

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**ALLIANCE FOR NATURAL HEALTH,
USA, et al.,**

Plaintiffs,

v.

UNITED STATES OF AMERICA, et al.,

Defendants.

Case No. 24-cv-2989 (CRC)

MEMORANDUM OPINION AND ORDER

Homeopathy is an alternative medical practice based on the theory of *similia similibus curantur*, or “like cures like.” In other words, homeopathic drugs are heavily diluted versions of the substances that cause the very symptoms they seek to cure. Homeopathy is recognized by the Federal Food, Drug and Cosmetic Act (“FFDCA”). For decades, however, homeopathic drugs went relatively unregulated as the Federal Drug Administration (“FDA”) focused its enforcement resources elsewhere. That began to change in 2019, when the agency formally withdrew its permissive policy toward homeopathic drugs. And, in 2022, it elaborated on its future enforcement approach toward the industry when it simultaneously denied a petition for rulemaking concerning homeopathic drug regulation and published a related guidance document.

Plaintiff Alliance for Natural Health, USA (“ANH”), is an advocacy organization that promotes freedom of choice in healthcare. Plaintiff Meditrend, Inc. (“Meditrend”), is a homeopathic drug developer and distributor. They filed this lawsuit challenging the December 2022 petition denial and guidance document under the Administrative Procedure Act (“APA”). The government has moved to dismiss Plaintiffs’ complaint for lack of subject-matter jurisdiction and failure to state a claim. For the following reasons, the Court will grant the

government's motion as to all of Plaintiff's claims save one, which the Court must wait to resolve until it receives the administrative record.

I. Background

A. Legal Background

1. Regulation of Drugs Generally

The FFDCa charges the FDA with “protect[ing] the health and safety of the public” by overseeing the production, sale, and distribution of food, drugs, and cosmetics. POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 108 (2014); see also 21 U.S.C. § 301. One way it seeks to achieve this objective is by mandating that all new drugs obtain FDA approval before entering the market. 21 U.S.C. § 355(a). The FFDCa defines “drug” to include “articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States [(“HPUS”)], or official National Formulary[.]” Id. § 321(g)(1)(A). A “new drug” is a drug “not generally recognized, among experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.” Id. § 321(p)(1). The corollary: A drug that *is* generally recognized as safe and effective (“GRAS/E”) is exempt from the approval process required for new drugs. Further excepted are any drugs that were “subject to” the FFDCa’s predecessor statute, the Food and Drugs Act of 1906. Id.

In 1972, the FDA established a review process for determining whether over-the-counter (“OTC”) drugs were GRAS/E. 37 Fed. Reg. 9464, 9473 (May 11, 1972) (codified at 21 C.F.R. pt. 130). Per these regulations, the FDA undertook notice-and-comment rulemaking to recognize OTC drugs as GRAS/E on a class-wide basis. Id.

2. Regulation of Homeopathic Drugs

Homeopathy is an alternative medical practice based on the theory that “diseases can be cured by substances that produce similar symptoms in healthy people.” MediNatura, Inc. v. FDA, 496 F. Supp. 3d 416, 424 (D.D.C. 2020) (citation omitted), aff’d, 998 F.3d 931 (D.C. Cir. 2021). Accordingly, homeopathic drugs typically contain substances that cause the very symptoms they seek to cure. But those substances are heavily diluted, often until “no molecules of the original substance remain.” Id. That’s because of another important principle in homeopathy, “the law of minimum dose—the notion that the lower the dose of the medication, the greater its effectiveness.” MediNatura, Inc. v. FDA, 998 F.3d 931, 935 (D.C. Cir. 2021) (quotation modified). As one example, the homeopathic ingredients in the cold-relief product “Coldcalm” include flowers, insects, and “poison” and are diluted to up to one part per trillion. Delarosa v. Boiron, Inc., 818 F. Supp. 2d 1177, 1180, 1183 (C.D. Cal. 2011).

Homeopathic drugs are typically marketed as safe and natural alternatives to conventional drugs. MediNatura, 496 F. Supp. 3d at 430–31. And the FFDCAs definition of “drug” includes homeopathic products. 21 U.S.C. § 321(g)(1). But the FDA has never approved a new homeopathic drug for market, and homeopathic drugs are excluded from the OTC drug review process. MediNatura, 496 F. Supp 3d at 424–25. All marketing of homeopathic drugs is thus technically in violation of the FFDCAs. Yet, for decades after the FFDCAs was first passed, the FDA did not regulate homeopathic drugs whatsoever. Id. at 422. Then, in 1988, the FDA issued Compliance Policy Guide 7132.15 § 400.400 (“CPG 400.400”), “Conditions Under Which Homeopathic Drugs May be Marketed.” FDA Mot. to Dismiss Ex. A (“Final Guidance”)

at 3.¹ CPG 400.400 listed conditions under which homeopathic manufacturers could “ordinarily” market drugs without approval. Compl. ¶ 28. In other words, CPG 400.400 drew “a line in the sand” behind which homeopathic drug manufacturers were generally safe from enforcement. MediNatura, 496 F. Supp 3d at 427 (citation omitted). That discretionary safe harbor has allowed the homeopathic industry to flourish in the United States, reaching a valuation of over \$6 billion. Compl. ¶ 9.

Due in part to growing safety concerns around unapproved drugs, the FDA began reevaluating CPG 400.400’s approach in 2015. See Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century, 80 Fed. Reg. 16,327, 16,327–28 (Mar. 27, 2015). In 2017, the agency published a draft guidance announcing its intention to “replace CPG 400.400 with a risk-based enforcement approach,” Drug Products Labeled as Homeopathic, 82 Fed. Reg. 60,403, 60,405 (Dec. 20, 2017), and in 2019, it finalized its withdrawal of CPG 400.400, Compliance Policy Guide Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed, 84 Fed. Reg. 57,439 (Oct. 25,

¹ Plaintiffs apparently intended to attach this guidance document and the FDA’s petition denial to their complaint but inadvertently did not. E.g., Compl. ¶ 10 (referencing “Exh. B,” labeled as the Final Guidance); id. ¶ 44 (same); id. ¶ 50 (referring to “Exh. E,” labeled as the petition denial); id. ¶ 91 (same). The Court may still consider them in assessing this motion to dismiss. See, e.g., Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 322 (2007) (“[C]ourts must consider the complaint in its entirety, [including] documents incorporated into the complaint by reference[.]”); Trudeau v FTC, 456 F.3d 178, 183 (D.C. Cir. 2006) (“In determining whether a complaint fails to state a claim,” courts may consider “any documents either attached to or incorporated in the complaint and matters of which we may take judicial notice.” (citation omitted)); cf. Delta Air Lines, Inc. v. Exp.-Imp. Bank of United States., 85 F. Supp. 3d 250, 259 (D.D.C. 2015) (recognizing that courts “may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction” (quoting Jerome Stevens Pharms., Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005))). And it also “may generally take judicial notice of materials published in the Federal Register without converting the motion to one for summary judgment.” Banner Health v. Sebelius, 797 F. Supp. 2d 97, 112 (D.D.C. 2011) (citing 44 U.S.C. § 1507).

2019). The notice announced that withdrawal was “applicable October 25, 2019.” Id. It further emphasized that “nothing in the [FFDCA] exempts homeopathic drug products from any of the requirements in the [FFDCA].” Id. at 57,440.

Shortly after the FDA withdrew CPG 400.400, Congress reformed and expedited the OTC drug-review process through the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act of 2020, replacing notice-and-comment rulemaking with “a more expedient administrative order process.” MediNatura, 496 F. Supp. 3d at 423; see also CARES Act §§ 3851–56, 21 U.S.C. § 355h. But homeopathic drugs were never eligible for the OTC procedures, and Congress specifically excluded them from these revisions, too. CARES Act § 3853 (“Nothing in this Act . . . shall apply to any nonprescription [homeopathic] drug”). It went on to reinforce that “[n]othing in this section shall be construed to preclude or limit the applicability of any other provision of the [FFDCA].” Id.

After the CARES Act and the rescission of CPG 400.400, the Americans for Homeopathy Choice Foundation (“AHCF”), which is not a party to this case, submitted a petition for rulemaking to the FDA. The petition sought, *inter alia*, GRAS/E determinations for homeopathic drugs and assurances against enforcement.² Compl. ¶¶ 39–41.

In December 2022, the FDA denied AHCF’s petition and published the final version of the 2017 draft guidance (“Final Guidance”). See Final Guidance; FDA Mot. to Dismiss Ex. B (“Petition Denial”). Both documents raised safety concerns with allowing unapproved

² Specifically, AHCF requested that the FDA (1) promulgate regulations stating, among other things, that homeopathic drugs were GRAS/E by default; (2) recognize as GRAS/E properly labeled and manufactured homeopathic drugs in HPUS; (3) prohibit drugs not listed in HPUS from being marketed as homeopathic; (4) ensure that drugs in HPUS are properly manufactured; (5) ensure that any potential risk-based enforcement policy uses “generally accepted standards and procedures of risk assessment”; and (6) hold a public hearing if the petition is denied. Compl. ¶ 41.

homeopathic drugs to reach market. E.g., Final Guidance at 3 n.12; Petition Denial at 4. The Final Guidance further described the FDA’s risk-based enforcement policy going forward. Final Guidance at 4–5. Under this approach, the FDA’s enforcement priorities for homeopathic drugs include unapproved “[p]roducts for routes of administration other than oral and topical,” “[p]roducts for vulnerable populations,” and products intended to treat or prevent “serious and/or life-threatening” ailments, among others. Final Guidance at 5.

B. Factual and Procedural Background

Plaintiff ANH is a nonprofit that describes itself as “work[ing] nationally to promote sustainable approaches to healthcare and defend[] freedom of choice in healthcare through lasting policy change and public education.” Compl. ¶ 16. Plaintiff Meditrend is a homeopathic drug distributor “engaged in the development and distribution of innovative health solutions, including OTC products marketed in the United States as homeopathic drugs.” Id. ¶ 17. Meditrend commented on AHCF’s petition, arguing that “the FDA lacks authority to require all OTC homeopathic drug products to have an approved new drug application to be lawfully marketed[.]” Id. ¶ 55.

ANH and Meditrend filed this lawsuit and asserted four counts challenging the FDA’s denial of AHCF’s petition and the Final Guidance. Count I alleges that subjecting homeopathic drugs to the new-drug approval process is unlawful under APA § 706(2)(A) and (C) because it contravenes the CARES Act and exceeds the FDA’s statutory authority. See id. ¶¶ 57–72. Count II claims that the FDA’s petition denial was arbitrary and capricious under APA § 706(2)(A) because it was based on “fundamental errors of law and fact.” See id. ¶¶ 73–80. Count III asserts that the FDA’s imposition of heightened regulatory requirements is arbitrary and capricious under APA § 706(2)(A) because it is based on “unsupported safety concerns.” See id.

81–98. Finally, Count IV contends that the Final Guidance violates Plaintiffs’ Fifth Amendment due process rights both under APA § 706(2)(B) and directly under the Constitution. See id. ¶¶ 99–111. The FDA moves to dismiss Plaintiffs’ complaint for lack of subject-matter jurisdiction and failure to state a claim. FDA Mot. to Dismiss at 7.

II. Legal Standard

Under Federal Rule of Civil Procedure 12(b)(1), the plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence. See Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992). “[T]he Court must treat the complaint’s factual allegations as true” but has “an affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority.” Delta Air Lines, Inc. v. Exp.-Imp. Bank of United States, 85 F. Supp. 3d 250, 259 (D.D.C. 2015) (citation modified).

When analyzing a motion to dismiss under Rule 12(b)(6), courts determine whether the complaint “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

III. Analysis

A. Plaintiffs’ Standing

At the outset, the Court must determine whether Plaintiffs have Article III standing to pursue their claims. To establish Article III standing, a plaintiff must show “(1) an injury in fact, (2) a sufficient causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision.” Susan B. Anthony List v. Driehaus, 573 U.S. 149, 157–58 (2014) (cleaned up). When a plaintiff is “‘an object of the action (or forgone action) at issue,’ then ‘there is ordinarily little question that the action or

inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.” Diamond Alt. Energy, LLC v. EPA, 145 S. Ct. 2121, 2134 (2025) (quoting Lujan, 504 U.S. at 561–62). The Court will evaluate each plaintiff’s standing one by one, as “Article III does not give federal courts the power to order relief to any uninjured plaintiff[.]” TransUnion LLC v. Ramirez, 594 U.S. 413, 431 (2021) (quoting Tyson Foods, Inc. v. Bouaphakeo, 577 U.S. 442, 466 (2016) (Roberts, C.J., concurring)). As the Court will explain, Meditrend satisfies the criteria for standing, though just barely. And because Meditrend is a member of ANH, ANH has representational standing based on Meditrend’s interests.

First, the Court concludes Meditrend has plausibly alleged standing. Meditrend offers a declaration from its founder attesting, albeit in a conclusory manner, that at some point during or after 2023, “Whole Foods . . . removed all Meditrend products from its stores” because of “the FDA’s revocation of [CPG 400.400],” Pls.’ Opp’n Ex. B (“Savage Decl.”) ¶ 11, “actions against the homeopathic industry,” id., and “harass[ment of] Homeopathics manufacturers and marketers,” id. Ex. B1 ¶ 4.³ The removal of Meditrend’s products from stores is a classic economic injury in fact. See Carpenters Indus. Council v. Zinke, 854 F.3d 1, 5 (D.C. Cir. 2017) (“Economic harm to a business clearly constitutes an injury-in-fact.”). But the government challenges whether this injury is traceable to the challenged actions, contending that Meditrend has not shown that Whole Foods removed its products specifically because of the petition denial or Final Guidance. FDA Reply at 6. At a threshold matter, the Court will generously construe the challenged “actions against the homeopathic industry” to include the petition denial and Final

³ The submission of Mr. Savage’s declaration as an exhibit to Meditrend’s opposition brief does not prevent the Court from considering the facts it asserts about Whole Foods because “where necessary” on a 12(b)(1) motion, courts “may consider . . . the complaint supplemented by undisputed facts[.]” Coal. for Underground Expansion v. Mineta, 333 F.3d 193, 198 (D.C. Cir. 2003) (quoting Herbert v. Nat’l Acad. of Scis., 974 F.2d 192, 197 (D.C. Cir. 1992)). The FDA did not challenge the facts asserted, instead arguing that they are too speculative to support standing. See FDA Reply at 5–9.

Guidance. And Meditrend has done just enough to show that its injury is traceable to these actions. The “predictable” reactions of third parties to adverse government action can satisfy the traceability and redressability requirements. Diamond Alt. Energy, 145 S. Ct. at 2134; see also Haitian Refugee Ctr. v. Gracey, 809 F.2d 794, 801 (D.C. Cir. 1987) (“The traceability and redressability requirements are closely related”; both “focus on the question of causation.” (citation modified) (citing Von Aulock v. Smith, 720 F.2d 176, 180 (D.C. Cir. 1983))). Here, it is at least plausible that the petition denial and issuance of the Final Guidance induced Whole Foods to stop selling homeopathic drugs out of fear of enforcement, and a judicial rebuke of those actions could alleviate that fear and encourage them to restart. Accordingly, at this early stage, the Court finds this allegation sufficient to bring Meditrend across the threshold for standing. But Meditrend must bear in mind that a plaintiff’s burden to demonstrate standing increases over the course of litigation, see Lujan, 504 U.S. at 561, and “this Court has a continuing duty to examine its subject matter jurisdiction and must raise the issue *sua sponte* when it comes into doubt,” Bronner v. Duggan, 324 F.R.D. 285, 294 (D.D.C. 2018) (citing Henderson ex rel. Henderson v. Shinseki, 562 U.S. 428, 434 (2011)). Should this litigation continue, Meditrend will likely need to provide stronger and more specific evidence of this Court’s subject-matter jurisdiction.

Turning next to ANH, the Court concludes it has representational standing. “An association has standing to bring suit on behalf of its members when its members would have standing to sue in their own right, the interests at stake are germane to the organization’s purpose, and neither the claim asserted nor the relief requested requires individual members’ participation in the lawsuit.” Friends of the Earth, Inc. v. Laidlaw Env’t Servs (TOC), Inc., 528 U.S. 167, 169 (2000). Meditrend is a member of ANH and has standing. The issue of

homeopathic drug regulation is “germane to” ANH’s claimed mission to “defend[] freedom of choice in healthcare.” Compl. ¶ 16. Therefore, even had Meditrend not brought this suit, ANH would be able to sue on its behalf.

The Court thus concludes that both Meditrend and ANH have plausibly alleged standing at this stage.

B. Finality of the FDA’s Actions

Without a separate statute providing jurisdiction, judicial review under the APA is available only for “final” agency actions. 5 U.S.C. § 704. To be “final,” an agency action must meet two conditions. First, it must be the “consummation of the agency’s decisionmaking process—it must not be of a merely tentative or interlocutory nature.” Bennett v. Spear, 520 U.S. 154, 177–78 (1997) (citation modified). Second, “the action must be one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” Id. (citation modified). Here, while the FDA’s petition denial satisfies the criteria for final agency action, the Final Guidance does not and is thus not reviewable under the APA.

1. *FDA’s Petition Denial*

It is well established that the denial of a rulemaking petition constitutes final agency action for purposes of APA review. See Fox Television Stations, Inc. v. FCC, 280 F.3d 1027, 1037 (D.C. Cir. 2002) (“There is no question an agency’s denial of a petition to initiate a rulemaking for the repeal or modification of a rule is a final agency action subject to judicial review.”); Gage v. U.S. Atomic Energy Comm’n, 479 F.2d 1214, 1222 n.27 (D.C. Cir. 1973). And third parties can challenge denials of petitions for rulemaking as long as they establish Article III standing to challenge that denial, as Plaintiffs have done here. Therefore, the FDA’s denial of AHCF’s petition is a final agency action reviewable here.

2. *The Final Guidance*

The 2022 Final Guidance, by contrast, is not final agency action because it has no legal consequences, failing the second Bennett prong. This situation approximates that in National Mining Ass’n v. EPA, 758 F.3d 243, 252 (D.C. Cir. 2014) (Kavanaugh, J.), where the EPA published a “Final Guidance” that the plaintiffs claimed made obtaining mining permits more difficult, but this Circuit concluded held no legal weight. Like that Final Guidance, the FDA’s Final Guidance here “imposes no obligations or prohibitions on regulated entities,” and it “may not be the basis for an enforcement action against a regulated entity.” Nat’l Mining, 758 F.3d at 252; see also Pac. Gas & Elec. Co. v. Fed. Power Comm’n, 506 F.2d 33, 38–39 (D.C. Cir. 1974). For example, if the FDA initiates an enforcement action against a homeopathic drug developer, it cannot point to the Final Guidance as justification—it must use its statutes and regulations. The revocation of CPG 400.400 brought homeopathic products under the mainstream requirements for new drugs; the Final Guidance does nothing to change that. Further, the FDA repeatedly emphasized that the guidance contains only “nonbinding recommendations,” Final Guidance at 1–5, and the document is “devoid of relevant commands”—exactly like the guidance in National Mining, 758 F.3d at 253. In form and effect, the Final Guidance is a “general statement of policy” and not final agency action. See id. at 252.

Plaintiffs counter by insisting that the Final Guidance was the true revocation of CPG 400.400, which, in turn, was a final action. Pls.’ Opp’n at 16–17. But the two actions are undeniably separate. As described above, the 2019 rescission of CPG 400.400 was explicitly “applicable October 25, 2019.” Compliance Policy Guide Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed, 84 Fed. Reg. 57,439 (Oct. 25, 2019). That rescission, not the Final Guidance, marked the end of the FDA’s longstanding policy toward

homeopathic drugs. Plaintiffs' argument also trips over itself by pointing to MediNatura to show that CPG 400.400 had legal effect. Pls.' Opp'n at 16. But MediNatura deemed that CPG 400.400's rescission was a final agency action in 2020—over two years before the Final Guidance. 496 F. Supp. 3d at 444. CPG 400.400 cannot have been revoked twice.

Accordingly, of the two challenged actions, only the FDA's petition denial is eligible for judicial review under the APA. The portions of Counts I, III, and IV that target the Final Guidance under the APA are therefore dismissed. The remainder of Counts I and III can be neatly folded into the alleged "errors of law and fact" in Count II. As a result, only Count II and the Fifth Amendment claim of Count IV proceed to the next stage of analysis.

C. Whether Plaintiffs Have Stated a Claim Upon Which Relief Can Be Granted

Plaintiffs bring a due process challenge to the Final Guidance directly under the Fifth Amendment. They also challenge the petition denial on four fronts under APA § 706(2)(A).

1. *Fifth Amendment Claim*

The Court will begin with Plaintiffs' Fifth Amendment challenge to the Final Guidance. Although Plaintiffs cannot challenge the Final Guidance under the APA because it is not final agency action, federal courts do have jurisdiction "to issue injunctions to protect rights safeguarded by the Constitution." Bell v. Hood, 327 U.S. 678, 684 (1946); see also Free Enter. Fund v. Pub. Co. Acct. Oversight Bd., 561 U.S. 477, 491 n.2 (2010). Therefore, Plaintiffs may proceed with such an implied equitable cause of action challenging the Final Guidance under the Fifth Amendment. But it, too, fails. Plaintiffs have not stated a claim for a Fifth Amendment violation because the requirements for homeopathic drugs are not "unconstitutionally vague." As Plaintiffs concede, there are clear processes for homeopathic drugs to lawfully reach the market—Plaintiffs just find them unsuitable. See Compl. ¶ 105 ("FDA fails to provide the

regulated class . . . with any standards . . . *other than . . . the Section 355 pre-market new drug approval requirements[.]*” (emphasis added)). Because Plaintiffs have no viable Fifth Amendment claim, the Court will dismiss Count IV in its entirety.

2. APA Claims

Moving to the APA § 706(2)(A) claims, the core of Plaintiffs’ challenges to the petition denial are as follows: (1) regulating homeopathic drugs under 21 U.S.C. § 355 is inconsistent with the CARES Act; (2) the FDA erroneously concluded that it lacks a statutory basis to define a separate GRAS/E standard for homeopathic drugs based on the views of homeopathic experts alone; (3) the FDA erroneously deemed all pre-1938 OTC homeopathic drugs to be “new drugs”; and (4) the FDA’s purported safety concerns about homeopathic drugs were insufficient to justify the petition denial. Compl. ¶¶ 79–80.

The Court must first parse what it can and cannot decide at this stage. Typically, a court cannot reach the merits of a § 706 claim “without having the entire administrative record before it.” Int’l Longshoremen’s Ass’n, AFL-CIO v. Nat’l Mediation Bd., No. 04-cv-824 (RBW), 2005 WL 850358, at *4 (D.D.C. Mar. 30, 2005); see also Walter O. Boswell Mem’l Hosp. v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984); 5 U.S.C. § 706 (“[T]he court shall review the whole record or those parts of it cited by a party[.]”). But when a challenge to agency action is “purely legal,” “there is no inherent barrier to reaching the merits at the 12(b)(6) stage.” Marshall Cnty. Health Care Auth. v. Shalala, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Questions that “can be resolved with nothing more than the statute and its legislative history” are reviewable here. Am. Bankers Ass’n v. Nat’l Credit Union Admin., 271 F.3d 262, 266 (D.C. Cir. 2001). Because Plaintiffs’ first three APA challenges raise purely legal questions of interpretation, the Court can safely decide

them now and will dismiss Plaintiffs' claims. The Court will, however, refrain from resolving the final question until an administrative record is available.

a. The CARES Act Challenge

Count II alleges that “[t]he FDA erroneously concluded that Congress pursuant to the CARES Act intended all homeopathics (including OTC homeopathic drugs) to be regulated under 21 U.S.C. § 355.” Compl. ¶ 79. This count fails for two reasons. First, the FDA came to no such conclusion. The FDA’s petition denial merely notes that the agency will not make GRAS/E determinations for homeopathic drugs under the CARES Act because the CARES Act’s OTC drug review reform “does not apply to homeopathic drug products.” Petition Denial at 3. It does not state that the CARES Act itself required the FDA to regulate all homeopathics under 21 U.S.C. § 355.

Second, and more important, Plaintiffs’ argument fails because regulating homeopathic drugs under 21 U.S.C. § 355 is perfectly consistent with the CARES Act. Section 3853(a) reads: “Nothing in this Act . . . shall apply to any nonprescription [homeopathic] drug . . . which was excluded by the [FDA] from the [OTC] Drug Review[.]” CARES Act § 3853(a). Section 3853(b) continues: “Nothing in this section shall be construed to preclude or limit the applicability of any other provision of the [FFDCA].” *Id.* § 3853(b). Homeopathic drugs were already excluded from the OTC drug review process before the CARES Act; Congress simply declined to bring them into its revamped version. Therefore, to read the provision differently—to relax *or* heighten regulatory burdens on homeopathic drugs—would be to rewrite it. See Lamie v. U.S. Trustee, 540 U.S. 526, 534 (2004) (“It is well established that when the statute’s language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.” (internal citation omitted)). Moreover,

construing § 3853(a) to exempt homeopathic products from the new-drug approval process under 21 U.S.C. § 355 would directly transgress § 3853(b), which maintains the applicability of all FDCA provisions.

In a last effort to save their interpretation, Plaintiffs invoke a “presumption against change in existing regulations” principle of statutory construction. But this argument again ignores that, by the time of the CARES Act, the FDA had already withdrawn CPG 400.400 and publicized its intent to tighten homeopathic drug enforcement. MediNatura, 496 F. Supp 3d at 444; Compl. ¶ 6. Thus, even if such a principle somehow controlled and crystallized the existing regulatory framework, it would not help Plaintiffs because the presumption would be in favor of tighter enforcement. As a result, the Court will dismiss Plaintiffs’ CARES Act challenge.

b. Statutory Basis to Define a Separate GRAS/E Standard for Homeopathic Drugs

Next, Plaintiffs attack the FDA’s conclusion that it has no “statutory basis,” Compl. ¶ 79, to “establish a separate standard for GRAS/E determinations” for homeopathic drugs, Petition Denial at 12. The Court rejects this challenge because the FDA’s conclusion is correct. Per 21 U.S.C. § 321(p), a drug must be deemed GRAS/E by “experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs[.]” And, as noted above, homeopathic drugs are “drugs” like any other under the FDCA. Other than the CARES Act, which the Court has already analyzed, Plaintiffs do not point to any statutory provision that could provide basis for a separate GRAS/E avenue for homeopathic drugs. The Court will therefore dismiss Plaintiffs’ claim on this front as well.

c. The FDA’s Determinations Regarding Pre-1938 Homeopathic Drugs

Plaintiffs’ third challenge to the petition denial fails because it conflicts with the decision’s language. Plaintiffs accuse the FDA of “deeming all OTC homeopathic drugs

marketed subject to HPUS monographs predating 1938 to be ‘new drugs’ under Section 321(p).” Compl. ¶ 80. But the petition denial reaches no such blanket conclusion. The FDA emphasized that “whether a drug product is or is not a new drug under the 1938 grandfather clause of the [FFDCA] is a fact-intensive determination[.]” Petition Denial at 15. And it explicitly refused to issue any categorical decisions, including AHCF’s sought default determination that “any specific homeopathic drug” is GRAS/E absent a finding otherwise. *Id.* at 13. Plaintiffs therefore attempt to challenge a nonexistent action, and this claim is also dismissed.

d. Whether the FDA had Sufficient Safety Concerns for the Petition Denial

Finally, without an administrative record, the Court cannot rule on whether the FDA had sufficient safety concerns about homeopathic drugs to justify the petition denial. The FDA lists several examples to substantiate its safety concerns, including “99 cases of adverse events consistent with belladonna toxicity,” “more than 130 reports of anosmia (loss of the sense of smell) associated with the use of Zicam homeopathic intranasal zinc products,” and a worry that consumers may forego other treatments for homeopathic drugs. *Id.* at 4. In its simultaneously published Final Guidance, the FDA asserts that these are but a few “examples among many.” Final Guidance at 3 n.12. The agency’s safety concerns may well be warranted. But whether they justify increased enforcement is a factual, not legal, determination. Therefore, the Court cannot reach a decision without a full record. *See Walter O. Boswell Mem’l Hosp.*, 749 F.2d at 792; 5 U.S.C. § 706.

IV. Conclusion

For the foregoing reasons, it is hereby

ORDERED that [ECF 5] Defendants’ Motion to Dismiss is GRANTED in part and DENIED in part. It is further

ORDERED that Defendants shall answer the remaining count, which alleges that the FDA had insufficient safety concerns to justify the petition denial, by July 29. It is further

ORDERED that the parties shall meet and confer and submit a proposed schedule for producing the Certified Administrative Record and briefing summary judgement by July 29.

SO ORDERED.

CHRISTOPHER R. COOPER
United States District Judge

Date: July 15, 2025