mfrs. Ass'n v. Dept. of Energy*, 654 F.3d 496, 504 (4th Cir. 2011) (quoting *Chevron*, 467 U.S. at 842-43). 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." *Chevron*, 467 U.S. at 842-43. If, however, "the statute is silent or ambiguous with respect to the specific issue," *id*. at 843, Congress has not spoken clearly, and a permissible agency interpretation of the statute merits judicial deference. Thus, "[t]he objective of *Chevron* step one is not to interpret and apply the statute to resolve a claim, but to determine whether Congress's intent in enacting it was so clear as to foreclose any other interpretation." *King v. Burwell*, No. 14-1158, 2014 WL 3582800, at *5 (4th Cir. July 22, 2014) (citing *Grapevine Imports, Ltd. v. United States*, 636 F.3d 1368, 1377 (Fed. Cir. 2011)).

Under the first step of *Chevron*, "a reviewing court is to 'employ [ ] traditional tools of statutory construction' to determine whether Congress addressed 'the precise question at issue.'" *Nat. Elec. Mfrs. Ass'n.*, 654 F.3d at 504 (quoting *Chevron*, 467 U.S. at 842, 843 n. 9). Courts, therefore, begin this analysis with the text and structure of the statute. *Id*. (citing *Cabell Huntington Hosp. Inc. v. Shalala*, 101 F.3d 984, 986 (4th Cir. 1996)). After all, "the plain language of the statute" is "the most reliable indicator of Congressional intent." *Schafer v.*

[7] In its April 29 Opinion addressing Otsuka's motion for temporary restraining order and/or preliminary injunction, the Court discussed, at length, Otsuka's likelihood of success on the merits. *See Otsuka Pharm. Co. v. Burwell*, No. 15-852, 2015 WL 1962240, at *5-10 (D. Md. Apr. 29, 2015). Because much of that discussion is relevant for present purposes, the forthcoming discussion of the two-step *Chevron* analysis involves some repetition from the Court's prior opinion. This opinion, however, also addresses new and additional arguments not previously discussed by the Court in its April 29 Opinion.

Astrue, 641 F.3d 49, 54 (4th Cir. 2011). Additionally, the Fourth Circuit has "described legislative history as one of the traditional tools of interpretation to be consulted at *Chevron*'s step one." *Nat. Elec. Mfrs. Ass'n.*, 654 F.3d at 504–05 (citing *Elm Grove Coal Co. v. Dir., O. W.C.P.*, 480 F.3d 278, 293-94 (4th Cir. 2007)).

Thus, the Court begins its *Chevron* step one inquiry into Congress's intent, as it must, from "the fundamental canon that statutory interpretation begins with the language of the statute itself." *Butler v. West*, 164 F.3d 634, 639 (D.C. Cir. 1999). Here, as mentioned, the relevant statute is 21 U.S.C. § 355a(o). Specifically, 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).

According to Otsuka, this language "directly [speaks] to the precise question of when pediatric indications and other information pertaining to pediatric use may be omitted from a generic's label." ECF No. 107 at 19. Specifically, Otsuka contends that, by enacting section 355a(o), "Congress provided that only pediatric labeling protected by patent and three-year new clinical studies exclusivity could be omitted from a generic's label." *Id.* Because the statute does not expressly permit pediatric labeling protected by orphan drug exclusivity to be omitted from a generic label, FDA cannot, according to Otsuka, "approv[e] a generic drug that omits [] pediatric labeling protected by orphan drug exclusivity." *Id.* To do so, would, according to Otsuka, "require[] adding text to the statute." *Id.* at 23.

As this Court held in its April 29 Opinion, in reaching this conclusion, "Otsuka ignores the critical fact that section [355a(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." *Otsuka Pharm. Co.*, No. 15-852, 2015 WL 1962240, at *7 (emphasis in original). Otsuka argues that this is a mere "linguistic distinction," and that because Congress used a double negative when it used the phrase "shall not be considered ineligible for approval," the correct interpretation of this phrase is "FDA shall approve." ECF No. 107 at 20-22. But in making this argument, Otsuka is attempting to change or add text to the statute. The Court will not follow Otsuka's lead. *See 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951) ("[O]ur problem is to construe what Congress has written. After all, Congress expresses its purpose by words. It is for us to ascertain – neither to add nor to subtract, neither to delete nor to distort."); *United States v. Sonmez,* 777 F.3d 684, 688 (4th Cir. 2015) ("We will not construe the statute in such a manner, because we are required to interpret statutory language as written and are not permitted to add words of our own choosing."). Regardless, neither the *actual* text of the statute nor Otsuka's suggested alternative tells FDA when it *may not* approve an ANDA. To do so, the text would need to be further rewritten to say "FDA shall *only* approve ANDAs with omitted pediatric indications if" or "FDA may not approve ANDAs with omitted pediatric indications *unless*."

To be clear, other provisions in the FDCA demonstrate that Congress knew how to specifically and affirmatively direct FDA's ability to *approve* an ANDA when it wanted to do so. For example, in section 355(j)(4), the FDCA provides that, "subject to Paragraph (5)", the FDA "*shall* approve an [ANDA] *unless* . . ." barred by one of a list of grounds for disapproval. Unlike section 355a(o), therefore, section 355(j)(4) directs a specific action unless a specified bar to that

action exists. By contrast, section 355a(o) merely tells FDA it may not *disapprove* an ANDA based on the omission of pediatric indications that is the result of patent or three-year new clinical study exclusivity with no language to indicate that it intended to restrict FDA's ability to *approve* ANDAs not covered by those two categories. [8] If Congress intended to limit FDA's approval authority, it could have done so explicitly using language similar to what it used in 355(j)(4). *See Jama v. Immigration and 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 greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest"). Otsuka cannot therefore turn a provision limiting FDA's disapproval authority into a provision limiting its approval authority.

Furthermore, although Otsuka goes to great lengths to try to distance itself from the *expressio unius est exclusio alterius* canon (the expression of one thing is the exclusion of another) upon which it previously relied when seeking a temporary restraining order and/or preliminary injunction, Otsuka's arguments remain fundamentally the same. *See* ECF No. 107 at 23-27 (arguing "The Text Only Refers To Patent Protection And Three-Year Exclusivity"). Indeed, Otsuka's reliance not on what the text of section 355a(o) includes, but on the significance of what it omits is, in effect, just a repackaged version of the same arguments previously rejected by this Court. Those arguments are no more persuasive now.

[8] Additionally, as FDA points out, Otsuka incorrectly reverses the language of "shall not be considered ineligible for approval" into "FDA shall approve." ECF No. 112 at 11-12. A correct reversal (which itself would be a departure from the statute's plain language) would read: "shall be considered *eligible* for approval." (emphasis added). By removing the words "considered eligible" in its variation of the phrase, Otsuka has entirely eliminated the critical concept of eligibility. Just because something must be considered qualified to be chosen does not mandate that it will actually be chosen. *See id.*

The Supreme Court has "long held that the *expressio unius* canon does not apply 'unless it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it,' and that the canon can be overcome by 'contrary indications that adopting a particular rule or statute was probably not meant to signal any exclusion.'" *Marx v. Gen. Revenue Corp.*, 133 S. Ct. 1166, 1175 (2013) (internal citations omitted); *see also Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) ("We do not read the enumeration of one case to exclude another unless it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it.").

Initially, Otsuka cited no evidence, and conceded there was no evidence found, that Congress even contemplated orphan drug exclusivity at the time section 355a(o) was proposed and enacted, much less that Congress expressly considered orphan drug exclusivity and purposefully excluded it. *See* ECF No. 99 at 17:8-15.

In its subsequent motion for summary judgment, however, Otsuka identified specific legislative history that, it contends, demonstrates that the Senate Health, Education, Labor, and Pension ("HELP") Committee was "considering orphan drug issues, and orphan drug exclusivity, specifically" when it "work[ed] on a predecessor bill" prior to the enactment of section 355a(o). ECF No. 77 at 9, 43. As Defendant-Intervenors correctly point out, however, Otsuka provides no evidence that the Senate HELP Committee ever discussed the implications of orphan drug exclusivity as it relates to section 355a(o). *See* ECF No. 108 at 17-19. Simply showing that some members of the Congress that enacted section 355a(o) were generally aware of the Orphan Drug Act or orphan drug issues hardly suggests that by not mentioning orphan drugs in section 355a(o) Congress intended, by negative implication, to limit FDA's existing carve-out authority under 21 U.S.C. §§ 355(j) and 360cc.

Thus, in the absence of evidence suggesting that Congress contemplated orphan drug exclusivity when it enacted section 355a(o), Otsuka cannot rely on the *expressio unius* canon, or similar arguments, to turn section 355a(o) into a restriction on FDA's carve-out authority. *See e.g.*, *Barnhart*, 537 U.S. at 170 ("The enunciation of two exceptions does not imply an exclusion of a third unless there is reason to think the third was at least considered."); *Clinchfield Coal Co. v. Fed. Mine Safety & Health Review Comm'n*, 895 F.2d 773, 779 (D.C. Cir. 1990) ("The drafter (here Congress) may simply not have been focusing on the point in the second context; and, where an agency is empowered to administer the statute, Congress may have meant that in the second context the choice should be up to the agency."); *Greene v. United States*, 79 F.3d 1348, 1355 (2d Cir.1996) ("The ancient maxim *expressio unius est exclusio alterius* . . . cautions us against engrafting an additional exception to what is an already complex [statutory scheme].").

The background and reasoning behind the passage of section 355a(o) further refutes Otsuka's interpretation of the provision. As a starting point, all parties agree that section 355a(o) was crafted to address the so-called "Glucophage loophole." *See* ECF Nos. 107 at 31-35, 108-1 at 33-36, 109-1 at 14-15. A discussion of the background of the Glucophage loophole is, therefore, useful.

Bristol Myers Squibb, Glucophage's sponsor, undertook pediatric studies of the drug, which already had an indication approved in adults, and earned three years of new clinical study exclusivity for a pediatric indication. As a result, FDA would not approve any ANDAs for Glucophage, even for the adult indication, until the three-year period of exclusivity resulting from its pediatric indication expired because the drug was approved for the same indication in adults making protected pediatric information necessary for the safe use of the drug. *See* AR 480-81 n. 24 (citing 147 CONG. REC. H10209). FDA's concern stemmed from its regulations

which stated that "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." 21 CFR 201.57(c)(9)(iv)(C) (emphasis added).[9] The result was *de facto* exclusivity for all populations and the prevention of generic products from reaching consumers.

Aware of the potential adverse consequences to consumers, Congress added section 355a(o) "to override the [existing] requirement that generic versions of pioneer drugs bear labeling for pediatric indications." 147 CONG. REC. H10210 (memorandum to the United States Congress Re: Proposed Amendment to the Hatch-Waxman Act (H.R. 2887), referring to the proposal as the "Anti-Glucophage Bill"). Representative John Dingell, the ranking minority member of the relevant House committee, expressly noted that the misuse of pediatric information to garner three-year exclusivity for a certain indication and wholly block generic competition for all approved indications is "a fundamental abuse of the system and were the FDA . . . to accept the claim, consumers would be harmed." 147 CONG. REC. H8105. Representative Dingell also noted that the provision that eventually became section 355a(o) "closes this potential loophole by instructing the FDA to approve generic drugs without proprietary pediatric labeling awarded to product sponsors under the Hatch-Waxman Act." *Id*; *see also* 147 CONG. REC. H10212 (same); *accord id*. at H10210 (statement of Rep. Eshoo) ("Importantly the bill we will vote on today . . . closes the 'Glucophage loophole' which allowed

[9] Otsuka points to other regulations as being the "relevant provisions," (*see* ECF No. 113 at 6), but those provisions contain similar language. *See* 21 C.F.R. § 201.80(f)(9)(ii) ("if there is a specific pediatric indication (*i.e., an indication different from those approved for adults*) that is supported by adequate and well-controlled studies in the pediatric population, it shall be described under the 'Indications and Usage' section of the labeling and appropriate pediatric dosage information shall be given under the 'Dosage and Administration' section of the labeling.") (emphasis added).

one company to get an additional 3 years of marketing exclusivity. This bill ensures that no company will be able to take advantage of the exclusivity granted by this very important legislation.").

Given this context, it would defy logic to believe that in enacting this measure to prevent a three-year exclusivity from becoming a "fundamental abuse of the system" that harmed consumers, Congress nonetheless intended to permit the seven-year exclusivity Otsuka seeks here. The Court concludes that it did not. [10] Otsuka also contends that the failure of section 355a(o) to address orphan drug issues means that the existing regulations foreclose approval here for the same reason that the FDA would not approve ANDAs for generic Glucophage. Again, the Court disagrees. The FDA's concern in Glucophage was that an unprotected adult indication existed while the corresponding pediatric indication was protected and would need to be carved-out. As stated by the FDA, "when 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 479-80. Therefore, in some of those cases, "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. Abilify® does not have an *adult* indication

[10] Defendant-Intervenors are correct to point out that the number of pediatric patients who suffer from Tourette's disorder (and therefore qualified Otsuka to receive orphan drug exclusivity for that indication) is fewer than 120,000. *See* ECF No. 77-2 at ¶ 10. Even if Abilify® were prescribed to this entire pediatric population, those sales still would be only a small percentage of the more than $4.7 billion worth of Abilify® sales in the United States in fiscal year 2013. *See* Otsuka Holdings Co., Ltd., Fact Book: Supplementary Materials, Financial Results FY 2014, 6 (2014), available at http://www.otsuka.com/en/financial/pdf.php?financial=338.at 11. Thus, as Defendant-Intervenors put it: "Otsuka seeks to block the approval and marketing of generic aripiprazole products for all uses when its orphan drug exclusivity by its own admission could at the very most cover fewer than 120,000 patients. This . . . would destroy the careful balance Congress struck when it enacted the Orphan Drug Act and the Hatch-Waxman Amendments to the FDCA." ECF No. 108 at 35.

for Tourette's syndrome. *See* ECF No. 77-2 at ¶ 7. Hence, the FDA's concerns with, and regulations applying to, the Glucophage problem do not exist here.

In sum, when the Court considers the text of section 355a(o), as well as its legislative history, the Court cannot conclude that section 355a(o) clearly proscribes FDA's ability to omit from a generic's label information pertaining to pediatric orphan drug exclusivity. Thus, if the Court's role here was simply to "interpret and apply the statute to resolve a claim," the Court would, without further analysis, side with the interpretation of FDA and Defendant-Intervenors. *See Chevron,* 467 U.S. at 842. However, given 355a(o)'s silence on orphan drug exclusivity, the Court cannot find that Congress's intent in enacting 355a(o), as it relates to its impact on orphan drugs, if any, is so clear as to completely foreclose Otsuka's interpretation. The Court must therefore proceed to *Chevron* step two.

C. *Chevron*—Step Two

Finding that Congress has not "directly spoken to the precise question at issue," the Court moves to *Chevron*'s second step. *Chevron,* 467 U.S. at 842. At step two, the Court asks whether the "agency's [action] is based on a permissible construction of the statute." *Id.* The Court may overturn the FDA's interpretation under *Chevron* step two only if the statute "unambiguously foreclosed the agency's statutory interpretation." *Catawba Cnty., N.C. v. E.P.A.*, 571 F.3d 20, 35 (D.C. Cir. 2009). Thus, the Court will not "usurp an agency's interpretive authority by supplanting its construction with our own, so long as the interpretation is not 'arbitrary, capricious, or manifestly contrary to the statute.'" *Philip Morris USA, Inc. v. Vilsack,* 736 F.3d 284, 290 (4th Cir. 2013) (quoting *Chevron*, 467 U.S. at 844, 845). "A construction meets this standard if it 'represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute.'" *Id*. Courts have been clear that "[r]eview under

this standard is highly deferential, with a presumption in favor of finding the agency action valid." *Ohio Vall. Envt'l Coalition v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009).

Moreover, an agency's construction of its own regulations is entitled to "substantial deference," *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994), and is accorded "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id*. Broad deference to an agency is especially appropriate where, as here, "a complex and highly technical regulatory program" is concerned, requiring "significant expertise" and the "exercise of judgment grounded in policy concerns." *Id*. (citing *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991)).

Under the FDCA, FDA has broad authority to approve ANDAs carving out exclusivities, including orphan drug exclusivity. That authority does not appear to be abrogated by section 355a(o), which, by its terms, constrains FDA's authority to refrain from approving an ANDA, instead of, as Otsuka urges, constraining its authority to approve ANDAs. While it is generally true that generic drugs must contain the same information on their labels as the label of their respective brand-name pioneer drug, this principle does not require a generic drug's labeling to be identical to that of the listed drug it references in every respect. Instead, the same labeling rules contained in the Hatch-Waxman Amendments "reflect Congress's intent that the generic drug be safe and effective for each condition of use prescribed, recommended, or suggested in the generic drug labeling but do not require that an ANDA be approved for each condition of use for which the listed drug is approved." AR 478. Indeed, the legislative history of these amendments demonstrates Congress's desire to permit ANDA applicants to carve out from their labels otherwise protected information. Specifically, Congress acknowledged that "[t]he bill permits an ANDA to be approved for less than all of the indications for which the listed drug has

been approved. . . . [T]he applicant need not seek approval for all of the indications for which the listed drug has been approved." H.R. REP. NO. 98-857(I), at 21 (1984).

The Orphan Drug Act further confirms FDA's authority to approve ANDAs carving out an orphan drug exclusivity. Specifically, 21 U.S.C. § 360cc(a) provides that "for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application under section 355 of this title . . . *for such drug for such disease or condition* . . . until the expiration of seven years from the date of the approval of the approved application" (emphasis added). Interpreting this language in *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141 (4th Cir. 2002), the Fourth Circuit opined:

> By using the words 'such drug for such disease or condition,' Congress made clear its intention that [section 360cc] was to be disease-specific, not drug-specific. In other words, the statute as written protects uses, not drugs for any and all uses. Congress could have written [section 360cc] more broadly by prescribing that the FDA 'may not approve another application . . . for such drug,' but it chose not to draft the statute in that way.

Id. at 145. As such, the Fourth Circuit upheld the right of an ANDA to carve out an indication protected by orphan drug exclusivity as a permissible difference between the generic's label and the pioneer's label due to a difference in manufacturer. *See also Bristol Myers Squibb v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (recognizing that the Orphan Drug Act "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").

Moreover, the interpretation Otsuka seeks is directly contrary to FDA's prior decisions on orphan drug exclusivity carve-outs where that exclusivity incorporated pediatric information. In fact, FDA has, on multiple occasions over the past decade, approved ANDA drug products during the NDA-holder's seven-year period of orphan drug exclusivity, despite the fact that the orphan indication covered a pediatric use. *See* AR 482-83; *see also* ECF No. 82 at 27-28. Because "FDA has been consistent in how it has interpreted" the carve-out provisions over an extended period of time, the deference afforded to FDA's interpretation of its statute is particularly high. *Hospira, Inc. v. Burwell*, No.14-02662, 2014 WL 4406901, at *13 (D. Md. Sept. 5, 2014); *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). The Court therefore finds FDA's interpretation of the statute to be permissible.

Otsuka, however, contends that FDA's decision to approve ANDAs to market generic versions of Abilify® for uses that are not protected by orphan drug exclusivity was impermissible insofar as it violates FDA's own pediatric labeling regulation, known as the Physician Labeling Rule which spells out certain general requirements for labeling in pediatric populations. *See* 21 C.F.R. § 201.57; *see also* ECF No. 107 at 45-46. Specifically, Otsuka argues that FDA's Physician Labeling Rule "require[s] all prescription drugs to contain pediatric labeling" and specifies that drugs without the labeling "would be considered misbranded." ECF No.107 at 46. Accordingly, Otsuka maintains that the Physician Labeling Rule should have blocked FDA's approval of ANDAs for generic versions of Abilify® because "FDA's general carve-out authority is limited by the agency's binding pediatric labeling regulation." *Id.* This case, however, is not about the general requirements for pediatric information in labeling; rather,

this case is about FDA's statutory authority to approve ANDAs that carve out an entire protected orphan pediatric indication, a permissible practice which the Physician Labeling Rule does not change. *See* 71 Fed. Reg. 3925, 3963 (Jan. 24, 2006) ("This [Physician Labeling] rule does not change the requirement to exclude any condition of use or indication from the labeling of a generic product when necessary (e.g., when the reference listed drug has patent protection or market exclusivity for an indication), nor does it prevent, as described at § 314.127(a)(7), approval of an ANDA when the reference listed drug has protected labeling.").[11] The Court, therefore, does not believe the Physician Labeling Rule limits FDA's general carve-out authority.

Furthermore, to the extent that Otsuka argues that the state of the law prior to section 355a(o)'s passage was that ANDAs could not be approved through a carve out of a pediatric indication protected by orphan drug exclusivity, and that the statute's silence on orphan drug exclusivity indicates FDA cannot now approve ANDAs without running afoul of its regulations, it is, in effect, challenging FDA's interpretation of its own regulations. At the hearing, Otsuka avoided acknowledging this position and for good reason. An agency's interpretation of its own regulations is "controlling unless plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997). It cannot be said that FDA's interpretation of its regulations here were plainly erroneous or inconsistent with the Physician Labeling Rule.

Indeed, FDA's regulations demonstrate the authority granted by the FDCA to permit labeling changes based on the "omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under [the FDCA]." 21 C.F.R. § 314.94(a)(8)(iv). The regulations

[11] The Court recognizes that FDA has acknowledged that this language was not present when this regulation was originally enacted in 1994. *See* ECF No. 117. To the extent the Court was interested in that distinction at the hearing, it was for the purpose of determining Congress's intent in passing section 355a(o), which occurred prior to the preamble's inclusion in 2006. The Court has made its determination regarding section 355a(o) but finds this passage relevant in addressing the regulation as it exists now.

permit FDA to approve an ANDA that omits "aspects of the listed drug's labeling [that] are protected by patent, or by exclusivity [if] such differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use." 21 C.F.R. § 314.127(a)(7). Additionally, section 314.94(a)(8)(iv) of the regulations also sets forth specific examples of permissible differences in labeling that may result because the generic drug product and listed drug product are produced or distributed by different manufacturers. These differences include "differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, *or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity* under section 505(j)(5)(F) of the act." 21 C.F.R. § 314.94(a)(8)(iv) (emphasis added).

The Court therefore finds that the FDCA, its legislative history, the case law, and FDA's 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. To be sure, Otsuka's reading of section 355a(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*. If that was Congress's intent, it is certainly left unclear by the statute and FDA's interpretation is reasonable.

IV. CONCLUSION

For the reasons stated above, the Court will DENY Otsuka's motion for summary judgment and will GRANT FDA's and Defendant-Intervenors' motions for summary judgment.

Dated: May 27, 2015

/S/
George J. Hazel
United States District Judge