UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHIBRO ANIMAL HEALTH CORP., **Plaintiff,** **v.** **U.S FOOD AND DRUG ADMIN., et al.,** **Defendants.**	**Civil Action No. 24-45 (JDB)**

MEMORANDUM OPINION

This case arises out of the United States Food and Drug Administration's ("FDA") decision to revoke its approval of a "regulatory method" used to establish the safety and effectiveness of the animal drug carbadox. Plaintiff Phibro Animal Health Corporation ("Phibro") alleges that the decision was arbitrary and capricious under the Administrative Procedure Act ("APA") and seeks declaratory and injunctive relief. Before the Court is defendants' motion to dismiss plaintiff's claims as untimely. For the following reasons, the Court will grant defendants' motion.

Background

I. Statutory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA") requires prior approval of drugs intended for food-producing animals. 21 U.S.C. § 360b. An applicant seeking approval of a new animal drug must file a New Animal Drug Application ("NADA") with FDA to establish, inter alia, the drug is "safe and effective for use." § 360b(b)(1). Generally, unless and until FDA approves the NADA, the drug is deemed "unsafe" and the FDCA prohibits its sale in interstate commerce. §§ 360b(a)(1), 351(a)(1), 331(a).

Under a provision of the FDCA known as the Delaney Clause, FDA must refuse to approve a NADA if, "after [providing] due notice to the applicant" and "giving [the applicant] an opportunity for a hearing," FDA finds that the "drug induces cancer when ingested by man or animal." § 360b(d)(1)(I). But a drug with cancer-causing potential may still be approved if it satisfies the Diethylstilbestrol ("DES") Proviso. Id. The DES Proviso directs FDA to approve the drug, notwithstanding its cancer-causing potential, if (1) the drug "will not adversely affect the animals for which it is intended," and (2) "no residue" of the drug is found "in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals." Id. As explained in the statute, an applicant must prove that "no residue" can be found using a "method[] of examination prescribed or approved by [FDA]." Id. This method is also known as a "regulatory method." See 21 C.F.R. § 500.88 (2024). As relevant here, the regulatory method must enable FDA to determine the point at which the residue of carcinogenic concern poses "no significant increase in the risk of cancer to the human consumer," and must be sensitive enough to detect a minimum concentration established by FDA. See §§ 500.82(b), 500.86(a)–(c), 500.88(b). FDA publishes approved regulatory methods in the Federal Register. § 500.88(c).

If FDA later concludes that the DES Proviso does cover an approved drug, and thus that the Delaney Clause applies, FDA must withdraw its approval of the drug, subject to notice and an opportunity for a hearing. 21 U.S.C. § 360b(e)(1). Once FDA publishes the proposed withdrawal, an applicant has 30 days to request a hearing and submit specific objections to the withdrawal, which must include "a detailed description and analysis of the factual information (including all relevant clinical and other investigational data) the applicant will present in support of [each] objection." 21 C.F.R. § 514.200(c)(1).

After reviewing "the data and information submitted in the objections and request for a hearing," § 514.200(c)(2), (3), the Commissioner of FDA (or the Commissioner's delegee) may grant a hearing "on any issue" for which the Commissioner determines that "a hearing is justified," § 12.35(a); see § 514.200(c)(3). If the Commissioner determines that a hearing is justified, the Commissioner will issue a notice that describes "[t]he parties to the hearing" and "the scope of the hearing and the matters on which evidence may be introduced." § 12.35(a)(3), (b). Alternatively, if the Commissioner determines that "no genuine and substantial issue of fact precludes . . . the withdrawal of approval of the application," he will issue an order denying the hearing. § 514.200(c)(2). If the Commissioner denies the hearing, the applicant may file a petition for the Commissioner to reconsider or stay the decision. §§ 12.28(c), 12.139.

II. Procedural Background

Phibro develops, manufactures, and markets animal health and nutrition products. Compl. for Decl. & Inj. Relief [ECF No. 1] ("Compl.") ¶ 23. Phibro owns three NADAs relating to carbadox, an antimicrobial drug used to treat dysentery, bacterial enteritis, and other conditions in swine. Id. FDA has granted approval for carbadox products several times over the past fifty years, most recently in 2004. Id.

In 1998, FDA's Center for Veterinary Medicine ("CVM") approved a regulatory method for carbadox "based on the understanding that no carcinogenic residue remained in animal tissue 72 hours after the drug had been administered." Mem. in Supp. of Defs.' Mot. to Dismiss the Compl. for Lack of Subject-Matter Jurisdiction [ECF No. 18-1] ("Mot.") at 1.[1] Subsequently, however, CVM concluded "there [was] not enough data to show that the 1998 regulatory method satisfie[d]" the requisite measurement of "'marker residues,'" and that carbadox thus did not

[1] CVM did not publish the approved regulatory method in the Federal Register, as required, but the parties have consistently treated the method as if it had been published in the Federal Register. See Mot. at 7 & n.7.

qualify under the DES Proviso. See Compl. ¶ 4; Mot. at 7–8. In December 2011, CVM informed Phibro it was required to submit "data showing that the bound carbadox residues posed no health risk." See Compl. ¶¶ 87–89. In April 2016, "CVM issued a Notice of Opportunity for Hearing . . . informing Phibro that CVM proposed to withdraw approvals for all of the carbadox NADAs." Id. ¶ 90. Phibro subsequently requested a hearing, and the then-CVM director recommended that FDA grant the hearing request in substantial part. Id. ¶ 94. FDA never conducted a hearing. Id. ¶ 97.

In July 2020, CVM (a) issued a notice withdrawing the 2016 Notice of Opportunity for Hearing ("NOOH"), and (b) "published a new proposed declaratory order, which, if finalized, would revoke the approved carbadox regulatory method." Id. ¶ 98. CVM further stated that once the 2020 Proposed Order was finalized, CVM intended to publish in the Federal Register a new NOOH proposing to withdraw all carbadox NADAs "based on the lack of an approved [regulatory] method." Id. ¶ 102 (alteration in original) (quoting Notice, Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method, 85 Fed. Reg. 43,853, 43854 (July 9, 2020)). Phibro filed a comment letter to the proposed order, presenting "extensive evidence and expert testimony showing that (a) the regulatory method approved in 1998 remains appropriate and fully consistent with applicable law, and (b) alternative regulatory methods . . . are available even if the 1998 method is withdrawn." Id. ¶¶ 106–07 (citing Phibro Animal Health Corporation's Comments on CVM's July 20, 2020 Proposed Order to Revoke the Regulatory Method of Carbadox [ECF No. 1-6] ("Phibro's 2020 Comments")). Phibro also submitted a citizen petition requesting that "FDA refrain from finalizing, and withdraw, the 2020 Proposed Order." Id. ¶ 110 (citing Citizen Petition Pursuant to 21 C.F.R. § 10.30 Docket No. FDA-2020-N-0955 [ECF No. 1-

8] ("Citizen Petition")). In 2022, CVM issued a written response to Phibro's objections and held an "informal" public meeting regarding carbadox. Id. ¶ 114.[2]

In November 2023, FDA (1) denied Phibro's citizen petition and (2) issued a final order revoking the 1998 carbadox regulatory method ("Revocation Order") due to CVM's conclusions. Id. ¶¶ 126–27, 140; see also Letter from William T. Flynn, Deputy Dir., CVM, to Jeannie Perron, J.D., DVM, Covington & Burling LLP (Nov. 2, 2023) [ECF No. 1-18] ("CP Denial"). In the Revocation Order, FDA explained that while the FDCA "requires an opportunity for a hearing prior to withdrawing an animal drug approval," a hearing on the regulatory method revocation itself was not required because it was only an "interlocutory revocation of an approved method." Final Order, Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method ("FDA Revocation"), 88 Fed. Reg. 76,760, 76,766–67 (Nov. 7, 2023); see also id. at 76,767 ("Because notice-and-comment rulemaking is not required to publish a regulatory method, it is not required to revoke a regulatory method."). FDA further claimed that Phibro was provided with "a meaningful opportunity to be heard" because it had a prior "opportunity to provide comments and other information" and to participate in a "public hearing." Compl. ¶ 137 (quoting FDA Revocation, 88 Fed. Reg. at 76,767). Simultaneously with the Revocation Order, CVM issued a NOOH on its proposal to withdraw approval of the carbadox NADAs. Phibro Animal Health Corp.; Proposal to Withdraw Approval of New Animal Drug Applications for Carbadox in Medicated Swine Feed; Opportunity for a Hearing, 88 Fed. Reg. 76756 (Nov. 7, 2023). The FDA assured it would "consider[] any request for hearing it receive[d]." FDA Revocation, 88 Fed. Reg. at 76,766.

[2] Phibro alleges that the meeting "lacked many of the procedural protections" required by FDA regulations, the panel overseeing the meeting was not impartial, panel members lacked authority to issue a ruling on the adequacy of the 1998 regulatory method, panel members discussed the issues with each other despite acknowledging that they should not have done so, and panel members mocked Phibro's presentation. Compl. ¶¶ 115–16.

Phibro objected to the proposed withdrawal of the carbadox NADAs and requested a hearing before the FDA commissioner. See Request for Hearing and Notice of Appearance from Judith A. Weinstein, SVP, Gen. Couns., & Corp. Sec'y, Phibro to FDA, (Nov. 21, 2023), https://perma.cc/VM5J-2DS2. At Phibro's request, the Commissioner agreed to "deem all documents or other evidence incorporated by specific reference from the [prior dockets related to carbadox] to be part of the [docket for carbadox withdrawal NOOH]." Letter from G. Matthew Warren, Dir., Off. of Sci. Integrity, FDA, to Jeannie Perron, DVM, Esq., Covington & Burling, LLP, & Nicole Pepperl, Esq., Off. of the Chief Couns., FDA, (Jan. 9, 2024), https://perma.cc/7PL3-LH4V. Phibro then submitted a report in support of its hearing request. See Letter from Jeannie Perron, Couns. to Phibro, Covington & Burling, LLP, to FDA (Feb. 3, 2024) ("Hearing Submission"), https://perma.cc/53BF-WL45. In this report, Phibro contends that FDA's denial of its citizen petition and the Revocation Order (together, the "Challenged Orders") violate the FDCA, the APA, and the Fifth Amendment's Due Process Clause. See Hearing Submission at 44–68. It further argues FDA should thus dismiss the NOOH proceeding or, at a minimum, must "hold a comprehensive evidentiary hearing." Id. at 68. CVM issued a response recommending that Phibro's request for a hearing be denied and that the carbadox NADAs approvals be withdrawn. See CVM's Response to Phibro's Request for a Hearing, FDA-2023-N-4742-0019 (May 6, 2024) ("CVM Response") at 41–42, https://perma.cc/QK9F-6NUE. The Commissioner has not yet ruled on Phibro's request.

In February 2024, Phibro filed this suit in federal court, alleging that the Challenged Orders are unlawful under the FDCA for reasons nearly identical to the reasons presented in its Hearing Submission. See Compl. ¶¶ 147–56; see also Mot. at 12–13 (comparing the two sets of allegations). Specifically, Phibro argues that the Challenged Orders: (1) violate the APA because

FDA will either deny Phibro's request for a hearing or will grant the hearing but, pursuant to the Revocation Order, will limit the hearing to address only "new or additional data to support" an approved method, Compl. ¶¶ 157–58 (quoting FDA Revocation, 88 Fed. Reg. at 76,769); see id. ¶¶ 147–61;[3] (2) deprive Phibro of "its right to have the regulatory-method issue adjudicated by an impartial decisionmaker," id. ¶ 166; see id. ¶¶ 162–72; (3) reflect an arbitrary and capricious departure from FDA practice, id. ¶¶ 173–83; and (4) are inconsistent with the record evidence, id. ¶¶ 184–201. It therefore requests that the Court declare the Challenged Orders "arbitrary, capricious, and contrary to law," vacate the Orders, and remand this matter to FDA. Id. at 69.

Defendants moved to dismiss the case under Federal Rule of Civil Procedure 12(b)(1), on the ground that "Phibro's claims [are] unfit for judicial review under the ripeness doctrine." Mot. at 1. Phibro filed an opposition, Pls.' Mem. of P. & A. in Opp'n to Mot. [ECF No. 23] ("Opp'n"), and defendants filed a reply, Reply in Supp. of Mot. [ECF No. 24] ("Reply"). The motion is now ripe for decision.

Legal Standard

Under Federal Rule of Civil Procedure 12(b)(1), the plaintiff bears the burden of establishing by a preponderance of the evidence that the federal court has jurisdiction over its claims. Fed. R. Civ. P. 12(b)(1); see Tremel v. Bierman & Geesing, LLC, 251 F. Supp. 2d 40, 43 (D.D.C. 2003). Courts must accept a complaint's factual allegations as true and draw all reasonable inferences in the plaintiff's favor. Tremel, 251 F. Supp. 2d at 43. "However, '[t]hreadbare recitals' and 'mere conclusory statements' do not suffice." Saline Parents v. Garland, 88 F.4th 298, 303 (D.C. Cir. 2023) (alteration in original) (quoting Ashcroft v. Iqbal, 556 U.S.

[3] In its opposition brief, Phibro no longer claims that a hearing will be limited to only new or additional data. See CVM Response at 37 ("To the extent Phibro found the revocation order unclear, Phibro has known since December 14, 2023, that CVM does not object to Phibro relying on information from other carbadox dockets in its request for a hearing.").

662, 678 (2009)). And because a court has "an affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority," the factual allegations "'will bear closer scrutiny in resolving a 12(b)(1) motion' than in resolving a 12(b)(6) motion for failure to state a claim." Grand Lodge of Fraternal Ord. of Police v. Ashcroft, 185 F. Supp. 2d 9, 13–14 (D.D.C. 2001) (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed. 1987)). Further, when ruling on a 12(b)(1) motion, a court may consider material outside of the complaint, so long as it still accepts the factual allegations in the complaint as true. See Jicarilla Apache Nation v. U.S. Dep't of Interior, 648 F. Supp. 2d 140, 144 (D.D.C. 2009); see also EEOC v. St. Francis Xavier Parochial Sch., 117 F.3d 621, 624 n.3 (D.C. Cir. 1997).

Analysis

Ripeness is a justiciability doctrine that "generally deals with when a federal court can or should decide a case." Am. Petroleum Inst. v. EPA, 683 F.3d 382, 386 (D.C. Cir. 2012). In the administrative law context, the ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies," and "protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Nat'l Park Hosp. Ass'n v. Dep't of Interior, 538 U.S. 803, 807–08 (2003) (quoting Abbott Lab'ys v. Gardner, 387 U.S. 136, 148–49 (1967)).

The parties agree that this case is ripe as a constitutional matter. But a case that is constitutionally ripe may nonetheless be prudentially unripe: the "prudential aspect of ripeness may provide an independent basis for a court not to exercise its jurisdiction." Delta Air Lines, Inc. v. Exp.-Imp. Bank of U.S., 85 F. Supp. 3d 250, 269 (D.D.C. 2015) (citing Nat'l Park Hosp., 538 U.S. at 807–08).

To assess prudential ripeness, a court first evaluates the "fitness of the issues for judicial decision," and second, considers "the hardship to the parties of withholding court consideration." Pfizer Inc. v. Shalala, 182 F.3d 975, 978 (D.C. Cir. 1999) (quoting Texas v. United States, 523 U.S. 296, 301 (1998)); see also Atl. States Legal Found. v. EPA, 325 F.3d 281, 284 (D.C. Cir. 2003) ("Issues that are ill-defined, or otherwise unfit for judicial decision at the moment, and those issues for which no substantial hardship would result from postponing review are not ripe." (cleaned up)). Under the first prong, "courts evaluate 'whether the agency action is final; whether the issue presented for decision is one of law which requires no additional factual development; and whether further administrative action is needed to clarify the agency's position.'" Nat'l Mining Ass'n v. Jackson, 768 F. Supp. 2d 34, 46 (D.D.C. 2011) (quoting Action All. of Senior Citizens v. Heckler, 789 F.2d 931, 940 (D.C. Cir. 1986)). Under the second prong, "courts consider a plaintiff's 'interest in immediate review.'" Delta Air Lines, 85 F. Supp. 3d at 272 (quoting Better Gov't Ass'n v. U.S. Dep't of State, 780 F.2d 86, 92 (D.C. Cir. 1986)).

As an initial matter, Phibro argues that the ripeness doctrine does not apply here, because the doctrine "normally arises" in "pre-enforcement challenges to agency action," when "a regulated party must wait until the agency actually applies its regulatory policy in a concrete factual situation." Opp'n at 16 (cleaned up). The Court disagrees. That the ripeness doctrine "normally" arises in a particular circumstance does not preclude this Court from considering it in another circumstance. See Am. Petroleum Inst., 683 F.3d at 386–87 (determining a claim was not prudentially ripe when the EPA had issued a proposed rule that would, if finalized, greatly change the challenged rule). Moreover, considerations regarding the finality or concreteness of an agency action go to the question whether a claim is ripe, not whether a court should consider whether a

claim is ripe in the first place. Action All. of Senior Citizens, 789 F.2d at 940. Hence, the Court will consider whether Phibro's claims are ripe. They are not.

I. Fitness Prong

Turning first to the "fitness of the issue for judicial decision," the parties disagree as to whether the Challenged Orders are final. An agency action is final if it is a "consummation of the agency's decisionmaking process," not "merely tentative or interlocutory," and it is one "by which rights or obligations have been determined, or from which legal consequences will flow." Harris v. FAA, 353 F.3d 1006, 1010 (D.C. Cir. 2004) (quoting Bennett v. Spear, 520 U.S. 154, 177–78, (1997)). Phibro argues that the "Revocation Order was published in the Federal Register as a 'final order,'" and the citizen petition denial is "final agency action . . . reviewable in the courts." Opp'n at 20–21 (first citing 5 U.S.C. § 552(a)(2), and then citing 21 C.F.R. § 10.45(d)). FDA responds that the Challenged Orders are not final because as part of the ongoing administrative proceeding, "the Commissioner will review Phibro's objections," "the Commissioner is free to grant a hearing on any issue . . . he determines . . . is justified," and "even th[o]se decisions may be subject to yet further administrative review." Reply at 6.

The Court need not decide whether the Challenged Orders are final agency actions[4] because even a final agency action can be "unripe for judicial review" if further proceedings affecting the agency action will take place or judicial consideration of the issue would benefit greatly from more certainty. See Pfizer, 182 F.3d at 980; see also Isenbarger v. Farmer, 463 F. Supp. 2d 13, 19 (D.D.C. 2006). And although the parties appear to agree that the relevant issues are purely legal, see CVM Response at 23, "[e]ven if a challenged action is final and the issues

[4] But see 88 Fed. Reg. 76,760 ("The Food and Drug Administration (FDA) is issuing a final order to revoke the approved method for detecting residues of carbadox.") (emphasis added); AstraZeneca Pharms. LP v. FDA, 850 F. Supp. 2d 230, 242 (D.D.C. 2012) ("[T]he Court agrees[] that FDA's denial of its citizen petitions constitutes final agency action.").

purely legal, a case is not ripe for adjudication if it rests upon 'contingent future events that may not occur as anticipated or may not occur at all,'" Isenbarger, 463 F. Supp. 2d at 19 (quoting Texas, 523 U.S. at 300).

Phibro agrees that a "party's claims may not be fit for review" when "a party challenges final action that is currently under reconsideration or subject to a new pending proceeding." Opp'n at 27; see also Clifton Power Corp. v. FERC, 294 F.3d 108, 110 (D.C. Cir. 2002) ("A request for administrative reconsideration renders an agency's otherwise final action non-final with respect to the requesting party."). It further concedes that "[i]f FDA grants Phibro a de novo formal evidentiary hearing on all the issues raised in Phibro's [Hearing Submission], then Phibro's claims in this litigation will be unripe." Opp'n at 27 (emphasis added). Phibro argues that its claims are ripe, however, because here there is only a "mere possibility that an agency might reconsider" its action. Id. at 26 (quoting Sackett v. EPA, 566 U.S. 120, 127 (2012)).

In support of this argument, Phibro relies on the Supreme Court's decision in Sackett v. EPA. But in Sackett, the Court considered whether an agency action was final or nonfinal, not whether a claim challenging agency action was ripe. See 566 U.S. at 127. More importantly, the Sackett Court focused on the fact that the relevant order, which "invited the [plaintiffs] to engage in informal discussion of the [order's] terms and requirements" with the EPA, "confer[red] no entitlement to further Agency review." Id. (cleaned up). And in Alcoa Power Generating Inc. v. FERC, another case Phibro relies upon, the agency had denied plaintiff's petition for a declaratory order and subsequently denied plaintiff's motion for rehearing. 643 F.3d 963, 965–67 (D.C. Cir. 2011).

Here, in contrast to the Sackett plaintiffs, Phibro is entitled to further agency review: its hearing request regarding the carbadox NADA withdrawal is currently pending before FDA, and

the Commissioner is required to rule on it. See 21 C.F.R. § 12.24(a) ("As soon as possible the Commissioner will review all objections and requests for hearing filed under § 12.22 and determine . . . [w]hether the regulation should be modified or revoked . . . [or] [w]hether a hearing has been justified."). And unlike the Alcoa plaintiff, Phibro has not yet received an agency denial (or grant) of its request. Although Phibro's hearing request relates to the NADA withdrawal NOOH, not to the Revocation Order itself, the issues substantially overlap, and plaintiffs challenge the Revocation Order in the ongoing FDA proceeding. See Mot. at 12–13.[5]

Furthermore, the ongoing FDA proceeding has helped flesh out some of the components of this action, as CVM clarified in the FDA proceeding that it "does not object to Phibro relying on information from other carbadox dockets in its request for a hearing," which was an issue Phibro raised in its federal complaint. See CVM Response at 37; accord Compl. ¶¶ 157–58; Reply at 13. And if FDA holds the hearing Phibro requests, FDA may continue to clarify its position in this matter, potentially resolving some, or all, issues pending here. This circumstance favors judicial restraint. See Isenbarger, 463 F. Supp. 2d at 21 ("The ripeness doctrine counsels that courts should refrain from deciding cases where the injury is speculative, and may never occur.").

FDA may very well deny Phibro's request for a hearing, in whole or in part. And as D.C. Circuit precedent makes clear, just because a challenged government action (here, a decision to withdraw approval of the carbadox regulatory method) is subject to change does not mean the agency action is not final or is unripe. See Appalachian Power Co. v. EPA, 208 F.3d 1015, 1022 (D.C. Cir. 2000) ("The fact that a law may be altered in the future has nothing to do with whether

[5] Also counseling against this Court exercising jurisdiction over Phibro's claims is the fact that Congress gave exclusive jurisdiction over appeals "from an order . . . refusing or withdrawing approval of an application" to the federal courts of appeals. 21 U.S.C. §§ 360b(h), 355(h). In other words, if FDA does withdraw the carbadox NADAs in the future, Phibro would be required to challenge the withdrawal in a court of appeals—not a district court. This Court ruling on Phibro's claims now would thus not only result in a ruling on issues FDA has yet to conclusively decide, but on issues over which this Court would lack jurisdiction once FDA does decide them.

it is subject to judicial review at the moment."). Indeed, FDA appears to consider its withdrawal of the regulatory method a "final," albeit "interlocutory," action. See FDA Revocation, 88 Fed. Reg. 76,760, 76,767. But these facts do not move the needle in Phibro's favor because the issues it raises here are identical to the issues currently briefed (and ripe) before the FDA Commissioner. Unless and until FDA denies Phibro's request for a hearing on some level, the Court agrees with FDA that Phibro's claims are not yet fit for judicial review, and that declining to rule on Phibro's claims may "avoid[] unnecessary adjudication." Delta Air Lines, 85 F. Supp. 3d at 269; see also Cephalon, Inc. v. Sebelius, 796 F. Supp. 2d 212, 216 (D.D.C. 2011) ("Ripeness also prevents a court from making a decision unless it absolutely has to, underpinned by the idea that if the court does not decide the claim now, it may never have to.").

II. Hardship Prong

The balance of hardships does not require consideration of Phibro's claims at this time. Phibro contends it "is already experiencing hardship from the lack of an approved carbadox regulatory method," as the "absence of a method has tarnished the company's reputation and undermined the goodwill built up in the carbadox brand as a safe and effective treatment for newborn pigs." Opp'n at 30. Phibro also expresses concern that because CVM has essentially concluded carbadox is an "adulterated" drug, CVM could decide to bring enforcement proceedings against Phibro at any time. See id. at 30–31 ("Carbadox remains on the market only because CVM has decided, in an exercise of its discretion, not to bring enforcement proceedings on that basis. CVM could modify that stance at any time." (citations omitted)).[6]

[6] FDA characterizes Phibro's opposition brief as "fleetingly invok[ing] the costs it has incurred responding to the withdrawal proceeding" as a hardship. Reply at 16 (citing Opp'n at 2). The Court does not read Phibro's brief to allege such a harm; nevertheless, the Court agrees that "[t]he burden of participating in further administrative and judicial proceedings does not constitute sufficient hardship to overcome the agency's challenge to ripeness." AT&T Corp. v. FCC, 349 F.3d 692, 702 (D.C. Cir. 2003).

Phibro's alleged harms do not pass muster under the hardship prong. Regarding Phibro's argument that it is exposed to potential liability for marketing an "adulterated" drug, Phibro has not shown that enforcement, and hence actual liability, is imminent, and thus "no irremediable adverse consequences [will] flow from requiring a later challenge." Pfizer, 182 F.3d at 979 (quoting Toilet Goods Ass'n v. Gardner, 387 U.S. 158, 164 (1967)). True, FDA withdrew its approval of the carbadox regulatory method. See FDA Revocation, 88 Fed. Reg. 76,769. But in denying Phibro's citizen petition, CVM advised Phibro that "carbadox can continue to be lawfully marketed unless and until the carbadox NADAs are withdrawn." CP Denial at 9. Thus, the actual hardship relating to enforcement proceedings will only come once FDA actually withdraws the NADAs. And to the extent Phibro's harm arises from the uncertainty of a NADA withdrawal, "the Supreme Court has squarely rejected the proposition that 'uncertainty as to the validity of a legal rule constitutes a hardship for purposes of the ripeness analysis.'" Toca Producers v. FERC, 411 F.3d 262, 266 (D.C. Cir. 2005) (quoting Nat'l Park Hosp., 538 U.S. at 811)). Nothing in the current NOOH requires Phibro "to adjust [its] conduct immediately," nor does it force Phibro to make a choice "between taking immediate action to their detriment and risking substantial future penalties for non-compliance," given that FDA has not actually withdrawn approval of Phibro's NADAs. See Delta Air Lines, 85 F. Supp. 3d at 273 (internal quotation marks omitted).

Finally, Phibro has not provided "concrete evidence" that it faces reputational harm. See Shaffer v. Def. Intel. Agency, 601 F. Supp. 2d 16, 25 (D.D.C. 2009) ("[T]here is no concrete evidence that he will suffer any hardship if his claims are not adjudicated at this time."). The only evidence Phibro offers as proof of its reputational harm is a letter from six senators urging FDA to grant a hearing. See Letter from Senators to Commissioner Robert M. Califf on Carbadox Regulation (Apr. 29, 2024) [ECF No. 23-2]. In this letter, though, the senators focus on carbadox's

importance to the meat industry and FDA's alleged departure from its typical practices. See id. at *2–3. Nothing in the letter supports Phibro's unsubstantiated claim of reputational harm.[7] The Court therefore is not persuaded that Phibro's alleged hardship warrants judicial review at this time.

Conclusion

Phibro's claims do not meet the standard for ripeness under either the fitness prong or the hardship prong of the prudential ripeness doctrine. Hence, the Court will dismiss the complaint. A separate order will issue.

/s/
JOHN D. BATES
United States District Judge

Dated: October 24, 2024

[7] Phibro itself notes that "the Revocation Order does not allege that carbadox is unsafe, either for pigs or humans who consume pork products," and that CVM has issued public guidance that "is not recommending that people make changes in their food choices during the time that CVM is working to remove the drug from the market." Compl. ¶ 128. Given that CVM publicly acknowledges that carbadox is safe to consume, it is hard to understand what "reputational" harm Phibro faces.