IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMACEUTICALS INC., Plaintiff, v. THOMAS E. PRICE, M.D., in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and SCOTT GOTTLIEB, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUG ADMINISTRATION, Defendants.	Supplemental to Civil Action No. 1:15-cv-802 (RC)

REPLY IN SUPPORT OF PLAINTIFF'S MOTION TO ENFORCE JUDGMENT

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In its opposition to Ferring's motion to enforce the judgment, the government premises most of its arguments on two contentions: (1) that *Ferring*, and not FDA, is somehow to blame for the agency's longstanding and oft-repeated position that sodium picosulfate was a novel active ingredient; and (2) that this Court's Order somehow was not dependent on this key fact, even though it was a necessary predicate to the Court's ruling that FDA acted arbitrarily and capriciously here. Neither proposition holds up to even the barest scrutiny.

I. FDA Affirmatively and Repeatedly Determined That Sodium Picosulfate Was Novel.

FDA contends in its opposition brief that the agency "relied upon Ferring's assertion that picosulfate was the active moiety in sodium picosulfate, and that it had never been previously approved by FDA, without conducting an independent evaluation of the chemical structure of the molecule." Opp. 2. There are a few fundamental problems with that assertion.

First, it is brand new—a litigation construct completely unsupported in the record before the agency. To the contrary, in fact, the agency admitted in its decision on remand—as recently as three months ago—that "[i]t is not clear from the administrative record how the Agency determined" that sodium picosulfate is a novel active ingredient. Ex. 1 (June 9, 2017 letter from FDA) at 7. Litigation counsel's post-hoc argument that FDA passively relied on Ferring's assertion is unsubstantiated and, if anything, only renders the agency's underlying decision that much more arbitrary and capricious. *Amarin Pharm. Ireland Ltd. v. FDA*, 106 F. Supp. 3d 196, 217 (D.D.C. 2015) ("An agency's action … must be upheld, if at all, on the basis articulated by the agency itself."); *see also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988) ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate.").

Second, it is implausible in the extreme that FDA blithely accepted an applicant's views on the novelty of an active ingredient, whether at the New Molecular Entity (NME) stage or the New Chemical Entity (NCE) stage.[1] For that to be believed, the Court would have to conclude that FDA fell asleep at the regulatory switch not just once, or twice, but multiple times throughout the regulatory process. For every single new drug that it reviews, FDA is required to look at the chemical structure of every ingredient and make an NME determination that significantly influences the rest of the approval process. According to statutory command and the agency's own regulations, FDA was required to assess or acknowledge the chemical novelty of sodium picosulfate on at least at the following occasions:

1. Investigational Stage. Early in the development process, FDA was required to determine whether to classify sodium picosulfate as an NME, and it in fact did so here—well before Ferring even submitted its New Drug Application (NDA). *See* Ex. 2 (May 13, 2009 Meeting Minutes) at 5 (requiring Ferring to conduct particular studies based on its determination that sodium picosulfate was an NME).

2. NDA Classification Code: FDA assigns a Classification Code to every NDA that it accepts for review. As part of this process, the agency must determine if the NDA contains an NME or, for example, is instead merely a new formulation of a previously approved drug. FDA tentatively assigns an NDA Classification Code at the time the NDA is accepted for filing and then "reassesses the code at the time of approval."[2] At all times since its approval, Prepopik has

[1] The government admits that the standard applicable to both inquiries is identical for present purposes. Opp. 6 n.3 (the test for an NME "is substantively the same as NCE").

[2] NDA Classification Codes, MAPP 5018.2 (eff. date Nov. 4, 2015) at 1, available at https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm470773.pdf%20target=%E2%80%9D_blank%E2%80%9D. Although MAPP 5018.2 was not in effect at the time of Prepopik's review, the substantive information and procedural mechanisms described in MAPP 5018.2 are consistent with earlier

been classified as a "Type 1 – New Molecular Entity" on Drugs@FDA.[3] FDA's initial assignment and then reassessment of Prepopik's NDA Classification Code required FDA to affirmatively determine the active moiety of each active ingredient in Prepopik, and to decide that sodium picosulfate was novel, not once but twice.

3. *Advisory Committee:* FDA is required to hold an advisory committee meeting prior to approving a drug "no active ingredient (including any ester or salt of the active ingredient) of which has been approved" or, alternatively, to explain in the approval letter why it did not do so. 21 U.S.C. §355(s). This statutory language parallels the NCE exclusivity provision, and FDA interprets it to apply to any drug product containing an NME. The Prepopik approval letter notes that Prepopik was not referred to an FDA advisory committee and explains the reasons as required by the statute, making clear that FDA considered Prepopik to be an NME at the time of its approval. NDA Approval Letter for Prepopik (NDA 202535) at 2 (July 16, 2012).[4]

4. *Approval Letter Signatory*: NDAs containing previously unapproved active moieties require office-level sign-off. By contrast, all other approvals may be signed by division-level personnel. For fixed-combination drug products containing both new and previously approved active moieties, FDA required and still requires office-level sign-off. *See* 2 FDA Staff Manual Guides 1410.104(l)(C) (granting division directors and deputy directors authority to approve NDAs other than those that contain "new molecular entities").[5] The Deputy Director for the

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iterations of this document that were in effect at the time. *See, e.g.*, Draft MAPP 7500.3, Drug and Application Classification (Eff. Dec. 2, 2009).

[3] *See Drugs@FDA FDA Approved Drug Products: Preopoik (NDA 202535),* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process.

[4] *Available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202535Orig1s000Approv.pdf.

[5] *Available at* https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM336918.pdf

Office of Drug Evaluation III signed the approval letter for Prepopik,[6] making clear that FDA considered the drug to contain a novel active ingredient.

5. *Annual Report of NME Approvals:* In the 2012 annual report of "Novel Drug Approvals," FDA identified Prepopik as an NME and an "innovative drug approval."[7]

6. *Publication of Review Documents:* Section 505(l) of the FDCA requires FDA to publish on its web site the review documents for an NDA within 30 days of approval of a drug "no active ingredient (including any ester or salt of the active ingredient)" of which has been approved in any other NDA. 21 U.S.C. § 355(1)(2)(A)(i). For all other drugs, Congress did not require FDA to post the review documents until the agency receives three requests for the approval package under the Freedom of Information Act. *Id.* § 355(1)(2)(A)(ii). The relevant web page for Prepopik indicates that it was created on August 3, 2012, less than 30 days after the approval of Prepopik on July 16, 2012.[8]

7. *NCE exclusivity*. Ultimately, at the time it approves a new drug product, FDA is required to make an exclusivity determination. For single ingredient drug products, an NME determination has typically been followed by an NCE exclusivity award, because the two standards are virtually indistinguishable. Under FDA's prior, unlawful interpretation, the only NME products that did not earn NCE exclusivity were certain fixed-combination products like Prepopik. Nevertheless, the agency reviewed all fixed-combination products to determine whether to award NCE exclusivity. A.R. 205. FDA in fact did so here, and determined that only two of the active ingredients had previously been approved. D.E. 66, Ex. 2 (identifying only

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[6] *See id.* at 6.
[7] *See* FY 2012 Innovative Drug Approvals (Dec. 2012) at 4, 26, available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM330859.pdf.
[8] FDA, *Drug Approval Package: Prepopik (sodium picosulfate, magnesium oxide, and anhydrous citric acid),* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202535_prepopik_toc.cfm.

magnesium oxide and citric acid, magnesium oxide and sodium carbonate irrigation as previously having been approved). The record shows that FDA determined that the active moiety in *sodium picosulfate* had not previously been approved. *Id*.

Ignoring all of the other instances in which FDA addressed the novelty of sodium picosulfate during the drug approval process, the government instead narrowly focuses on its NCE exclusivity determination. In that regard, the government argues that, in filling out the NCE Exclusivity Summary, FDA simply stopped after it determined that two of the active ingredients had previously been approved. Opp. 3 ("FDA did not need to address the question of whether sodium picosulfate contained a previously approved active moiety to decide Prepopik's eligibility for 5-year NCE exclusivity because the other drug substances in Prepopik both contained previously approved active moieties."). That argument defies logic. For one thing, if that were the case, FDA would surely have stopped after identifying *one* non-novel active ingredient, not two. But lest there be any doubt, it is clear from the public record of other Exclusivity Summaries that FDA routinely completes a novelty determination for *all* active ingredients in fixed-combination products—not simply stopping after one or two as FDA now contends. *See, e.g.*, Exclusivity Summaries for Tribenzor, Amturnide, Complera, Suclear, Atripla, Edarbyclor, Advil Allergy & Congestion Relief, Jentadueto, Dymista, Qsymia.[9] In all

[9] *Available at*
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/200175Orig1s000Admincorres.pdf;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/200045Orig1s000AdminCorres.pdf;
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202123Orig1s000AdminCorres.pdf;
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https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201281Orig1s000AdminCorres.pdf;

of these examples, FDA denied NCE exclusivity on the basis that *all* of the active ingredients in each product had previously been approved. Nevertheless, these summaries make clear that FDA reviewed *every* ingredient—in direct contradiction to what the agency claims it did for Prepopik.

And of course, even assuming that FDA somehow made a "mistake" repeatedly throughout the approval process of Prepopik and in evaluating its request for NCE exclusivity, the agency had more than ample opportunity to correct that "mistake" before it became the centerpiece of a lawsuit before this Court. Instead, FDA doubled down on its assertion that sodium picosulfate was a novel active ingredient in its Response to Ferring's Citizen Petition, A.R. 201 ("The new active moiety in Prepopik, picosulfate, a stimulant laxative, had not been previously approved in any NDA prior to the approval of Prepopik"), and it did so again in response to Ferring's Petition for Reconsideration, A.R. 46 (same). Nor did the agency change its approach in its opposition to Ferring's initial motion for summary judgment, its reply brief, its supplemental brief on retroactivity, nor its opposition to Ferring's motion for reconsideration, all filed with this Court. And it did not catch its purported error before filing its notice of appeal seeking review in the D.C. Circuit. When confronted with all of this evidence, there can be no logical conclusion other than that FDA, at numerous points, determined that sodium picosulfate contained a new active moiety. The agency's unwillingness to admit as much now speaks volumes.

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https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202236Orig1s000AdminCorres.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/022580Orig1s000AdminCorres.pdf.

II. This Court Relied on FDA's Determination In Rendering Its Decision.

It also cannot seriously be disputed that this Court relied on the parties' joint representations that sodium picosulfate contained a novel active moiety in deciding that FDA acted arbitrarily and capriciously here. *See, e.g.*, D.E. 60 at 8 (noting that "sodium picosulfate, a stimulant laxative, had never previously been approved in any NDA"). Nor can it plausibly be argued that the novelty of sodium picosulfate was somehow immaterial or extraneous to this Court's decision. As Ferring has already explained, Ferring Br. 7–8, the novelty of sodium picosulfate was not some abstract musing tangential to these proceedings. It was the very reason for the proceedings. If sodium picosulfate were not a novel active ingredient, there would have been no practical or legal basis for the Court's decision. *See United Pub. Workers of Am. (C.I.O.) v. Mitchell*, 330 U.S. 75, 89 (1947) ("As is well known the federal courts established pursuant to Article III of the Constitution do not render advisory opinions."); *see also Cierco v. Mnuchin*, 857 F.3d 407, 414 (D.C. Cir. 2017) ("Because the exercise of judicial power under Article III depends upon the existence of a case or controversy, a federal court may not render advisory opinions or decide questions that do not affect the rights of parties properly before it."); *Larsen v. U.S. Navy*, 525 F.3d 1, 4 (D.C. Cir. 2008) (holding unavailable relief that "would accomplish nothing—amounting to exactly the type of advisory opinion Article III prohibits.").

Once these two introductory issues are resolved, the remainder of the government's legal arguments collapse on top of themselves, as explained below.

III. FDA's Conduct Violates The Law Of The Case Doctrine.

As Ferring explained in its opening brief, the law of the case prevents FDA from re-litigating issues already resolved by this Court. *See Sloan v. Urban Title Servs., Inc.*, 770 F. Supp. 2d 216, 223 (D.D.C. 2011) ("The law of the case doctrine 'posits that when a court decides

upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'"). Because this Court's September 2016 Order found that FDA's treatment of Prepopik was arbitrary and capricious, and because it rested on the critical factual issue that sodium picosulfate contained a novel active moiety, FDA was not free on remand to reverse course on this fundamental issue.

Accepting these basic principles, FDA disputes only the notion that this Court actually decided that sodium picosulfate was a novel active ingredient. According to the government, "whether sodium picosulfate contains a new active moiety was never raised as a disputed issue to be decided during the litigation." Opp. 6. True—but not in the way FDA envisions. The question was never raised as a "disputed issue" *because no one disputed it*. That the parties both agreed that sodium picosulfate was novel does not mean that the issue was not "actually decided" by the court. There is no requirement that an issue be "disputed" in order to trigger the law-of-the-case principle.[10] *See Belizan v. Hershon*, 495 F.3d 686, 693 (D.C. Cir. 2007) (holding that insufficiently pled allegations whose insufficiency "plaintiffs did not dispute" on appeal "became the law of the case"); *United States v. Turtle Mountain Band of Chippewa Indians*, 612 F.2d 517, 521 (Ct. Cl. 1979) ("Indeed, a prior decision is the law of the case even when the original decision was rendered without dispute."). Here, the entire predicate for the Court's ruling was the shared understanding that sodium picosulfate was novel. This Court would not have found

[10] FDA cites no authority for its (incorrect) assertion that an issue must be "disputed" to become law of the case. But FDA may be forgiven for its confusion, at least in part, as the doctrine is often discussed in terms that are less than crystal clear. *See, e.g.*, *United States v. Kayser-Roth Corp.*, 103 F. Supp. 2d 74, 83 (D.R.I. 2000) ("Some confusion regarding the contours of the law-of-the-case doctrine arises from the fact that the doctrine is applied in a variety of different circumstances."), *aff'd sub nom. United States v. Kayser-Roth Corp.*, 272 F.3d 89 (1st Cir. 2001). As described above, however, the case law clearly demonstrates that an issue actually decided, including by necessary implication, becomes law of the case, whether explicitly "disputed" or not. Here, after all, the question whether a novel active moiety contained in a fixed combination product was entitled to exclusivity *was* the dispute.

the agency's conduct arbitrary and capricious—and Ferring would not have had standing to bring this lawsuit—if sodium picosulfate were not novel.

It is true that this Court did not explicitly direct FDA to make a "particular finding" as to the active moiety in sodium picosulfate. Opp. 7. But as explained in Ferring's opening brief, the law of the case doctrine applies to both "a court's explicit decisions" *and* "those issues decided by necessary implication." *Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.*, 810 F.2d 243, 250 (D.C. Cir. 1987). And as discussed above, far from being some idle curiosity, the novelty of picosulfate was the basis for this litigation.

FDA had one job on remand: apply a non-arbitrary standard for NCE exclusivity. Instead it seeks a complete do-over, to which it is not entitled.

IV. FDA's Actions On Remand Are Barred By Judicial Estoppel

FDA's actions on remand are also barred by judicial estoppel. By way of recap, the agency's actions satisfy all the factors that Courts traditionally rely on in the judicial estoppel context: (1) FDA has taken clearly inconsistent positions, first asserting sodium picosulfate's novelty and then flip-flopping on remand; (2) FDA's prior position led this Court to issue an opinion on the merits of FDA's treatment of fixed-dose combination products, including Prepopik; and (3) FDA's inconsistency imposed substantial costs on both Ferring and this Court in litigating an issue that FDA now claims was beside the point. *See New Hampshire v. Maine*, 532 U.S. 742, 750–51 (2001). This Court should reject FDA's attempt to evade the scope of its remand order for this reason as well.

The government offers two rationales for why its actions on remand should not be judicially estopped here. First, it asserts that FDA's "good faith mistake" should not result in estoppel because the agency did not reverse itself to "gam[e] the judicial system in order to gain

a litigation advantage." Opp. 8–9. Second, the government claims that, whatever its intent, the agency did not "'succeed[] in persuading a court to accept [its] earlier position" because "FDA did not derive any benefit" from the Court's adoption of the shared understanding that sodium picosulfate contained a novel active moiety. Opp. 9–10. Neither rationale holds water.

With respect to FDA's argument that it acted in "good faith" and is therefore immunized against judicial estoppel, Opp. 8-9, FDA is wrong on several fronts. First, there is nothing in the doctrine that categorically precludes its application to mistake or inadvertence. In keeping with the flexible nature of the doctrine, courts retain the discretion to estop inconsistencies arising from mistakes or inadvertence that would otherwise work harm to the administration of justice—as is the case here. The Supreme Court case cited by the government, *New Hampshire v. Maine*, 532 U.S. 742, noted only that "it *may* be appropriate to resist application of judicial estoppel when a party's prior position was based on inadvertence or mistake." (emphasis added). And indeed a number of courts have refused to acknowledge any good-faith exception to the doctrine. *See Marshall v. Honeywell Tech. Sys. Inc.*, 828 F.3d 923, 932 (D.C. Cir. 2016) (declining to address the existence and scope of a "good faith" exception to judicial estoppel in the bankruptcy context); *see also Slater v. U.S. Steel Corp.*, 820 F.3d 1193, 1210 (11th Cir. 2016) (Tjoflat, J., specially concurring), *reh'g en banc granted, opinion vacated* (Aug. 30, 2016).

Moreover, even assuming for the sake of argument there were such a categorical "good faith" exception, FDA's conduct here would not qualify for that exception. A litigant's belated arrival at a "new understanding of the facts may not excuse a party who has failed a standard of ordinary negligence." *Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 35–36 (1st Cir. 2004) (quoting 18B Charles Alan Wright, *et al.*, Federal Practice & Procedure § 4477 (2d ed. 2002)). FDA's marked inability to explain its about-face, particularly when coupled with

litigation counsel's eyebrow-raising argument that the agency merely accepted Ferring's representation on this critical issue, cannot excuse FDA's reversal of that position on remand. Put bluntly, FDA's inability to present a coherent explanation of its change in position surely flunks any "standard of ordinary negligence."

Nor does the government's claim that FDA failed to reap a benefit in this litigation, Opp. 9, fare any better. *See id.* at 33 ("Thus, benefit is not a sine qua non to the applicability of judicial estoppel."); *Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. Gen. Motors Corp.*, 337 F.3d 314, 325 (3d Cir. 2003) ("the application of judicial estoppel does not turn on whether the estopped party actually benefitted from its attempt to play fast and loose with the court."). FDA does not disagree that both parties convinced this Court to adopt the position that picosulfate was a novel active moiety. It asserts only that its failure to prevail on the overall merits of the case as whole renders this Court's reliance on its original position on this one critical issue irrelevant. This is simply not the law.

V. This Court May Properly Consider The Other Ways In Which FDA's Actions On Remand Are Unlawful.

Finally, the government argues that the remainder of Ferring's arguments are not properly raised on a motion to enforce judgment. Opp. 10-11. In support of this claim, FDA cites a single case, *Heartland Regional Medical Center v. Leavitt*, 415 F.3d 24 (D.C. Cir. 2005). There is nothing, however, in either *Heartland Regional* or the government's logic that would preclude Ferring from also challenging FDA's improper actions on remand on retroactivity, due-process, and arbitrary-and-capricious grounds now. *Heartland Regional* stands for the unremarkable position that a motion to enforce judgment is limited to the scope of the judgment in question. In the ordinary APA case in which a court rejects an agency's deficient legal position and remands for reconsideration, an agency is generally "free to reinstate the original

result on remand" if there are alternative reasons not before the Court for doing so. *See id.* at 25–26, 29. True enough. Also irrelevant. For yet again, the government's argument depends on the mistaken notion that this Court's remand order *did not* rely on the agreed-upon novelty of sodium picosulfate. Because this Court's remand order plainly *did* rely on all parties' shared understanding that sodium picosulfate contained a novel active moiety, as explained above, FDA's attempted do-over is within the scope of the issues on remand. As a result, all of the arguments made in Ferring's motion are properly before the Court now.

Nonetheless, if this Court were inclined to rule otherwise, Ferring could simply either amend its Complaint or file a new APA complaint raising these same arguments. Doing so would elevate form over substance, and would seem to be highly inefficient. *Cf. SEC v. Chenery Corp.*, 332 U.S. 194, 202 (1947) ("To insist upon one form of action to the exclusion of the other is to exalt form over necessity."). However, in the event that the Court prefers one or the other procedural avenue, Ferring requests leave to present its further arguments in whatever form the Court prefers.

A. FDA's Conduct Violates Principles Of Retroactivity.

As Ferring argued in its opening brief, FDA purported to apply a new, previously unannounced definition of "ester" to Prepopik, long after Prepopik's approval. Ferring Br. 11-12, citing *Retail Wholesale & Dep't Store Union v. NLRB*, 466 F.2d 380, 390 (D.C. Cir. 1972).

In response, the government argues that FDA has always recognized that "esters" could contain central sulfur molecules—although admittedly not in the NCE exclusivity context. Opp. 11–12. But that argument ignores a critical fact: the agency's longstanding treatment of sodium picosulfate *itself*. As argued in Ferring's opening brief, regardless of what the term "ester" itself means or meant, FDA consistently treated sodium picosulfate as novel for *years* before suddenly

reversing course and finding that it contained a so-called "sulfur ester" for purposes of NCE exclusivity. Ferring Br. at 4–5, 13–14. FDA's treatment of sodium picosulfate stretches all the way back to the agency's initial classification of Prepopik as an NME during the precursor to the drug approval process. The agency's belated about-face on this policy on remand—years after approval of Prepopik—simply cannot be applied retroactively to its exclusivity decision for Prepopik. This is especially true given FDA's position that exclusivity attaches at the time of approval. D.E. 21 at 25 ("As Ferring acknowledges, the exclusivity period begins on the date the NDA is approved, and thus the interpretation in effect on that date applies.").

B. FDA's Conduct Violates Principles Of Due Process.

FDA's conduct also violates due process. Given the agency's longstanding view that picosulfate was the active moiety in sodium picosulfate, it is quite clear that FDA did not contemplate the existence of a sulfur-based functional group that counts as an "ester" for purposes of NME or NCE exclusivity. Ferring could not have known of this change in policy "with ascertainable certainty," *see, e.g., Trinity Broad. of Fla., Inc. v. FCC*, 211 F.3d 618, 628 (D.C. Cir. 2000), nor could it have conformed its conduct accordingly. By announcing its brand new "ester" definition on remand, years after the agency took a contrary position on Prepopik, FDA flouted its due process obligations, changing the rules on Ferring after the company spent years pursuing NCE exclusivity.

In response, the government conclusorily states that "FDA did not announce a new policy with no warning that deprived Ferring of a property interest to which it was entitled." Opp. 13. But in fact that is exactly what FDA did here. In a footnote, the government appears to qualify its argument, suggesting that Ferring may not have a cognizable property interest in the five years of statutory NCE exclusivity. Curiously, FDA appears to suggest that *federal* statutory

entitlements do not trigger the Constitution's minimum guarantee of due process of law. Opp. 13 n.5 ("The single case on which Ferring relies concerns protected property interests under *state law*.") (emphasis in original).

Ferring does not dispute that the case it cited, *Mpras v. District of Columbia*, 74 F. Supp. 3d 265, 270 (D.D.C. 2014), involved a claimed interest arising from state, or more accurately, District of Columbia, law. But of course, the seminal case on point arose in the context of Social Security disability benefits, a federally created statutory entitlement. *See Mathews v. Eldridge*, 424 U.S. 319, 332 (1976). FDA must adhere to constitutionally mandated principles of due process as a result, which the agency failed to do here.

C. FDA's Actions On Remand Were Arbitrary And Capricious.

Last but not least, FDA's actions on remand were arbitrary and capricious because the little explanation that the agency gave for its about-face here was completely illogical. *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983); *see also Clark Cty. v. FAA*, 522 F.3d 437, 441-442 (D.C. Cir. 2008). The government's responsive brief only strengthens this argument, because it for the first time purports to blame *Ferring* for FDA's "mistake," in direct conflict with the agency's previously stated position.

The government also attempts to cloak the agency's conduct with the usual paean to scientific deference. Opp. 13. But a generalized plea for deference does not cure otherwise arbitrary agency conduct, such as an unexplained about-face on a critical issue. For one thing, "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Veh. Mfrs. Ass'n,* 463 U.S. at 50. And for another, in its decision below, FDA articulated *no* explanation for its change in position. Ex. 1 (June 9, 2017 letter from FDA) at 7 ("It is not clear from the administrative record how the Agency determined that sodium picosulfate was

considered to be an NME, as no documentation of a structural analysis of this active ingredient has been found."). Its lawyers cannot belatedly devise that explanation for them. *See Bowen*, 488 U.S. at 213.

Conclusion

This Court has the authority and the latitude to fashion appropriate remedies to enforce its judgment against recalcitrant litigants. Granting NCE exclusivity to Prepopik—instead of allowing FDA yet another go-around on remand—is the appropriate remedy here.

For the foregoing reasons, and those in its initial motion, this Court should grant the motion to enforce judgment and order FDA to recognize the long-overdue NCE exclusivity to which Prepopik is entitled.

Respectfully submitted,

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Dated: September 8, 2017

CERTIFICATE OF SERVICE

I certify that on September 8, 2017, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
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