IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

	:	
MALLINCKRODT INC.	:	
v.	:	Civil Action No. DKC 14-3607
	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.	:	

MEMORANDUM OPINION

Plaintiff Mallinckrodt Inc. ("Mallinckrodt"), a pharmaceutical manufacturer, brings this action seeking judicial review of actions taken by the United States Food and Drug Administration ("FDA"), regarding its methylphenidate hydrochloride extended-release tablets, a generic version of the brand-name drug Concerta. Presently pending and ready for review in this action are several motions: (1) a motion to dismiss filed by Defendants FDA and United States of America ("Defendants") (ECF No. 30); (2) a motion to compel production of the administrative record filed by Mallinckrodt (ECF No. 31); (3) a motion for summary judgment filed by Mallinckrodt (ECF No. 34); and (2) two motions to seal filed by Mallinckrodt (ECF Nos. 4 and 20). The relevant issues have been briefed, and the court now rules, no hearing being deemed necessary. Local Rule 105.6. For the following reasons, Defendants' motion to dismiss will be granted in part, and summary judgment will be granted in part

against Plaintiff. Mallinckrodt's motion to compel production of the administrative record will be denied as moot, and Mallinckrodt's motions to seal will be denied.

I. Background

A. Statutory and Regulatory Background

The FDA regulates the approval, manufacture, sale, and labeling of prescription drugs. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*, provides FDA authority over the approval and monitoring of drugs in the marketplace. The FDCA requires different procedures for approval of brand-name drugs and generic drugs. In order to market and sell a brand-name drug, a pharmaceutical company must submit a New Drug Application ("NDA") to FDA for approval. The NDA requires the applicant to submit extensive scientific data demonstrating the safety and effectiveness of the drug. The NDA must also include, among other things: the drug's components; a description of how the drug is manufactured, processed, and packaged; and proposed labeling describing the uses for which the drug may be marketed. 21 U.S.C. § 355(b)(1).

"Once the FDA has approved a brand manufacturer's drug, another company may seek permission to market a generic version pursuant to legislation known as the Hatch–Waxman Amendments. *See* Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585. Those amendments allow a generic

competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 132 S. Ct. 1670, 1676 (2012); 21 U.S.C. § 355(j). An ANDA applicant may obtain approval of a generic drug, without conducting the extensive clinical and non-clinical studies required for an NDA, if it can show that the drug is "the same" as the previously approved brand-name drug. 21 U.S.C. § 355(j). The previously approved drug is called the reference listed drug ("RLD"), and is defined as "the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application." 21 C.F.R. § 314.3(b). ANDA applicants are permitted to rely on FDA's prior finding of safety and effectiveness for the RLD, and therefore are not required to submit the same types of clinical investigations that are needed for NDA approval. Rather, an ANDA must demonstrate that it is "the same" as the RLD with respect to active ingredients, dosage form, route of administration, strength, conditions of use, and labeling. 21 U.S.C. § 355(j)(2)(A); 21 § C.F.R. 314.94. In addition, before approving an ANDA, FDA must determine that the proposed generic drug is "bioequivalent" to the RLD. 21 U.S.C. § 355(j)(4)(F); 21 C.F.R. § 314.127(a)(7). Generally, a drug is considered to be bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference

from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions[.]"[1] 21 U.S.C. § 355(j)(8)(B). FDA must approve an ANDA unless it finds that there is insufficient evidence of the foregoing or there is inadequate information to ensure the identity, strength, quality, or purity of the drug. 21 U.S.C. § 355(j)(4).

FDA continues to monitor the safety and efficacy of drugs after they are approved. Under certain circumstances described in 21 U.S.C. § 355(e), FDA is authorized to take a drug off the market "after due notice and opportunity for hearing to the applicant[.]" These circumstances include if the Secretary finds that: the "drug is unsafe for use under the conditions of use . . . which the application was approved" or "on the basis of new information . . . evaluated together with the evidence available to [the Secretary] when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." *Id.;* 21 C.F.R. § 314.150(a). "An appeal may

[1] "Bioavailability" is the "rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action[,]" 21 U.S.C. § 355(j)(8)(a), whereas "bioequivalence" essentially means that the RLD and generic drug's bioavailability are "the same," 21 U.S.C. § 355(j)(8)(B).

be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section." 21 U.S.C. § 355(h).

The FDCA also requires that FDA publish a list of all drugs that are approved. FDA fulfills this statutory duty by publishing the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A)(i). The Secretary is required to revise this list every thirty days. 21 U.S.C. § 355(j)(7)(A)(ii). Among other things, the Orange Book contains FDA's evaluations of "therapeutic equivalence." Products evaluated as being therapeutically equivalent ("TE") can be expected, in the judgment of FDA, to have equivalent clinical effects. Orange Book Preface at vii. FDA considers drug products to be therapeutically equivalent if they have: (i) pharmaceutical equivalence (*e.g.,* have the same active ingredient, dosage form, and route of administration), and (ii) bioequivalence. *Id.* at vi-vii; 21 C.F.R. § 320.1(c). FDA lists therapeutic equivalence ratings in the Orange Book in the form of two-letter codes, *e.g.,* AA, AB, BP, BX. The first letter of the code signifies whether the FDA has evaluated the drug as being TE to another product, while the second letter provides additional information regarding the basis of FDA's evaluation. Codes beginning with the letter "A" signify that the FDA

considers the product to be TE to another product, while those beginning with the letter "B" signify actual or potential bioequivalence problems. Orange Book Preface at xiii-xviii. According to FDA, the TE codes "have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. Therapeutic equivalence evaluations in [the Orange Book] are not official FDA actions affecting legal status of products under the Act." *Id.* at iv. The Orange Book states that the TE ratings do not mandate what drugs may or may not be prescribed, purchased, dispensed, or substituted for one another. *Id.* at xi. In addition, it provides that FDA may change TE ratings in order to reflect new data or information that it receives pertaining to a drug's TE rating. *Id.* at xiii.

B. The Parties' Dispute[2]

Mallinckrodt markets and sells methylphenidate hydrochloride extended-release tablets ("methylphenidate ER tablets"), in 27 mg, 36 mg, and 54 mg strengths. (ECF No. 1 ¶ 17). Methylphenidate ER tablets are used to treat patients suffering from attention-deficit hyperactivity disorder

[2] The following facts are set forth in the complaint or are evidenced by documents referenced or relied upon in the complaint. Additional facts will be provided below in the analysis of each claim.

("ADHD"). (*Id.*). On December 30, 2010, Mallinckrodt filed its ANDA with the FDA to demonstrate that its methylphenidate ER tablets were a safe and effective generic substitute for the brand-name drug Concerta's Extended-Release tablets. Mallinckrodt's ANDA application was designated as ANDA 202608. The FDA issued new biostudy requirements on July 19, 2012, pertaining to ANDAs that referenced Concerta, and on September 14, 2012, issued new draft biostudy recommendations for methylphenidate ER tablets ("2012 Draft Guidance"). (*Id.* ¶ 19). As part of ANDA 202608, Mallinckrodt submitted a bioequivalence study that satisfied FDA's 2012 Draft Guidance. (*Id.*). FDA approved ANDA 202608 on December 28, 2012. (*Id.* at 20). FDA's approval letter stated that: "We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling." (ECF No. 8-1). The letter to Mallinckrodt also stated that: "The Division of Bioequivalence has determined your Methylphenidate Hydrochloride Extended-Release Tablets USP, 27 mg, 36 mg, and 54 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Concerta Extended-Release Tablets, 27 mg, 36 mg, and 54 mg, respectively[.]" (*Id.*). The FDA listed Mallinckrodt's methylphenidate ER tablets as "AB" rated in the Orange Book, designating that FDA considered that the

ANDA contained "adequate scientific evidence established through *in vivo* and/or *in vitro* studies the bioequivalence of the product to a selected reference listed drug." (ECF No. 1 ¶ 21). Following FDA's approval, Mallinckrodt launched its methylphenidate ER tablets as the first generic alternative to Concerta. (*Id.* ¶ 22).

Since FDA's approval of Mallinckrodt's methylphenidate ER tablets, Mallinckrodt has not made any changes to the ingredients or formulation of its tablets. (*Id.* ¶ 23). Mallinckrodt supplies its methylphenidate ER tablets to many customers, including retail drug store chains, large wholesale distributors, and the federal government. More than 88 million doses of Mallinckrodt's methylphenidate ER tablets have been prescribed since it was first approved. (*Id.* ¶ 25). Mallinckrodt alleges that since its drug's approval, there have been only "68 adverse events [reported] related to lack of efficacy when the patient switched from Concerta to Mallinckrodt's methylphenidate ER tablets." (*Id.*).

On November 12, 2014, FDA informed Mallinckrodt during a teleconference that FDA would be reclassifying Mallinckrodt's methylphenidate ER tablets from a TE rating of AB in the Orange Book to a BX rating. (*Id.* ¶ 26). Mallinckrodt alleges that the BX rating means that the drug is "presumed to be therapeutically inequivalent" to Concerta. (ECF No. 1). According to

Mallinckrodt, FDA based its reclassification of the drug on application of new draft guidance regarding bioequivalence for methylphenidate hydrochloride products. (*Id.* ¶ 27). The draft guidance had just been issued by FDA on November 6, 2014 ("2014 Draft Guidance"), and was to remain open for public comment through January 5, 2015. (*Id.*). Mallinckrodt objected to FDA's reclassification of its drug's TE rating, arguing that it was not supported by adequate evidence and requesting that FDA give it an opportunity to address the agency's concerns over the drug's bioequivalence. (*Id.* ¶ 28). On November 13, 2014, FDA reclassified Mallinckrodt's methylphenidate ER tablets to a BX rating in the Orange Book. (*Id.* ¶ 29). Mallinckrodt alleges that FDA has not provided it an opportunity to be heard since announcing its reclassification of the methylphenidate ER tablets. (*Id.* ¶ 28). In addition, Mallinckrodt alleges that its drug's former TE rating of AB, which indicated that its product was therapeutically equivalent to Concerta, is essential for pharmacies to be able automatically to substitute Concerta prescriptions with its generic drug. (*Id.* ¶ 30). Mallinckrodt asserts that due to FDA's reclassification of its product to a BX rating, pharmacies will not continue to use its methylphenidate ER tablets to fill Concerta prescriptions, which "effectively takes Mallinckrodt's methylphenidate ER tablets off the market." (ECF No. 1). Mallinckrodt further asserts that

FDA's reclassification is harming Mallinckrodt's relationships with its customers, its reputation, and its market share. (*Id.* ¶ 31).

Mallinckrodt commenced this action against Defendants on November 17, 2014. (*Id.*). "United States of America is named as a [D]efendant pursuant to 5 U.S.C. §§ 702-703, because this is an action for judicial review of actions of any agency of the United States that have affected Plaintiff adversely." (*Id.* ¶ 4). The complaint asserts multiple claims against Defendants under the Administrative Procedure Act ("APA") and a direct cause of action under the Fifth Amendment's Due Process Clause. Count I alleges that FDA's reclassification action without a hearing violated Mallinckrodt's Fifth Amendment due process rights because it was a "final agency action that deprives Plaintiff of a property right in the ANDA approval" in violation of 5 U.S.C. 706(2)(B). (*Id.* ¶¶ 35-36). In Count II, Mallinckrodt asserts a direct right of action under the Fifth Amendment based on FDA's failure to provide Mallinckrodt a hearing in conjunction with the TE rating change. (*Id.* ¶¶ 41-43). Count III alleges that FDA's reclassification was in excess of its statutory authority in violation of 5 U.S.C. § 706(2)(C) because "FDA has no authority to take a drug off the market without following the procedures set forth in 21 U.S.C. § 355(e)." (*Id.* ¶ 48). Count IV alleges that FDA violated 5

U.S.C. § 553 by issuing the 2014 Draft Guidance, which purportedly constitutes a legislative rule, and relied on it to reclassify its drug, without first going through the required notice and comment procedure. Mallinckrodt asserts that FDA's implementation of its 2014 Draft Guidance without first going through notice and comment procedures is a final agency action "without observance of procedure required by law" in violation of 5 U.S.C. § 706(2)(D). Finally in Count V, Mallinckrodt alleges that FDA's reclassification action was "arbitrary and capricious" in violation of 5 U.S.C. § 706(2)(A) because it did "not satisfy the evidentiary standard set forth in the Orange Book's description of code BX[,]" was "not the product of reasoned decisionmaking, is not rationally related to the facts, and/or does not account for evidence contrary to its conclusions." (ECF No. 1 ¶¶ 62-63). Mallinckrodt requests that the court hold unlawful and set aside FDA's reclassification of its drug's TE rating and FDA's 2014 Draft Guidance.

Along with its complaint, Mallinckrodt also filed a motion for a temporary restraining order ("TRO") on November 17, 2014, requesting that the undersigned reverse the FDA's reclassification decision on a temporary basis until the court could consider the merits of the case. (ECF No. 2). Along with its motion for a TRO, Mallinckrodt filed motions to seal declarations that were filed in support of its TRO motion. (ECF

Nos. 4 and 20). Defendants opposed Mallinckrodt's motion for a TRO on November 20, 2014 (ECF No. 25), and a motions hearing was held on November 25, 2014. During the hearing, Mallinckrodt's motion was denied because it was found that Mallinckrodt had failed to show a likelihood of success on the merits.

Defendants moved to dismiss the complaint on December 23, 2014 pursuant to Federal Rules of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction and 12(b)(6) for failure to state plausible claims. (ECF No. 30). On the same day, Mallinckrodt moved to compel Defendants to produce the administrative record in this case. (ECF No. 31). On January 9, 2015, Mallinckrodt opposed Defendants' motion to dismiss and cross-moved for summary judgment. (ECF No. 34). These motions have been briefed and are ready for resolution.

II. Standards of Review

Mallinckrodt asserts multiple claims challenging separate actions taken by FDA: (1) FDA's reclassification of Mallinckrodt's drug's TE rating; (2) FDA's issuance of new Draft Guidance on November 6, 2014; and (3) FDA's failure to provide a hearing in conjunction with its reclassification of Mallinckrodt's drug's TE rating. Defendants' arguments for dismissal of these claims implicate different standards of review.

1. Counts I, III, and V: Subject-Matter Jurisdiction Under Rule 12(b)(1)

Counts I, III, and V of Mallinckrodt's complaint assert violations of the APA based on FDA's purportedly improper reclassification of Mallinckrodt's methylphenidate ER tablets from a TE rating of AB to BX. Defendants contend that these claims must be dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) because FDA's reclassification of the TE rating does not constitute a "final agency action" and therefore is not reviewable under the APA.

A motion to dismiss for lack of subject matter jurisdiction is governed by Federal Rule of Civil Procedure 12(b)(1). Generally, "questions of subject matter jurisdiction must be decided 'first, because they concern the court's very power to hear the case.'" *Owens-Illinois, Inc. v. Meade,* 186 F.3d 435, 442 n.4 (4th Cir. 1999) (*quoting* 2 James Wm. Moore, et al., Moore's Federal Practice § 12.30[1] (3d ed. 1998)). The plaintiff always bears the burden of proving that subject matter jurisdiction properly exists in federal court. *See Evans v. B.F. Perkins Co., a Div. of Standex Int'l Corp.,* 166 F.3d 642, 647 (4th Cir. 1999). In considering a Rule 12(b)(1) motion, the court "may consider evidence outside the pleadings" to help determine whether it has jurisdiction over the case before it "without converting the proceeding to one for summary judgment."

Richmond, Fredericksburg & Potomac R.R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991); *see also Evans,* 166 F.3d at 647. The court should grant such a motion "only if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Richmond,* 945 F.2d at 768.

2. Counts II and IV: Summary Judgment

Defendants have moved to dismiss counts II and IV of the complaint under Rule 12(b)(6) for failure to state plausible claims.[3] (ECF No. 30). Defendants urge the court to dismiss

[3] Defendants lump all of Mallinckrodt's claims together, arguing that the court lacks subject matter jurisdiction over them because they are not ripe and that FDA's reclassification of the TE rating was not a final agency action. As will be seen, the court agrees that it does not have jurisdiction over counts I, III, and V, which challenge FDA's reclassification of Mallinckrodt's drug's TE rating because the reclassification was not a final agency action. Count II, a due process claim, is not subject to the APA's finality requirement, however. *Brezler v. Mills,* No. 14-CV-7424 JFB, 2015 WL 668652, at *7 (E.D.N.Y. Feb. 18, 2015) ("Constitutional claims brought independently of the APA are not subject to the finality requirement."). This procedural due process claim, which challenges FDA's failure to give a hearing in conjunction with the TE rating change, is ripe. *See Abbott Laboratories v. Gardner,* 387 U.S. 136, 149 (1967), *overruled on other grounds by Califano v. Sanders,* 430 U.S. 99 (1977) (noting that to determine whether an agency action is ripe for review the court must "evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration" and the fitness of an issue for resolution in turn depends on whether it is purely legal, whether further administrative proceedings are anticipated, and whether the action is sufficiently final). Count II is fit for resolution because it presents a legal issue — whether FDA violated Mallinckrodt's procedural due process rights by failing to give a hearing in conjunction with the TE

these claims because they are not plausible, but its arguments as to why they are not plausible require the court to assess facts and documents not referenced in the complaint. Specifically, the facts and documentation pertaining to whether Mallinckrodt has stated a due process violation and whether FDA's 2014 Draft Guidance document was a legislative rule must be gleaned from documents in the record, not all of which are integral to or explicitly relied upon in the complaint. *See Zak v. Chelsea Therapeutics Int'l, Ltd.,* 780 F.3d 597, 606-07 (4th Cir. 2015) ("Consideration of a document attached to a motion to dismiss ordinarily is permitted only when the document is integral to and explicitly relied on in the complaint[.]") (internal citation and quotation marks omitted).

Mallinckrodt opposes Defendants' motion to dismiss and has cross-moved for summary judgment on all of its claims. (ECF No. 34). Mallinckrodt asserts that "[t]here is no reason to delay entering summary judgment for [it], because when a party seeks review of agency action under the [APA], the district judge sits

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rating change — that is not contingent on any future event. Count IV of Mallinckrodt's complaint challenges FDA's issuance of the 2014 Draft Guidance. Defendants make a cursory argument that this claim is not relevant and is "premature," but fail to explain how it is premature or unripe. (ECF No. 30-1, at 18 n.6). Defendants do not argue that this was not a final agency action and based on a review of the record, this claim also presents a legal issue — whether FDA violated the APA by issuing its 2014 Draft Guidance without going through formal notice and comment procedures — that is fit for judicial review.

as an appellate tribunal . . . [and] [t]he entire case on review is a question of law." (ECF No. 34-1, at 11) (*quoting Am. Bioscience, Inc. v. Thompson,* 269 F.3d 1077, 1083 (D.C. Cir. 2001)) (internal quotation marks omitted). In addition, Mallinckrodt asserts that Defendants' refusal to produce the full administrative record should not preclude summary judgment because most of its APA claims "address pure questions of law unrelated to that record" and for the remaining claims the relevant portions of the administrative record are either public or have been produced by FDA, providing a "sufficient factual basis for summary judgment at this time[.]" (ECF No. 34-1, at 12). Mallinckrodt further asserts that it has introduced facts into the record by filing exhibits and declarations in connection with its motion for a TRO and exhibits in connection with its motion for summary judgment, and that "[t]he government has not introduced any contrary evidence into the record that would create a genuine dispute of material fact." (ECF No. 34-1, at 11 n.1). The materials submitted by Mallinckrodt include, among other things, FDA's TSI Summary Memorandum (ECF No. 8-4), FDA's Questions and Answers document (ECF No. 8-3) and FDA's November 13, 2014 Press Release (ECF No. 8-2), which are relevant to Count II, and copies of the Draft Guidance issued by FDA in 2012 and 2014 (ECF Nos. 34-2, 40-1, and 40-2), which are relevant to Count IV.

"If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Fed.R.Civ.P. 12(d); *see Laughlin v. Metro. Washington Airports Auth.,* 149 F.3d 253, 260-61 (4th Cir. 1998) (noting that the district court has no obligation formally to notify a party that a motion to dismiss will be converted to one for summary judgment when the opposing party's motion's caption and attachments indicate that it could be treated as one for summary judgment); *see also Finley Lines Joint Protective Bd. Unit 200 v. Norfolk S. Corp.,* 109 F.3d 993, 997 (4th Cir. 1997) ("[A] Rule 12(b)(6) motion to dismiss supported by extraneous materials cannot be regarded as one for summary judgment until the district court acts to convert the motion by indicating that it will not exclude from its consideration of the motion the supporting extraneous materials."). As noted by Judge Grimm in *Pegues v. Wal-mart Stores, Inc.,* 63 F.Supp.3d 539, 542 (D.Md. 2014):

> "[A] district judge has 'complete discretion to determine whether or not to accept the submission of any material beyond the pleadings that is offered in conjunction with a Rule 12(b)(6) motion and rely on it, thereby converting the motion, or to reject it or simply not consider it.'" *Sager v.*

> *Hous. Comm'n,* 855 F.Supp.2d 524, 542 (D.Md. 2012) (*quoting* 5C Charles Alan Wright et al., Federal Practice & Procedure § 1633, at 159 (3d ed.2004, 2011 Supp.)) "This discretion 'should be exercised with great caution and attention to the parties' procedural rights.' In general, courts are guided by whether consideration of extraneous material 'is likely to facilitate the disposition of the action,' and 'whether discovery prior to the utilization of the summary judgment procedure' is necessary." *Id.*

Here, it is appropriate to consider additional materials outside of the pleadings that have been filed by Mallinckrodt in conjunction with its motions for a TRO and for summary judgment, as consideration of these materials is likely to facilitate disposition of this case and as Mallinckrodt has indicated that the portions of the administrative record relevant to its claims have already been produced by FDA or are public documents. In addition, Mallinckrodt has filed its own motion for summary judgment, and is therefore, clearly on notice that this action may be adjudicated as one for summary judgment. Rule 56(f) provides that "[a]fter giving notice and an opportunity to respond, the court may: (1) grant summary judgment for a nonmovant; (2) grant the motion on grounds not raised by a party; or (3) consider summary judgment on its own after identifying for the parties material facts that may not be genuinely in dispute." *See Jones v. Union Pac. R. Co.,* 302 F.3d 735, 740 (7th Cir. 2002) ("When there are no issues of material

fact in dispute, a district judge may grant summary judgment in favor of the non-moving party or may grant summary judgment even though no party has moved for summary judgment."); *McCarty v. United States,* 929 F.2d 1085, 1088 (5th Cir. 1991) ("If one party moves for summary judgment, the court *sua sponte* may grant summary judgment for the nonmoving party provided all of the procedural safeguards of Rule 56 are followed."); *see In re Doctors Hosp. of Hyde Park,* Inc., 504 B.R. 900, 904 (N.D.Ill. 2014) (noting that "an unusual though well-recognized procedural consequence" of moving for summary judgment is that it "allows courts to enter summary judgment for nonmovants" under Rule 56(f)). Defendants, who had notice of Mallinckrodt's motion for summary judgment, chose not to supplement the record with any additional evidence. Nor did Defendants argue that further discovery was necessary adequately to oppose summary judgment, by making a motion under Rule 56(d). *Laughlin,* 149 F.3d at 261; *see also Tsai v. Maryland Aviation,* 306 F.App'x 1, at *5 (4th Cir. 2008) (noting that an attorney, who had notice of a summary judgment motion but failed to make a Rule 56(f) motion for additional discovery, "waived any argument for additional discovery").[4] Accordingly, it is appropriate to evaluate counts II and IV under the summary judgment standard.

[4] The Advisory Committee Notes concerning the 2010 Amendments to Federal Rules of Civil Procedure explain that Rule

A motion for summary judgment shall be granted only if there exists no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. *See* Fed.R.Civ.P. 56(a); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 250 (1986). The moving party bears the burden of showing that there is no genuine dispute as to any material fact. However, no genuine dispute of material fact exists if the nonmoving party fails to make a sufficient showing that a genuine dispute exists. *Celotex,* 477 U.S. at 322–23. Therefore, on those issues on which the nonmoving party has the burden of proof, it is his or her responsibility to confront the summary judgment motion with an affidavit or other similar evidence showing that there is a genuine dispute for trial.

In *Anderson v. Liberty Lobby, Inc.,* the Supreme Court of the United States explained that, in considering a motion for summary judgment, the "judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." 477 U.S. at 249 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a

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56(d) "carries forward without substantial change the provisions of former subdivision (f)[,] permitting a party to "seek an order deferring the time to respond to the summary-judgment motion."

verdict for the nonmoving party." *Id.* at 248. Thus, "the judge must ask himself not whether he thinks the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented." *Id.* at 252.

In undertaking this inquiry, a court must view the facts and the reasonable inferences drawn therefrom "in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986) (*quoting United States v. Diebold, Inc.,* 369 U.S. 654, 655 (1962)); *see also E.E.O.C. v. Navy Fed. Credit Union,* 424 F.3d 397, 405 (4th Cir. 2005). The mere existence of a "scintilla" of evidence in support of the non-moving party's case is not sufficient to preclude an order granting summary judgment. *See Anderson,* 477 U.S. at 252. A "party cannot create a genuine dispute of material fact through mere speculation or compilation of inferences." *Shin v. Shalala,* 166 F.Supp.2d 373, 375 (D.Md. 2001) (citation omitted).

III. Analysis

A. APA Claims Challenging FDA's Reclassification (Counts I, III, and V)

Defendants have challenged whether the court has subject matter jurisdiction over these claims, arguing that the APA only permits review of "final agency actions" and that FDA's

reclassification of Mallinckrodt's drug's TE rating does not constitute a "final agency action." The United States Court of Appeals for the Fourth Circuit has expressed that reviewability of claims is "a threshold jurisdictional question that must be determined before the merits of the case may be reached." *Angelex Ltd. v. United States,* 723 F.3d 500, 505-06 (4th Cir. 2013) (internal citation and quotation marks omitted). In *Angelex,* the Fourth Circuit discussed the reviewability of APA claims in particular, noting that although § 706 of the APA permits a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be[,]" *inter alia,* arbitrary or capricious or contrary to constitutional right, § 704 of the APA limits judicial review of agency action to "final agency action for which there is no other adequate remedy in a court[.]" *Id.* The Fourth Circuit has interpreted § 704's "final agency action" requirement as being a threshold requirement for entitlement to judicial review. *See Whitner v. United States,* 487 F.App'x 801, 803 (4th Cir. 2012) ("We further conclude that Whitner's allegations fail to state any plausible basis for granting her relief pursuant to the APA, as she fails to identify any final agency action entitling her to review in this court."); *see also Gold & Zimmerman, LLC v. Domenech,* 599 F.3d 426, 431 (4th Cir. 2010) (finding that the challenged agency action "did not constitute final agency action reviewable in

court" and affirming the district court's dismissal of the case for lack of subject matter jurisdiction).

In order for an agency action to be reviewable under § 704 of the APA, it must constitute an "agency action" as defined in 5 U.S.C. § 551(13), *and* be "final" as defined by the Supreme Court of the United States in *Bennett v. Spear,* 520 U.S. 154, 177-78 (1997). *Golden & Zimmerman, L.L.C. v. Domenech,* 599 F.3d 426, 431 (4th Cir. 2010). "Agency action" is defined as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13). The Supreme Court explained in *Norton v. Southern Utah Wilderness Alliance,* 542 U.S. 55, 62 (2004) that the categories of "agency action" defined in § 551(13):

> involve circumscribed, discrete agency actions, as their definitions make clear: "an agency statement of . . . future effect designed to implement, interpret, or prescribe law or policy" (rule); "a final disposition . . . in a matter other than rule making" (order); a "permit . . . or other form of permission" (license); a "prohibition . . . or . . . taking [of] other compulsory or restrictive action" (sanction); or a "grant of money, assistance, license, authority," etc., or "recognition of a claim, right, immunity," etc., or "taking of other action on the application or petition of, and beneficial to, a person" (relief). §§ 551(4), (6), (8), (10), (11).
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> . . . .

> The final term in the definition, "failure to act," is in our view properly understood as a failure to take an agency action-that is, a failure to take one of the agency actions (including their equivalents) earlier defined in § 551(13).

To be "final," first, "the action must mark the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature. *And* second, the action must be one by which rights or obligations have been determined or from which legal consequences will flow." *Bennett,* 520 U.S. at 177-78 (internal quotation marks and citations omitted) (emphasis added). Section 704 expressly states that "[a] preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."

Defendants argue that Mallinckrodt's claims should be dismissed because it fails to state "as a legal or factual matter, whether or how the TE rating change constitutes 'agency action' under the APA." (ECF No. 36, at 12). Defendants also contend that a TE rating does "not determine legal rights of any drug manufacturer or distributor, nor impose any requirement or restriction upon any person" (ECF No. 30-1, at 13); rather, the TE ratings are "advisory, informational, and non-binding." (*Id.*). According to Defendants, Mallinckrodt cannot identify any legal consequences that flow from the product's TE rating

change; instead, the consequences identified by Mallinckrodt purportedly are the "effects of intervening acts of third parties, such as state legislators and pharmacists, none of which stem from FDA action." (*Id*.). In addition, Defendants contend that even if the conduct does constitute agency action, it is not "final" because the "TE rating assigned to Plaintiff's product, a BX rating, reflects FDA's continued effort to evaluate the therapeutic equivalence of the product and does not present a case or controversy that is ripe for judicial review." (ECF No. 36, at 1). Specifically, Defendants assert that:

> If Plaintiff provides adequate additional data to support the therapeutic equivalence of its product, as FDA has requested, the Orange Book would be updated accordingly. FDA has not made a final determination regarding the therapeutic equivalence of Plaintiff's drug product, and has not made any determination to withdraw the product's approval. If Plaintiff fails to provide the data requested, then FDA would consider whether taking any additional actions would be appropriate based on information available at that time.

(*Id.* at 1-2). Defendants contend that judicial review of FDA's reclassification would "interrupt FDA's ongoing process to reach a final determination on [Mallinckrodt's] product's TE, a scientific matter within FDA's expertise." (*Id.* at 18).

Mallinckrodt argues that FDA's reclassification of its product from AB to BX is an "affirmative determination that [the] drug is not therapeutically equivalent (based on lack of

evidence) [and] is directly analogous to an FDA decision withdrawing an ANDA for lack of effectiveness (which is also based on lack of effectiveness)." (ECF No. 34-1, at 24). Mallinckrodt asserts that withdrawal of an ANDA for lack of effectiveness requires a showing that there is a "lack of substantial evidence that the drug will have the effect it purports" and is judicially reviewable (*Id.* (citing 21 U.S.C. § 355(e)(3)), and therefore, Mallinckrodt argues that a TE reclassification based on lack of evidence should also be judicially reviewable. Mallinckrodt also argues that the FDA's reclassification of its TE rating is "final" because the reclassification action was complete on November 13, 2014 when it was published in the Orange Book and is not contingent on future events. (*Id.* at 30). In addition, Mallinckrodt asserts that FDA has conceded that the reclassification action is final, pointing to a statement purportedly made by an FDA official during the November 12, 2014 phone call with Mallinckrodt. (ECF No. 7 ¶ 20). Mallinckrodt adds that the finality of the reclassification is supported by the fact that FDA has "requested Mallinckrodt to withdraw its ANDA," which it believes discredits Defendants' assertion that the review of its product is "ongoing." (ECF No. 34-1, at 31). Mallinckrodt acknowledges that FDA has given it the "option of generating new data" to submit to FDA as a basis for reconsidering its TE rating, but

argues that "FDA's data invitation is based on an underlying standard that lacks adequate scientific basis" and it is speculative whether its submission of additional data would result in a change in its Orange Book classification. (*Id.*). Moreover, Mallinckrodt argues that the reclassification of its TE rating is "final" within the meaning of *Bennett* because it has had concrete and harmful effects on it under federal and state law because "[i]n 31 states (including Maryland) and the District of Columbia, it is *unlawful* for a pharmacist to fill a prescription with a generic drug (by substituting it for the corresponding brand-name drug) if the generic is rated 'B' (*i.e.,* not therapeutically equivalent) in the Orange Book." (*Id.* at 25).

Most of Mallinckrodt's arguments focus on the purported legal consequences and harm that have flowed from the agency's decision to reclassify Mallinckrodt's drug to a BX rating. Mallinckrodt fails to establish, however, that FDA's reclassification of its methylphenidate ER tablets from a TE rating of AB to BX is a final agency action, as the record does not indicate that the reclassification constitutes an "agency action" within the meaning of APA § 551(13) or that it "mark[s] the consummation of the agency's decisionmaking process." *Bennett,* 520 U.S. at 178.

During the November 12, 2014 teleconference with FDA, FDA informed Mallinckrodt that it planned to reclassify its methylphenidate ER tablets to a BX rating. (ECF No. 7, at 6-7). Mallinckrodt was also given a memorandum by FDA on November 12, 2014 titled "Tracked Safety Issue (TSI) #1349 – Methylphenidate ER Summary and Conclusions" ("TSI Summary Memorandum") (*see* ECF No. 8-4), which summarizes the data the agency relied upon in support of its decision to reclassify Mallinckrodt's product. (ECF No. 7). The TSI Summary Memorandum provides that "the therapeutic intent of prescribing Concerta to a patient with ADHD is to provide control of behavior for the active 12 hour time frame of daily living (school, work) and not to interfere with the ability of the patient to sleep at night. . . . Critical to the therapeutic effect of this drug is the manner of release." (ECF No. 8-4, at 2). Moreover, the memorandum states that "[b]rand name extended-release methylphenidate products are not intended to be substitutable for each other. They have different release profiles, and patients who do not do well on one, may have success on another." (*Id.* at 3). The memorandum informs Mallinckrodt that FDA's Office Of Generic Drug/Division of Clinical Review Safety Team ("the Safety Team"), which "routinely monitors newly approved ANDA products as they begin to penetrate the market[,]" had received numerous reports from FDA's Adverse Event Reporting System beginning in May 2013 and

reaching a sufficient number in September 2013 indicating the drug's possible therapeutic inequivalence such that the Safety Team began a systematic investigation. (ECF No. 8-4, at 5). FDA's Office of Surveillance and Epidemiology, Division of Pharmacovigilance also contacted the Safety Team "noting a concerning number of complaints during the 12/28/12 – 10/9/13 time frame. Additional complaints were received from multiple other sources[.]" (*Id.*). The Safety Team then performed an "in-depth re-evaluation of the basis for approval of the product" and the Office of Generic Drugs Science Staff "prepared a comparative analysis of design, composition, dissolution, and API degradation between [Concerta] and the Mallinckrodt products. Their analysis indicated concern for potential therapeutic equivalence based on multimedia dissolution testing. They recommended opening a [Tracked Safety Issue or "TSI"]." (*Id.*). FDA's TSI Summary Memorandum goes on to explain the ensuing investigation performed by FDA, which included several methods of evaluating Mallinckrodt's drug's therapeutic equivalence, all of which led the agency to have concerns over the therapeutic equivalence of Mallinckrodt's product in the latter phases of a twelve-hour dose. (*Id.* at 8-10). Specifically, the memorandum notes that "[i]n this investigation, a formulation of methylphenidate ER devised by Mallinckrodt was found to have some fundamental differences in

the characteristics of drug release that strongly support the patient complaints that, when substituted for their originally prescribed medication, [Concerta,] therapeutic failure occurred." (*Id.* at 13). The memorandum also informs Mallinckrodt of FDA's conclusions following the investigation:

> 1. The draft guidance for methylphenidate ER should be removed and new guidance developed that incorporates the lessons learned during the course of this TSI regarding the importance of the shape of the pharmacokinetic curve.
>
> 2. FDA has reason to believe that Mallinckrodt products may not be therapeutically equivalent to Concerta. Therefore, the Orange Book should be updated to reflect a change in the TE rating for the Mallinckrodt product to BX.
>
> 3. FDA should ask Mallinckrodt to voluntarily withdraw its product from marketing or commit to completing new BE studies in accordance with the new guidance within a certain timeframe.

(*Id.* at 15). Mallinckrodt acknowledges that during the November 12 teleconference with FDA, FDA indicated that it had "'compelling' supporting data, including case report forms, and referenced a detailed report of over 100 pages supporting [its] decision." (ECF No. 7 ¶ 21). Mallinckrodt takes issue with the fact that FDA did not provide it the underlying reports and that it only received the TSI Summary Memorandum. It also challenges the data and metrics relied upon by FDA in the TSI Summary

Memorandum, arguing that they are flawed, and the overall sufficiency of FDA's evidence.

When FDA reclassified Mallinckrodt's drug to a BX rating on November 13, 2014, it also issued a press release regarding its concerns over the therapeutic equivalence of Mallinckrodt's product (ECF No. 8-2), and a "Questions and Answers" document about the product's reclassification (ECF No. 8-3). Consistent with the agency's statements in the TSI Summary Memorandum, the press release provides that: "FDA has asked that within six months, Mallinckrodt [] confirm the bioequivalence of [its] product using the revised bioequivalence standards, or voluntarily withdraw [its] product from the market." (ECF No. 8-2). Moreover, FDA's Questions and Answers document clarifies that Mallinckrodt's product is still approved and able to be prescribed:

> **Will the generic methylphenidate hydrochloride ER made by Mallinckrodt [] be taken off the market or recalled?**
>
> FDA has asked that within six months, Mallinckrodt [] confirm the bioequivalence of [its] products using the revised bioequivalence standards, or voluntarily withdraw [its] products from the market. FDA has changed the therapeutic equivalence (TE) rating for the Mallinckrodt [] products in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") from AB to BX. This means that the data are insufficient to show that the Mallinckrodt [products] provide the same therapeutic effect as

> Concerta[.] A drug with a BX rating is still approved and can be prescribed, but is not recommended as automatically substitutable at the pharmacy (or by a pharmacist) for the brand-name drug.

(ECF No. 8-3, at 2).

As an initial matter, Mallinckrodt has not established that FDA's reclassification of its TE rating in the Orange Book is an "agency action," as defined in 5 U.S.C. § 551(13). *See Golden & Zimmerman, LLC,* 599 F.3d at 431-432 (finding that an agency's publishing of a reference guide, including the challenged information therein, did not constitute "agency action" and that finding a "publication of the Reference Guide constitutes agency action would quickly muzzle any informal communications between agencies and their related regulated communities") (internal citations and quotation marks omitted); *see also Pharmaceutical Mfrs. Ass'n v. Kennedy,* 471 F.Supp. 1224, 1226-31 (D.Md. 1979) (finding that FDA's issuance of the Orange Book, containing numerous TE ratings, was not a challengeable "agency action" within the meaning of the APA because it did not require plaintiffs to "engage in or refrain from any action"). Indeed, it is not clear whether Mallinckrodt is arguing that the TE rating change is a rule, order, license, sanction, or otherwise. *Id.* at 1226 (noting that "not every 'action' or activity undertaken by an agency constitutes 'agency action' within the statutory context"). To the extent Mallinckrodt is arguing that

the agency has "failed to act" by failing to provide a hearing in conjunction with the reclassification, it has pointed to no authority showing that the agency is obligated to provide a hearing before reclassifying a drug's TE rating. *See Norton*, 542 U.S. at 63 ("[T]he only agency action that can be compelled under the APA is action legally *required*.") (emphasis in original). Mallinckrodt has argued that FDA's decision to withdraw an ANDA is a judicially reviewable action and therefore, FDA's change in its drug's TE rating which has resulted in an "effective withdrawal" of Mallinckrodt's ANDA is also judicially reviewable. The record does not support Mallinckrodt's "effective withdrawal," argument, however, as Mallinckrodt's product is still approved and continues to be prescribed and it is not clear at this juncture that FDA will even instigate a proceeding to withdraw Mallinckrodt's ANDA.

More importantly, Mallinckrodt's allegations and the record as a whole do not show that FDA's challenged action is "final." First, the statements made by FDA to Mallinckrodt in the TSI Summary Memorandum and to the public in the November 13 press release and Questions and Answers documents do not support Mallinckrodt's arguments that FDA has made a final determination that its drug is therapeutically inequivalent. Instead, these documents reflect that FDA has concerns over whether Mallinckrodt's tablets are therapeutically equivalent to and

have the same clinical effect as Concerta, which is why FDA changed the drug's TE rating. They also reflect that FDA has asked Mallinckrodt to submit additional information in order to establish that its tablets are in fact therapeutically equivalent to Concerta or to voluntarily withdraw its product from the market. Second, the TE rating itself does not reflect finality. As stated in the Orange Book, a BX rating is:

> assigned to specific drug products for which the data have been reviewed by the Agency are *insufficient to determine therapeutic equivalence* under the policies stated in this document. In these situations, the drug products are *presumed* to be therapeutically inequivalent *until* the Agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence.

Orange Book Preface at xxi (emphasis added). The product will retain this rating only until FDA comes to a final decision on therapeutic equivalence. Third, the purported statement made by an FDA official during the November 12, 2014 teleconference that the TE rating change was a "final agency action," does not magically transform the challenged action into a final agency action within the meaning of the law, nor is this statement binding on the agency. See 21 C.F.R. § 10.85(k) (A statement or advice given by an FDA employee orally . . . is an informal communication that represents the best judgment of that employee at the time but does not . . . bind or otherwise obligate or

commit the agency to the views expressed); *see Holistic Candlers & Consumers Ass'n v. FDA,* 664 F.3d 940, 945-46 (D.C. Cir. 2012) (finding that statements purportedly made by FDA officials during a meeting with a medical manufacturer that it "would never approve" their product did not bind or otherwise commit the agency).

Accordingly, FDA's reclassification of the drug's TE rating is not a final agency action, but rather appears to be an intermediate step taken by FDA to inform the public that Mallinckrodt's drug may not be therapeutically equivalent and therefore have "the same" clinical effect as Concerta. *See* 5 U.S.C. § 704 (noting that "intermediate agency action" or other rulings not directly reviewable may be reviewed upon review of the "final agency action"). The record also indicates that the agency's position concerning the therapeutic equivalence of Mallinckrodt's product is a tentative one: FDA indicates that it may take steps in the future to remove Mallinckrodt's product from the market if the drug's TE is not established, but at this time it has not made a final decision as to the product's TE or that Mallinckrodt's ANDA must be removed from the market. *See Holistic Candlers & Consumers Ass'n,* 664 F.3d at 943-44 (finding that warning letters sent by FDA were not "final" agency action because "they plainly do not mark the consummation of FDA's decisionmaking," as they gave the manufacturer an opportunity to

submit information to FDA that FDA would evaluate to determine whether the product could be marketed). FDA has not instigated formal proceedings to withdraw Mallinckrodt's product from the market, it has simply indicated that pending further review it may choose to instigate a withdrawal proceeding if it determines that Mallinckrodt's product is not TE. *See Natural Res. Def. Council, Inc. v. Unites States Food & Drug Admin.,* 760 F.3d 151, 167-69 (2d Cir. 2014) (noting that FDA's decision to instigate a hearing for withdrawal of an animal drug from the market was not a formal finding and "only after the hearing does the *final agency action* result in formal findings and a resultant order"); *Id.* at 175 ("[W]e conclude that the decision whether to institute or terminate a hearing process that may lead to a finding requiring withdrawal of approval for an animal drug is a discretionary determination left to the prudent choice of the FDA."); *see also Sterling Drug, Inc. v. Weinberger,* 384 F.Supp. 557, 560 (S.D.N.Y. 1972) (noting that FDA's "proposed withdrawal of approval" of an NDA is "not a final order" and therefore not reviewable in the district court). Although FDA has asked Mallinckrodt voluntarily to withdraw its ANDA, it has not compelled or ordered Mallinckrodt to take any action. *Holistic Candlers & Consumers Ass'n,* 664 F.3d at 944 (finding that warning letters sent by FDA to a manufacturer were not "final agency action" because they did not determine the rights or

obligations of the manufacturer or compel action by the recipient or the agency). Should FDA choose to instigate a withdrawal proceeding, then all procedures required under 21 U.S.C. § 355(e), including notice and hearing, would apply, and if FDA makes a determination following these proceedings that Mallinckrodt's drug is not therapeutically equivalent to Concerta and revokes its ANDA approval, this final agency decision would be subject to judicial review.

B. APA Claim Challenging FDA's Issuance of the 2014 Draft Guidance (Count IV)

Count IV of Mallinckrodt's complaint alleges that FDA's new draft guidance that was issued on November 6, 2014 ("2014 Draft Guidance") is a legislative rule and a final agency action. (ECF No. 1 ¶¶ 55-56). It further alleges that FDA violated 5 U.S.C. § 553, which required the agency "to follow notice and comment procedures, or to publish written findings establishing good cause that notice and comment procedures were impracticable, unnecessary, or contrary to the public interest, before issuing the draft guidance and relying upon it to reclassify Plaintiff's drug" before implementing the rule. (*Id.* ¶ 57). Mallinckrodt asserts that FDA's issuance and reliance on the 2104 Draft Guidance, constitutes a final agency action "without observance of procedure required by law" in violation of 5 U.S.C. § 706(2)(D). Based on these purported violations,

Defendants ask the court to "hold unlawful and set aside both the draft guidance and the reclassification action." (*Id.* ¶ 58).

Defendants move to dismiss Count IV of Mallinckrodt's complaint, arguing that: (1) Defendants have not plausibly alleged that FDA relied upon the guidance to change its product's TE rating; and (2) FDA was not required to go through notice-and-comment rulemaking before issuing the document because it is an interpretive rule.[5] (ECF Nos. 30-1, at 18 n.6

[5] In Defendants' initial motion they challenge this claim on the grounds that it is "premature" and that the complaint did not plausibly allege that FDA relied on the draft guidance to change the TE rating for Mallinckrodt's product. (ECF No. 30-1, at 18 n.6). Defendants raised for the first time in their reply brief/opposition that this claim should fail as a matter of law because the purported legislative rule was in fact an interpretive rule, and therefore, not subject to formal notice and comment procedures. (ECF No. 36, at 18). As noted by Judge Titus in *Clawson v. FedEx Ground Package System, Inc.,* 451 F.Supp.2d 731, 734-35 (D.Md. 2006):

> The ordinary rule in federal courts is that an argument raised for the first time in a reply brief or memorandum will not be considered. However, the power to decline consideration of such arguments is discretionary, and courts are not precluded from considering such issues in appropriate circumstances. The concern that the ordinary rule addresses is that an opposing party would be prejudiced by an advocate arguing an issue without an opportunity for the opponent to respond.

Here, Defendants give little attention to Count IV of the complaint in their initial motion to dismiss, but Mallinckrodt in cross-moving for summary judgment on this claim raised the

and 36, at 18). The undersigned need only address Defendants' second argument that FDA's 2014 Draft Guidance was an interpretive rather than a legislative rule, as it is dispositive.

In *Berlex Laboratories, Inc. v. Food and Drug Administration,* 942 F.Supp. 19, 25-27 (D.D.C. 1996), the United States District Court for the District of Columbia addressed whether a guidance document issued by FDA was an interpretive or legislative rule. The court explained some of the distinguishing factors of legislative and interpretive rules:

> The APA requires notice-and-comment rulemaking when an agency issues new "legislative" or "substantive" rules that establish binding norms having the force of law. 5 U.S.C. § 553; *American Mining Congress v. Mine Safety & Health Admin.,* 995 F.2d 1106, 1109 (D.C. Cir. 1993). "Interpretive" rules, however, are expressly excused from the notice-and-comment requirements. 5 U.S.C. § 553(b)(3)(A). An interpretive rule is one "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Shalala v. Guernsey Memorial Hosp.,* 514 U.S. 87, ––––, 115 S.Ct. 1232, 1239, 131 L.Ed.2d 106 (1995). In this circuit, a rule is legislative, rather than interpretive, if any one of the following four questions is answered in the affirmative:

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issue of whether the 2014 Guidance Document was a legislative rule. Both Mallinckrodt and Defendants have had an adequate opportunity to address this issue, and accordingly, it is appropriate to consider it.

> (1) whether in the absence of the rule there would not be an adequate legislative basis for . . . agency action to confer benefits or ensure the performance of duties,
>
> (2) whether the agency has published the rule in the Code of Federal Regulations,
>
> (3) whether the agency has explicitly invoked its general legislative authority, or
>
> (4) whether the rule effectively amends a prior legislative rule.

American Mining Congress, 995 F.2d at 1112.

In *Berlex*, the court found that the guidance document in question was an interpretive rather than a legislative rule because all four of the criteria articulated in *American Mining Congress* were answered in the negative. As to the fourth criterion, the court noted that:

> The existing FDA regulation requires the submission of "data derived from nonclinical laboratory and clinical studies." 21 C.F.R. § 601.2(a). In the guidance document, FDA interpreted that language to include data from clinical studies completed on "comparable" biological products. Comparability Guidance Document, 3. That interpretation extended the boundaries of previous FDA actions and policies, to be sure, but it did not "run[] 180 degrees counter to the plain meaning of the regulation," as did the agency directive at issue in *National Family Planning and Reproductive Health Ass'n, Inc. v. Sullivan,* 979 F.2d 227, 235 (D.C. Cir. 1992).

More recently, in *National Mining Association v. McCarthy,* 758 F.3d 243 (D.C. Cir. 2014), the United States Court of Appeals for the District of Columbia Circuit addressed whether a guidance document issued by the Environmental Protection Agency ("EPA") was a general policy statement or a legislative rule subject to judicial review:

> An agency action that purports to impose legally binding obligations or prohibitions on regulated parties – and that would be the basis for an enforcement action for violations of those obligations or requirements – is a legislative rule. An agency action that sets forth legally binding requirements for a private party to obtain a permit or license is a legislative rule. (As to interpretive rules, an agency action that merely interprets a prior statute or regulation, and does not itself purport to impose new obligations or prohibitions or requirements on regulated parties, is an interpretive rule.) An agency action that merely explains how the agency will enforce a statute or regulation – in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule – is a general statement of policy.

The court emphasized that in determining whether something is a legislative rule "[t]he most important factor concerns the actual legal effect (or lack thereof) of the agency action in question on regulated entities." *Id.* at 252. The court noted that the guidance document in question, did "not tell regulated parties what they must do or may not do in order to avoid liability[,]" did not impose "obligations or prohibitions on

regulated entities[,]" could not serve as "the basis for an enforcement action against a regulated entity[,]" and did "not imposed any requirements in order to obtain a permit or license." *Id.* In addition, the court assessed the agency's characterization of the guidance, and noted that the document itself "disclaims any intent to require anyone to do anything" and the language used throughout the document was devoid of commands, requirements, or orders. *Id.* at 252-53. Finally, the court rejected the plaintiffs' argument that based on "EPA's statutory role within the permitting programs . . . [they] really [had] no choice when faced with EPA 'recommendations' except to fold . . . [because] EPA will not issue the permit unless its recommendations are followed." *Id.* at 253. The court noted that "while regulated parties may feel pressure to voluntarily conform their behavior because the writing is on the wall about what will be needed to obtain a permit, there has been no order compelling the regulated entity to do anything. States and permit applicants may ignore the Final Guidance without suffering any legal penalties or disabilities, . . . and permit applicants ultimately may be able to obtain permits even if they do not meet the recommendations in the Final Guidance." *Id.* (internal citations and quotation marks omitted).

Assessment of the factors in *Berlex* and *National Mining Association* results in the conclusion that FDA's Draft Guidance

document issued on November 6, 2014 was an interpretive rule rather than a legislative rule, and therefore the agency did not violate the APA by failing to go through formal notice and comment procedures before issuing the document. First, even in the absence of the 2014 Draft Guidance, FDA would have an adequate legislative basis to confer benefits or ensure the performance of duties relating to bioequivalence of regulated entities' drugs. *See Am. Min. Congress,* 995 F.2d at 1110 (noting that a rule is interpretive if it "spells out the scope of any agency's or regulated entity's pre-existing duty"). Here, there is already a pre-existing duty for FDA to ensure that Mallinckrodt's drug is "bioequivalent" to the RLD, Concerta, 21 U.S.C. § 355(j)(8)(B)(i) ("A drug shall be considered to be bioequivalent to a listed drug if . . . the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered . . . under similar experimental conditions[.]"), and to ensure that all drugs being marketed are safe and *effective* for the conditions for which they are prescribed, 21 U.S.C. § 355(e), 21 C.F.R. § 320.1(f) ("Bioequivalence requirement . . . must be satisfied as a condition of marketing."). FDA has broad discretion to determine whether bioequivalence has been adequately established. *See, e.g., ViroPharma Inc. v. Hamburg,* 898

F.Supp.2d 1, 23-24 (D.D.C. 2012) ("The [FDCA] and a number of the FDA's own regulations grant the agency wide discretion in determining whether bioequivalence has been established." (internal citation and quotation marks omitted)). FDA also retains discretion to determine what types of evidence and metrics are sufficient to demonstrate bioequivalence for a given product, which is reflected in FDA's bioequivalence regulations. *See* 21 C.F.R. § 320.24 (describing the types of evidence that may be required to measure bioequivalence and noting that "FDA may require in vivo or in vitro testing, or both" or "[a]ny other approach deemed adequate by FDA to measure bioavailability or establish bioequivalence"); *see also* 21 C.F.R. Ch. I, Subch. D, Pt. 320 (regulations governing "Procedures for Determining the Bioavailability or Bioequivalence of Drug Products").[6]

[6] In *Schering Corp. v. Food and Drug Administration,* 51 F.3d 390, 399-400 (3d Cir. 1995), the Third Circuit found that FDA's interpretation of 21 U.S.C. § 355(j)(7)(B) as not providing the exclusive means for determining bioequivalence of generic drugs approved via the ANDA process was due deference. The court noted in relevant part that:

> [T]he FDA stated its preferred method was to determine bioequivalence on a case-by-case basis depending on the drug under consideration for approval pursuant to an ANDA. The FDA is the agency charged with implementing the Food, Drug and Cosmetic Act as amended. Its judgments as to what is required to ascertain the safety and efficacy of drugs falls squarely within the ambit of the FDA's expertise and merit deference from us. As such, the FDA's

Moreover, FDA's regulations provide that it may consider a wide range of criteria "when supported by well-documented evidence, to identify specific pharmaceutical equivalents and pharmaceutical alternatives that are not or may not be bioequivalent drug products." *See* 21 C.F.R. § 320.33 (describing the criteria and types of evidence used to assess potential bioequivalence problems and noting that "[t]he Commissioner of Food and Drugs shall consider the following factors," including among other things evidence from well-controlled bioequivalence studies and pharmacokinetic evidence). Accordingly, even in the absence of the 2014 Draft Guidance, FDA has the authority to require Mallinckrodt to establish the bioequivalence of its drug using the criteria and measurements FDA finds necessary for the given product, especially once potential bioequivalence problems have been identified.

Moreover, FDA did not invoke its general legislative authority under 21 U.S.C. § 371, when publishing the 2014 Draft Guidance document, as it did not promulgate a new regulation in the Code of Federal Regulations. Although Mallinckrodt alleges that the 2014 Draft Guidance is binding because FDA has required

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> interpretation of section 355(j)(7)(B) as not limiting its discretion to determine what tests or studies would provide it with adequate information from which to determine bioequivalence is a reasonable construction of the Act.

that it conform to the testing standards provided in the 2014 Draft Guidance in order to have FDA reevaluate its TE rating, the language used by FDA in the document itself does not purport to "impose legally binding obligations" on regulated entities or to "set forth legally binding requirements" that pharmaceutical companies must meet in order to obtain or retain their licenses. *Nat'l Min. Ass'n,* 758 F.3d at 251-52. Indeed, the Draft Guidance reads:

> This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

(ECF No. 40-1). Moreover, FDA lists throughout the 2014 Draft Guidance its purported "recommendations" as to what studies should be performed and what metrics should be assessed to measure methylphenidate hydrochloride ER tablets' bioequivalence and indicates that it will consider alternative approaches. Accordingly, the document itself is devoid of commands, orders, or binding requirements. Although FDA has asked that Mallinckrodt submit additional documentation to establish bioequivalence, the 2014 Guidance Document would not necessarily compel Mallinckrodt to submit particular evidence as the

document itself acknowledges that its recommendations are not binding and alternative approaches may satisfy the bioequivalence statutes and regulations.[7]

Finally, FDA's 2014 Guidance Document did not effectively amend a prior legislative rule because it "neither repudiates nor is inconsistent with any pre-existing FDA regulations." *Berlex Labs,* 942 F.Supp. at 26. The existing FDA regulations on bioequivalence state that "Bioequivalence means the absence of a significant difference in the rate and extent to which the active ingredient . . . becomes available at the site of drug action when administered . . . under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1(e). Mallinckrodt has argued that the revised Guidance Document is a substantive rather than interpretive rule because it adds new content or obligations for regulated entities, but the substantive requirement to establish a product's bioequivalence already existed. FDA has not added additional substantive requirements, it has merely fine-tuned the measures and metrics it believes are most useful in measuring bioequivalence in methylphenidate ER tablets. It has done so by altering its 2012 Guidance Document (ECF No. 40-2) to tweak its recommendations on

[7] Here, Mallinckrodt challenges only the procedural posture of the Draft Guidance document. Mallinckrodt's substantive challenges relate to the reclassification action, which as previously discussed is not a final agency action subject to review.

what measures are most helpful in determining this particular product's bioequivalence. The recommended studies and metrics in the 2014 Guidance Document are consistent with the agency's regulations on bioequivalence and with the recommendations made in the 2012 Guidance Document. The revised 2014 Guidance Document merely requests some additional metrics to ensure the drug's bioequivalence, as the prior metrics may not adequately capture the bioequivalence and efficacy of the drug in the later phases of the twelve-hour dose. The additional metrics requested by FDA fall within the normal range of evidence and measures that FDA may request as part of its process of assessing bioequivalence. *See, e.g.,* 21 C.F.R. § 320.23, 21 C.F.R. § 320.24, and 21 C.F.R. § 320.33. Accordingly, FDA's 2014 Guidance Document is not irreconcilable with nor does it repudiate FDA's regulations on bioequivalence or FDA's prior 2012 Guidance Document. The Guidance Document merely clarifies the metrics FDA believes are helpful in showing bioequivalence. *See Berlex Labs*, 942 F.Supp. at 26 (noting that FDA's challenged guidance document was an interpretive rule because "it did not run 180 degrees counter to the plain meaning of the regulation" and "did not conflict with any other FDA regulation[,]" but rather was a "policy development with identifiable antecedents"). Accordingly, FDA's 2014 Guidance Document is an

interpretive rule and FDA was not required to follow formal notice and comment procedures before issuing it.

Mallinckrodt has also argued that even if the draft guidance was an interpretive rule, FDA still violated the APA's notice and comment requirements which apply to significant amendments of agency's interpretive rules. The Supreme Court recently held, however, that the APA's exemption of "interpretive rules from the notice-and-comment process is categorical," overruling "a line of cases beginning with *Paralyzed Veterans of America v. D.C. Arena L.P.,* 117 F.3d 579 ([D.C. Cir.] 1997), that an agency must use the APA's notice-and-comment procedures when it wishes to issue a new interpretation of a regulation that deviates significantly from one the agency has previously adopted." *Perez v. Mortgage Bankers Ass'n,* 135 S.Ct. 1199, 1203, 1206 (2015). Thus, FDA was not obligated to complete notice and comment procedures to amend its prior Guidance Document because both are interpretive rather than legislative rules.

C. Due Process Claim Challenging FDA's Failure to Provide a Hearing in Conjunction with Its Reclassification (Count II)

Count II of Mallinckrodt's complaint asserts a direct right of action under the Due Process Clause of the Fifth Amendment. Mallinckrodt alleges that "FDA's reclassification action deprives Plaintiff of a property right in the ANDA approval for methylphenidate ER tablets. By failing to give Plaintiff a

hearing in connection with the reclassification action, FDA has violated Plaintiff's Fifth Amendment due process right to a hearing in connection with deprivation of a property right." (ECF No. 1 ¶¶ 42-43). Mallinckrodt asks the court to "hold unlawful and set aside FDA's reclassification" under the Fifth Amendment and to "enjoin FDA from reclassifying Plaintiff's methylphenidate ER tablets in the future without a hearing." (*Id.* ¶¶ 44-45).

Defendants assert that Mallinckrodt's due process claim is premised on it having a protected property interest in its ANDA, and having been deprived, or at least partially deprived, of that property right by an alleged "effective withdrawal" of its ANDA from the market. Defendants argue that an ANDA approval gives the drug's sponsor the right to market its product, and that FDA, through its TE rating change, has neither restricted or impaired Mallinckrodt's right lawfully to market its product. (ECF No. 36, at 13). Defendants assert that Mallinckrodt's due process claim should be dismissed because its "constructive withdrawal" theory does not amount to a due process violation as Mallinckrodt "remains able to lawfully market its product in interstate commerce[.]" (*Id.*). Defendants contend that the "TE rating change in and of itself has not prohibited or limited Plaintiff's product's sale or purchase, or altered its legal status," as these rating are "advisory, informational, and non-

binding." (*Id.* at 14). Defendants add that "[e]ven if the Court were to find a deprivation of property deserving Fifth Amendment protection, FDA's conduct would not require the process to which Plaintiff claims it is entitled. The FDCA does not require withdrawal proceedings under 21 U.S.C. § 355(e) prior to changing a product's TE rating, and the public and administrative interests at stake weigh against the need for such process." (*Id.* at 15).

Mallinckrodt opposes Defendants' motion, arguing that it has stated a plausible due process violation. Mallinckrodt asserts that "[w]hen FDA approves an ANDA, it grants the ANDA sponsor permission to market its drug lawfully in interstate commerce," and argues that "such a government-issued permit or license is a property interest protected by the Due Process Clause." (ECF No. 34-1, at 45). According to Mallinckrodt, "[w]hen [FDA] reclassified Mallinckrodt's methylphenidate ER, FDA eviscerated the company's right in its ANDA by effectively taking the drug off the market." (*Id.* at 46). Mallinckrodt asserts that "[p]rohibiting generic substitutions effectively takes the drug off the market[] because pharmacists will not substitute the drug in filling brand-name prescriptions, and Mallinckrodt's distributor customers will not buy it." (*Id.* at 41). Mallinckrodt argues that "FDA had no constitutional authority to impair Mallinckrodt's property right to *any* extent

(even partially) without giving Mallinckrodt notice and an opportunity to be heard." (*Id*. at 46) (emphasis in original). Mallinckrodt contends that FDA violated its "due process rights by affording *no hearing* whatsoever at *any* time" in connection with the reclassification of its drug's TE rating. (ECF No. 40, at 9) (emphases in original).

The facts underlying this claim are not in dispute. Rather, the parties dispute whether the facts provided by Mallinckrodt are sufficient to constitute a due process violation.

The Due Process Clause of the Fifth Amendment provides that a person shall not be "deprived of life, liberty or property, without due process of law." U.S. Const. amend. V. Mallinckrodt's complaint asserts a procedural due process claim, as it challenges the sufficiency of process it was given in connection with the reclassification of its drug's TE rating. To establish a violation of procedural due process, Mallinckrodt must show that (1) it had a property interest, (2) of which the Government deprived it, (3) without due process of law. *Sunrise Corp. of Myrtle Beach v. City of Myrtle Beach,* 420 F.3d 322, 328 (4th Cir. 2005). As noted by the Fourth Circuit in *United States v. Hicks,* 438 Fed.Appx. 216, 218 (4th Cir. 2011):

> Procedural due process requires, at a minimum, fair notice and an opportunity to be heard. *Mathews v. Eldridge,* 424 U.S.

> 319, 333, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). In order to determine whether an individual has received fair notice, we "must examine the relevant facts of each case." *United States v. Hoechst Celanese Corp.,* 128 F.3d 216, 224 (4th Cir. 1997). Beyond the minimum requirements of notice and an opportunity to be heard, due process is "flexible and calls for such procedural protections as the particular situation demands." *Morrissey v. Brewer,* 408 U.S. 471, 481, 92 S.Ct. 2593, 33 L.Ed.2d 484 (1972).

Mallinckrodt's due process claim is premised on the following: (1) it has a property interest in its ANDA; (2) FDA's reclassification of its drug's TE rating resulted in the "effective withdrawal" or a "partial deprivation" of Mallinckrodt's property right; and (3) FDA violated its due process rights by failing to provide it a hearing in conjunction with the reclassification. Defendants do not challenge whether Mallinckrodt has a property interest in its ANDA; rather, they dispute whether Mallinckrodt has been deprived of its property right and whether it was given sufficient process. A short discussion of Mallinckrodt's property interest is necessary, however, as Mallinckrodt's claim is dependent on it showing that it has been deprived of something to which it has a "legitimate claim of entitlement." *Bd. of Regents of State Colleges v. Roth,* 408 U.S. 564, 577 (1972).

1. Mallinckrodt's Property Interest

In *Roth*, the Supreme Court explained what "property interests" are protected by procedural due process:

> To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it. . . .
>
> Property interests, of course, are not created by the Constitution. Rather they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law — rules or understandings that secure certain benefits and that support claims of entitlement to those benefits.

Id. at 577. The Court went on to explain that property interests grounded in statutes are "created and defined by statutory terms," providing the example that a person asserting entitlement to welfare benefits provided by a statute would need to show that he or she met the statutorily-prescribed terms of eligibility for such a benefit. Moreover, courts have recognized that a government-issued permit or license "which can be suspended or revoked only upon a showing of cause creates a property interest protected" by the Due Process Clause. *Richardson v. Town of Eastover,* 922 F.2d 1152, 1156 (4th Cir. 1991); *see also Barry v. Barchi,* 443 U.S. 55, 64 (1979).

Mallinckrodt's claim is based on it having a property interest in its ANDA approval, which it equates with a license

or permit to market its product. Specifically, Mallinckrodt asserts that "[w]hen FDA approves an ANDA, it grants the ANDA sponsor *permission to market its drug lawfully in interstate commerce*." (ECF No. 34-1, at 45) (citing 21 U.S.C. § 355(a); 21 C.F.R. § 314.105)) (emphasis added). Mallinckrodt also asserts that in order to withdraw approval of an ANDA and consequently take a drug off the market, FDA must follow the procedures provided in 21 U.S.C. §355(e), which includes providing the ANDA sponsor with notice and a hearing. In addition, Mallinckrodt asserts that to withdraw a drug from the market based on a lack of effectiveness, FDA must meet an evidentiary burden of showing that "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have." (*Id.* at 47) (*citing* 21 U.S.C. § 355(e)(3)). Although FDA does not dispute that Mallinckrodt has a property interest in its ANDA approval, it emphasizes the confines of Mallinckrodt's interest as being the *ability to market* its product lawfully in interstate commerce. (ECF No. 36, at 13) (*citing* 21 U.S.C. §355(a); 21 C.F.R. § 314.105(d)).

2. Defendants' Deprivation of Mallinckrodt's Property Interest

The complaint does not assert nor does the record show that FDA has revoked Mallinckrodt's ANDA or instigated a withdrawal proceeding, and for a good reason – Mallinckrodt's ANDA remains

approved and it is still permitted to market its product. (*See, e.g.,* ECF No. 8-2, at 3) (noting that Mallinckrodt's product is "still approved and can be prescribed, but [is] no longer recommended as automatically substitutable at the pharmacy" for Concerta). FDA has not revoked or impaired Mallinckrodt's property interest in its ability to sell its product lawfully in interstate commerce. Instead, Mallinckrodt's deprivation theory is that its drug has been "effectively taken off the market" by FDA and its property right has been "at least partially impaired" because FDA deprived it of its TE rating. (ECF No. 34-1, at 46). Mallinckrodt's "effective withdrawal" argument is premised on the fact that pharmacists will no longer automatically substitute its drug for Concerta and fewer of its major distributors will purchase its drug due to its new TE rating, which will purportedly result in decreased market share and profits for Mallinckrodt. (ECF No. 34-1, at 41). Mallinckrodt asserts that "FDA had no . . . authority to impair Mallinckrodt's property right to any extent (even partially) without giving Mallinckrodt notice and an opportunity to be heard." (ECF No. 34-1, at 46). This argument is unsupported by the statutory provisions creating Mallinckrodt's ANDA rights, and by the case law cited by Mallinckrodt.

Mallinckrodt cites numerous cases that purportedly stand for the proposition that even a partial or *de minimis*

deprivation of property is protected by the Due Process Clause. (*Id*. at 46 n.20). The cases Mallinckrodt cites, however, do not support that the Due Process Clause requires government agencies to provide notice and a hearing to a person prior to taking any action that impacts *to any degree* a product in which that person has a property right. Rather, the majority of these cases stand for the proposition that a due process violation may result even if a person is not *wholly* deprived of their property – meaning it is taken and never returned, but is *partially* deprived – meaning the property itself or the use or benefit of the person's property interest is taken for a short period of time. *See Goss v. Lopez,* 419 U.S. 565, 576 (1975) (finding that a student's ten-day suspension from school was not a *de minimis* deprivation even though it did not result in total expulsion, and emphasizing that "the length *and consequent severity* of a deprivation . . . is not decisive of the basic right to a hearing") (emphasis added) (internal citation and quotation marks omitted); *see also Garraghty v. Jordan,* 830 F.2d 1295, 1299 (4th Cir. 1987) (finding that an employee's five-day suspension, although less severe than a discharge, was not a *de minimis* deprivation because the employee lost the benefits of his office for the period of the suspension); *but see Weathersbee v. Baltimore City Fire Dep't,* 970 F.Supp.2d 418, 435-36 (D.Md. 2013) (noting that an employee's indefinite

demotion, which resulted in a pay cut, was not a *de minimis* deprivation, but that the employee's due process claim failed because he could not point to a "procedural irregularity" or "other deficiency" in the process by which he was demoted). The cases cited by Mallinckrodt are also factually dissimilar from the current case because the property interests at issue in them — the benefits obtained through the property interest (*e.g.,* of attending school or compensation) — were directly deprived by the government's action; whereas here, FDA has not suspended or revoked Mallinckrodt's permission to sell its product. The impairments to its product's marketability identified by Mallinckrodt are that: its distributor customers may reduce or cancel their orders of the drug (ECF No. 19); and pharmacists in many states may no longer automatically substitute its product for Concerta either due to state pharmacy laws or professional guidelines that incorporate the Orange Book's TE ratings and prohibit or discourage automatic substitution of generic drugs that are not therapeutically equivalent (ECF No. 2-4). These impairments, however, are caused by actions of third parties, who may rely on FDA's Orange Book ratings, but are by no means being compelled directly by FDA to change their drug dispensing or drug buying habits. In addition, these purported impairments do not impact whether Mallinckrodt is permitted to sell its drug, but rather whether pharmacists are willing and able to

dispense it and whether customers are willing to buy it. Accordingly, the true deprivation at issue here is not the loss of its property right to sell its ANDA, but the consequential impacts the TE rating change has had on the volumes of drug that are sold in the marketplace and Mallinckrodt's overall market share. The deprivation or impairment identified by Mallinckrodt is the decrease in its market share and financial losses that resulted from FDA's reclassification of its drug's TE rating, which is not a sufficiently direct deprivation of property to state a due process violation. *See, e.g., Gen. Elec. Co. v. Jackson,* 610 F.3d 110, 113-14 (D.C. Cir. 2010) (finding that "consequential injuries" that did not result directly from EPA's order to clean up waste, but from market reactions to the order, such as "depressing the recipient's stock price, harming its brand value, and increasing its cost of financing[,]" were "insufficient to merit Due Process Clause protection").

Mallinckrodt's "effective withdrawal" argument based on its drug's TE classification change is nearly identical to the arguments raised by plaintiffs/appellants in *Industrial Safety Equipment Association, Inc. v. Environmental Protection Agency,* 837 F.2d 1115 (D.C. Cir. 1988). There, appellants, who were a national association of safety equipment manufacturers and corporate manufacturers of federally certified asbestos protection respirators filed suit against the EPA, asserting APA

claims and a due process claim, seeking review of a Guide published by EPA and National Institute of Occupational Safety and Health ("NIOSH"). The agencies were authorized by statute to disseminate health information to the public. *Id.* at 1116. Their regulations required that "asbestos-protection respirators be selected from among those certified by NIOSH[,]" which included thirteen federally certified respirators. *Id.* at 1117. In April of 1986, EPA and NIOSH published a Guide with the "stated purpose of providing a single source for the best and most current information on worker respiratory protection against asbestos." *Id.* (internal citation and quotation marks omitted). The Guide "carefully distinguish[ed] between the thirteen respirators all of which [met] federal standards and two types that the Guide recommends because they provide the maximum amount of worker protection." *Id.* Specifically, the Guide stated that "respirator types numbered 3 through 13 . . . are *not* recommended by NIOSH or EPA for use against asbestos. However, various existing regulations allow their use[.]" *Id.* Appellants challenged the Guide arguing that the agencies' disapproval of eleven lawfully certified devices "effectively decertified the existing respirators" marketed or used by appellants. *Id.* Appellants asserted a due process claim, arguing that "the Guide's warning against the use of certain respirators will deprive appellants of property interests –

notably the market value of the certifications of their respirators." The United States Court of Appeals for the District of Columbia Circuit found that:

> There is no question that appellants possess cognizable property interests in their respirator certifications. *See Bell v. Burson,* 402 U.S. 535, 539, 91 S.Ct. 1586, 1589, 29 L.Ed.2d 90 (1971) (licenses are property interests that cannot be deprived without procedural due process). We do not find, however, that publication of the Guide deprived appellants of these interests. [Appellants'] core error again is to assume that the Guide's disapproval of various respirators effectively repeals the agency's legal certification of these same items for industry use. The two agency actions are separate, and can coexist, however uneasily. The Guide's goal of maximum protection leaves intact the existing, minimum certification standards as well as the validity of all presently possessed certificates. We may be confident that industry buyers of asbestos-protection respirators are fully cognizant of this fact. Although [appellants] offer[] a few affidavits from industry buyers who might shift to purchase the more protective devices, in no way has appellants' property been rendered valueless. The EPA and NIOSH have not revoked any certificates; rather, they have only introduced new information into the market with a possible effect on competition. This indirect effect on lawful certificate holders of information not demonstrated to be false can hardly be said to constitute a constitutional deprivation of property deserving fifth amendment protection. *See Wells Fargo Armored Serv. Corp. v. Georgia Pub. Serv. Comm'n,* 547 F.2d 938, 941 (5th Cir.1977).
>
> Even were we to view the publication as a deprivation, the EPA and NIOSH are

> discharging their statutory duty to alert the public to potentially hazardous work conditions. Applying the three-part test of *Mathews v. Eldridge,* 424 U.S. 319, 335, 96 S.Ct. 893, 903, 47 L.Ed.2d 18 (1976), we note that the largely speculative industry claim of diminished respirator sales, coupled with no charge of falsity, is easily outweighed by the NIOSH and EPA's responsibility to inform American employers and workers alike of hazards to public health.

Id. at 1122.

For the same reasons articulated in *Industrial Safety Equipment Association*, Mallinckrodt's theory of deprivation based on an "effective withdrawal" of its ANDA approval is insufficient. FDA's reclassification of Mallinckrodt's TE rating in the Orange Book did not deprive Mallinckrodt of its ANDA approval. Mallinckrodt has argued that because of its new TE rating in the Orange Book pharmacists will no longer automatically substitute its drug for Concerta and fewer customers will purchase its drug, resulting in a loss of market share and profits. Mallinckrodt has provided some evidence, albeit mainly internal estimates and market predictions of the *anticipated* impact on its market share, shortly following the TE rating change (ECF Nos. 19, 19-1, and 19-2), and declaration indicating that some of its largest distributor customers reduced their orders following the TE rating change. (ECF No. 19). Evidence of the impact on its market share and sales,

however, does not show that its property right – the ability to sell its product lawfully – has been deprived by FDA and instead, shows third party and market reactions to FDA's reclassification. Like EPA and NIOSH in *Industrial Safety Equipment Association*, FDA did not compel the pharmacists or Mallinckrodt's customers to change their dispensing and buying habits. It merely changed the drug's TE classification in the Orange Book in accordance with its duty to provide updated drug information to the public on a regular basis. 21 U.S.C. § 355(j)(7)(A). Taking Mallinckrodt's facts as true, it has failed to show a deprivation of its property interest by FDA.

Tellingly, Mallinckrodt does not argue that it had a property interest in its TE rating, likely because it could not state "a legitimate claim of entitlement" to such a rating, as it would not be supported by the relevant statutory and regulatory provisions governing ANDAs. *Cf. Int'l Custom Products, Inc. v. United States,* No. 2014-1644, 2015 WL 3953705 (Fed. Cir. June 30, 2015) (dismissing an importer's due process claim because it lacked a constitutionally protected property interest or a "legitimate claim of entitlement to a specific classification" of its product and the associated duty rate). Simply because an ANDA sponsor provides evidence with its initial application that satisfies FDA that its drug is safe or effective and thereby obtains a particular TE rating, does not

mean that the drug sponsor is entitled to that TE rating indefinitely, even if evidence later surfaces that its drug is not safe and effective. Moreover, although the statutory scheme provides that FDA is required to provide a hearing and make an evidentiary showing that a drug lacks substantial effectiveness before withdrawing an ANDA, FDA has not instigated a withdrawal proceeding, and FDA's statutes and regulations do not require it to make a certain evidentiary showing or to give a hearing before changing a drug's TE rating.

Defendants are entitled to summary judgment on count II because Mallinckrodt has not shown that it has been deprived of its property right in its ANDA, and its partial deprivation theory based on pharmacists and customers' reactions to FDA's reclassification are insufficient to support a due process violation.

IV. Mallinckrodt's Motions to Seal

Mallinckrodt filed two unopposed motions to seal declarations that were filed in conjunction with its motion for a TRO. (ECF Nos. 4 and 20). It seeks to seal three declarations: two declarations made by Walt Kaczmarek, the President, Multi-Source Pharmaceuticals, for Mallinckrodt (ECF Nos. 5 and 19); and a third declaration made by Dr. Mario Saltarelli, the Chief Science Officer for Mallinckrodt (ECF No. 7).

"The right of public access to documents or materials filed in a district court derives from two independent sources: the common law and the First Amendment." *Va. Dep't of State Police v. Wash. Post*, 386 F.3d 567, 575 (4th Cir. 2004). "The common law presumes a right of the public to inspect and copy 'all judicial records and documents,'" *id.* at 575 (*quoting Stone v. Univ. of Md. Med. Sys. Corp.*, 855 F.2d 178, 180 (4th Cir. 1988)), although this presumption "'can be rebutted if countervailing interests heavily outweigh the public interests in access.'" *Id.* (*quoting Rushford v. New Yorker Magazine, Inc.*, 846 F.2d 249, 253 (4th Cir. 1988)); *see also Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597–99 (1978). Under this common law balancing analysis, "[t]he party seeking to overcome the presumption bears the burden of showing some significant interest that outweighs the presumption." *Rushford*, 846 F.2d at 253. "Ultimately, under the common law[,] the decision whether to grant or restrict access to judicial records or documents is a matter of a district court's 'supervisory power,' and it is one 'best left to the sound discretion of the [district] court.'" *Va. Dep't of State Police*, 386 F.3d at 575 (*quoting Nixon*, 435 U.S. at 598–99) (second alteration in original).

In addition to the public's common law right of access, the First Amendment provides a "more rigorous" right of access for certain "judicial records and documents." *Va. Dep't of State*

Police, 386 F.3d at 575-76; *see also In re Application of the United States for an Order Pursuant to 18 U.S.C. Section 2703(D)*, 707 F.3d 283, 290 (4th Cir. 2013) (explaining the "significant" distinction between the two rights of access). Where the First Amendment does apply, access may be denied "only on the basis of a compelling governmental interest, and only if the denial is narrowly tailored to serve that interest." *Stone*, 855 F.2d at 180.

"For a right of access to a document to exist under either the First Amendment or the common law, the document must be a 'judicial record'" in the first instance. *In re Application*, 707 F.3d at 290. The Fourth Circuit recently held that judicially authored or created documents are "judicial records," as are documents filed with the court that "play a role in the adjudicative process, or adjudicate substantive rights." *Id.* (*citing Rushford*, 846 F.2d at 252; *In re Policy Mgt. Sys. Corp.*, 67 F.3d 296 (4th Cir. 1995) (unpublished table decision)). "[T]he more rigorous First Amendment standard should . . . apply to documents filed in connection with a summary judgment motion in a civil case." *Va. Dep't of State Police*, 386 F.3d at 578 (*quoting Rushford*, 846 F.3d at 253) (alteration in original).

Thus, as a substantive matter, when a district court is presented with a request to seal certain documents, it must determine two things: (1) whether the documents in question are

judicial records to which the common law presumption of access applies; and (2) whether the documents are also protected by the more rigorous First Amendment right of access. *In re Application*, 707 F.3d at 290; *see also Va. Dep't of State Police*, 386 F.3d at 576.

The sealing of any judicial record must also comport with certain procedural requirements. First, the non-moving party must be provided with notice of the request to seal and an opportunity to object. *In re Knight Publ'g Co.*, 743 F.2d 231, 235 (4th Cir. 1984). This requirement may be satisfied by either notifying the persons present in the courtroom or by docketing the motion "reasonably in advance of deciding the issue." *Id.* at 234. In addition, "less drastic alternatives to sealing" must be considered. *Va. Dep't of State Police*, 386 F.3d at 576; *see also* Local Rule 105.11 (requiring any motion to seal to include both "proposed reasons supported by specific factual representations to justify the sealing" and "an explanation why alternatives to sealing would not provide sufficient protection"). Finally, if sealing is ordered, such an order must "state the reasons (and specific supporting findings)" for sealing and must explain why sealing is preferable over its alternatives. *Va. Dep't of State Police*, 386 F.3d at 576.

Applying these principles here, it must first be determined whether the materials Mallinckrodt seeks to seal are judicial

records, as recently defined by the Fourth Circuit. The declarations of Walt Kaczmarek describe facets of the generic drug market and the expected impact the TE rating change may have on Mallinckrodt's business, its market share, its drug's reputation, and its customer relationships. (ECF Nos. 5 and 19). Mr. Kaczmark's declarations have played a role in adjudicating the substantive rights of the parties, as they provided evidence of "harm" for the TRO proceeding and were incorporated by Mallinckrodt in support of its motion for summary judgment as evidence that its ANDA had been "effectively withdrawn from the market." In particular, they have been relied upon in assessing the viability of Mallinckrodt's due process claim. Accordingly, the declarations are judicial records to which the common law right of public access attaches. The declaration of Dr. Mario Saltarelli describes the regulatory history of Mallinckrodt's methylphenidate ER tablets, communications between FDA and Mallinckrodt surrounding the TE rating change, and Mallinckrodt's objections to the 2014 Draft Guidance and the evidence and testing purportedly relied upon by FDA as the basis for its drug's TE rating change. Dr. Saltarelli's declaration has played a role in the adjudicatory process, as it was relied upon in assessing the merits of Mallinckrodt's motion for TRO and in assessing Defendants' motion to dismiss. The complaint fails to provide many

allegations regarding the TE rating change, and therefore it was necessary to rely upon this declaration as well as FDA's TSI Summary Memorandum, Press Release, and Questions and Answers document to determine whether the TE rating change was in fact a final agency action and for an understanding of Mallinckrodt's arguments as to why FDA's 2014 Draft Guidance document is purportedly a legislative rule. Therefore, to justify sealing, Mallinckrodt must establish a significant countervailing interest that outweighs the public's interest in openness.

Mallinckrodt requests to seal these declarations, arguing that they contain "business-sensitive and proprietary information about Mallinckrodt's products, including competitive information and market share data." (ECF No. 4, at 1). Mallinckrodt asserts that Mr. Kaczmarek's declaration contains "information related to the generic pharmaceutical industry and Mallinckrodt's customer relationships, non-public market analyses and data related to market share and market volume for all competitors concerning methylphenidate ER, financial information, and similar competitively sensitive information relevant to Mallinckrodt's business and its key product." (*Id.* at 3). Mallinckrodt argues that Mr. Kaczmarek's supplemental declaration should be sealed because it contains information "related to customer orders and related financial estimates and projections" and that its "company's specific volumes of sales

to specific customers should not be disclosed to the public, or to competitors." (ECF No. 19, at 3). As for Dr. Saltarelli's declaration, Mallinckrodt argues that it should be sealed because the information contained therein is confidential and proprietary because it is *non-public* information regarding the drug's "regulatory history, private communications with the Food and Drug Administration regarding specific details of Mallinckrodt's key product, proprietary analysis, and information about Mallinckrodt's customer relationships." (*Id.*). Mallinckrodt contends that releasing the information in these declarations would provide Mallinckrodt's competitors with an unfair business advantage and could cause competitive harm to Mallinckrodt. It also contends that the "non-sensitive information in the declarations is largely repeated in Mallinckrodt's public filings" and the "minimal public interest in the non-sensitive information, makes an alternative to placing the declarations under seal unnecessary." (*Id.* at 4).

These conclusory assertions do not satisfy Mallinckrodt's burden of establishing a significant countervailing interest that outweighs the public right of access to these declarations, which provide facts that are relevant to the court's jurisdiction over and the merits of Mallinckrodt's claims. Mallinckrodt's motions to seal do not provide specific factual details regarding the purported competitive disadvantage that it

would face upon unsealing the information in these declarations. For example, it is not clear how information regarding expected changes in its market share are wholly "confidential" or "sensitive" when market changes are reported in the news, as indicated by Mallinckrodt's filing of a pharmaceutical article discussing expected market changes. Moreover, it is not clear how this information could be used to gain an unfair competitive advantage. (ECF No. 6-1). Nor is it clear how the regulatory history of Mallinckrodt's methylphenidate ER tablets or FDA's discussions with Mallinckrodt regarding its drug's TE rating change are "confidential" when there are already publicly filed documents discussing this same subject matter. (*See, e.g.,* ECF Nos. 8-1 to 8-4). The only information identified by Mallinckrodt that may be commercially sensitive is its financial projections and details pertaining to specific customer relationships and orders. Although Mallinckrodt asserts that most of the non-sensitive information in these declarations is already contained elsewhere on the public record, this is not so. Mallinckrodt makes very general assertions regarding the TE rating change's impact on customer relations and Mallinckrodt's market share in its papers, as well as provides sparse details of its interactions with FDA in its complaint, but the facts underlying these assertions and events are contained almost exclusively in the declarations. Moreover, the undersigned

cannot rely on general assertions by the parties when adjudicating a motion for summary judgment, but rather must rely on evidence in the record. Finally, Mallinckrodt has not provided sufficient justifications why the declarations must be sealed in their entirety rather than the "sensitive information" contained therein being redacted.

Mallinckrodt's motions to seal will be denied and it will be given fourteen days to propose reasonable redactions to these declarations that accord with Local Rule 105.11, or to provide sufficient justifications as to why these declarations must be sealed in their entirety. In addition, the undersigned will not endeavor to determine what portions (if any) of this Memorandum Opinion contain information that is, or should remain, under seal. Rather, the Memorandum Opinion will be filed under seal temporarily, and the parties are directed to review it and within fourteen days suggest *jointly* any necessary redactions that should be made before it is released to the public docket.

V. Conclusion

For the foregoing reasons, the motion to dismiss filed by Defendants will be granted in part. Summary judgment will be entered against Plaintiff in part. Mallinckrodt's motion to compel production of the administrative record will be denied as moot. Mallinckrodt's motions to seal will be denied. A separate order will follow.

/s/
DEBORAH K. CHASANOW
United States District Judge