UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MEDINATURA, INC.,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION et al.,

Defendants.

Civil Action No. 20-2066 (RDM)

MEMORANDUM OPINION AND ORDER

This case concerns the Food and Drug Administration's ("FDA") regulation of homeopathic drugs. For many years, the FDA did not regulate homeopathic drugs at all, promising to get around to them eventually. Then in 1988, to bring homeopathic drugs into at least partial compliance with the Federal Food, Drug, and Cosmetic Act ("FFDCA" or "Act"), the FDA issued Compliance Policy Guide 7132.15, Section 400.400 ("CPG 400.400" or "Policy"). CPG 400.400 established conditions under which homeopathic drugs could "ordinarily" be marketed without the FDA's premarket approval, so long as the drugs complied with statutory and regulatory requirements for labeling, manufacturing, and registration. Three decades later, as part of an ongoing effort to change the regulatory framework that applies to homeopathic drugs, the FDA withdrew CPG 400.400 in 2019.

Plaintiff MediNatura, Inc. is a purveyor of homeopathic products, including six prescription injectable drugs that it imports from Germany. In June 2020, following the withdrawal of the Policy, the FDA sent MediNatura a warning letter asserting that its injectable products violated the FFDCA. The agency also added the products to an Import Alert

recommending that officials detain them at the border. MediNatura filed this lawsuit challenging the withdrawal of CPG 400.400 and the Import Alert and sought a preliminary injunction. In response, the FDA moved to dismiss. For the following reasons, the Court will **GRANT** in part and **DENY** in part the FDA's motion to dismiss and will **DENY** MediNatura's motion for preliminary injunction.

I. BACKGROUND

A. Statutory and Regulatory Background

1. *The FDA's Regulation of New Drugs*

The FFDCA requires drug manufacturers to secure approval from the FDA before marketing any new drug. 21 U.S.C. § 355(a). The FFDCA defines "drug" to include, *inter alia*, articles recognized in either the "official United States Pharmacopœia" or the "official Homœopathic Pharmacopœia of the United States" ("HPUS"); articles intended for the "diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;" and articles, other than food, "intended to affect the structure or any function of the body of man or other animals." *Id*. § 321(g). The Act defines "new drug," in turn, as any drug "the composition of which is such that [it] is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." *Id*. § 321(p). Even if a drug is so recognized, it is still a new drug if it has not "been used to a material extent or for a material time under such conditions." *Id*. In other words, the FFDCA exempts drugs that are already in the marketplace and generally recognized as safe and effective ("GRAS/E") from the requirements for new drugs.

The primary means for a drug manufacturer to obtain the FDA's approval for a new drug is through a New Drug Application ("NDA"), which must include "full reports of investigations" showing that the drug is both safe and effective for its intended uses.[1] *Id*. § 355(b). The statute instructs the FDA to deny an NDA if those investigations fail to show that the drug is safe and effective for its intended uses; if the manufacturing process for the drugs is "inadequate to preserve its identity, strength, quality, and purity;" or if the drug's labeling is "false or misleading in any particular." *Id*. § 355(d); *see also* 21 C.F.R. § 314.105(c) ("FDA will approve an NDA after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling . . . ."). The statute further instructs the agency, in considering these various factors, to "implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks." 21 U.S.C. § 355(d).

In 1972, the FDA launched a review process for classifying over-the-counter ("OTC") drugs as GRAS/E, known as the OTC Drug Review. Procedures for Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9464 (May 11, 1972). Over time, that OTC Drug Review became a separate avenue by which manufacturers could bring over-the-counter drugs to market. *See* 21 C.F.R. §§ 330.1, 330.10. Through notice and comment rulemaking, the FDA established monographs recognizing classes of OTC drugs as GRAS/E. *Id*. Drugs manufactured in accordance with those monographs are GRAS/E and thus exempt from the NDA process. In

[1] Although not at issue in this case, the statute also creates an Abbreviated New Drug Application ("ANDA") process through which drug manufacturers may seek approval of generic versions of previously approved drugs. 21 U.S.C. § 355(j). Under the ANDA process, a drug manufacturer "need not submit clinical studies proving the drug's safety or effectiveness but may, instead, demonstrate that the generic drug is, among other things, the chemical equivalent and bioequivalent of the relevant previously approved branded drug." *See STI Pharma, LLC v. Azar*, No. 18-1231 (RDM), 2020 WL 1332004, at *2 (D.D.C. Mar. 23, 2020).

2020, Congress reformed the OTC process in the CARES Act, replacing the notice-and-comment procedure for recognizing OTC drugs as GRAS/E with a more expedient administrative order process. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, §§ 3851–3856, 134 Stat. 281, 435–58 (2020).

2. *The FDA's Import Enforcement Policies*

In addition to drugs manufactured in the United States, the FFDCA applies to imported drugs. 21 U.S.C. § 381(a). If it "appears" that an imported drug violates applicable FFDCA requirements, including the premarket approval requirements, that drug is subject to refusal of admission. *Id*. Chapter 9 of the FDA's Regulatory Procedures Manual ("RPM") governs the agency's import operations. *See* Dkt. 11-3 (Ex. A) (RPM § 9). Before FDA denies admission to an imported drug, it first detains the drug. Dkt. 11-1 at 13. Because the FFDCA permits refusal of admission based on "examination of such samples *or otherwise*," 21 U.S.C. § 381(a) (emphasis added), FDA regulations allow for "detention without physical examination" where other information or evidence suggests the drug is inadmissible, Dkt. 11-3 at 37–38 (Ex. A) (RPM § 9-8-2). Once a drug is detained, the FDA field office provides the importer notice and an opportunity to be heard. 21 C.F.R. § 1.94. A detained drug is formally denied admission only after the importer is given a chance to present evidence at an import hearing. Dkt. 11-3 at 55–56 (Ex. A) (RPM § 9-10-5). After the hearing, the FDA field office will either release the drug, allow it to be brought into compliance with the FFDCA, or refuse admission. Dkt. 11-1 at 14. An importer may seek reconsideration of a field office's decision to refuse admission. *See* 21 C.F.R. § 10.33.

To guide FDA field officers in reviewing imports, the FDA issues import alerts. Dkt. 11-3 at 76 (Ex. A) (RPM § 9-15-4). Import alerts "identify those products or shippers that have met

the criteria for detention without physical examination." *Id*. at 75 (Ex. A) (RPM § 9-15-3). The alerts "significantly improve the uniformity of enforcement in import problem areas," *id*. at 76 (Ex. A) (RPM § 9-15-4), but an importer whose drugs are detained pursuant to an import alert may still administratively challenge the detention using the procedures described above.

3. *The FDA's Regulation of Homeopathic Drugs in CPG 400.400*

Homeopathy is a system of alternative medicine developed in Germany in the late 18th century. *See* National Institutes of Health, *Homeopathy*, https://www.nccih.nih.gov/health/homeopathy (last updated July 2018). Homeopathic medicine generally relies on two "unconventional" theories. *Id*. The first, known as "like cures like," is the notion that diseases can be cured by substances that produce similar symptoms in healthy people. *Id*. The second, known as the "law of minimum dose," is the idea that smaller amounts of an active ingredient produce greater effects. *Id*. In accordance with the latter theory, "[m]any homeopathic products are so diluted that no molecules of the original substance remain." *Id*.

Although homeopathic drugs are included in the FFDCA's definition of "drug" and are therefore subject to regulation by the FDA, *see* 21 U.S.C. § 321(g), the agency has never approved an NDA for a homeopathic drug, nor has it determined that any homeopathic drugs are exempt from the NDA process because they are GRAS/E, *see* Dkt. 11-1 at 15. And yet, millions of Americans receive homeopathic treatments every year. *See* Dkt. 1 at 11 (Compl. ¶ 41) (citing National Institutes of Health, *Homeopathy*, https://www.nccih.nih.gov/health/homeopathy (last updated July 2018)). The continued distribution of homeopathic drugs in apparent violation of the FFDCA has resulted from a long-standing detente between Congress, the FDA, and the homeopathic drug industry.

In 1972, the American Institute of Homeopathy commented on FDA's notice of proposed rulemaking for the OTC Drug Review program and requested that the agency exclude homeopathic medicines from the review. The agency obliged: "Because of the uniqueness of homeopathic medicine, the Commissioner has decided to exclude homeopathic drugs from this OTC drug review and to review them as a separate category at a later time after the present OTC drug review is complete." 37 Fed. Reg. at 9,466. The OTC Drug Review then became an ongoing program that, although reformed in the CARES Act, has never been completed, and the FDA has not gone on to review homeopathic drugs as a separate category. As a result, there are currently no FDA drug monographs for homeopathic medicines, nor has the agency created any other separate review process for determining the safety and effectiveness of homeopathic drugs, whether OTC or prescription. Dkt. 1 at 5 (Compl. ¶ 19).

Instead, in 1988, the FDA issued CPG 400.400, titled "Conditions Under Which Homeopathic Drugs May [B]e Marketed." Dkt. 1 at 29 (Ex. A); *see also id.* at 40 (Ex. B) (dating CPG 400.400 to 1988). In its "Background" section, the document included a brief history of homeopathy, which noted that traditionally "homeopathic drugs have been marketed on a limited scale by a few manufacturers who have been in business for many years and have predominantly served the needs of a limited number of licensed practitioners." Dkt. 1 at 29 (Ex. A). As a result, homeopathic drugs historically bore little or no labeling. *Id.* But in the years leading up to 1988, the FDA had observed "significant" growth in the homeopathic industry. *Id*. The agency therefore issued CPG 400.400 to "provide[] guidance on the regulation of OTC and prescription homeopathic drugs and [to] delineate[] those conditions under which homeopathic drugs may ordinarily be marketed in the U.S." *Id*.

Although CPG 400.000 noted that "[a] product's compliance with requirements of the" Homœopathic Pharmacopœia of the United States, the United States Pharmacopœia, or the National Formulary "does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use," *id*. at 31 (Ex. A), the Policy said nothing further about the FFDCA's NDA or safety and effectiveness requirements. Instead, the Policy referred its audience to Dr. John Henry Clarke's *A Dictionary of Practical Materia Medica* as a "guide to the use of homeopathic drugs (including potencies, dosing, and other parameters)." *Id.* And CPG 400.400 instructed the FDA's "compliance personnel . . . particularly [to] consider whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy," in which case "priorities and procedures concerning the agency's policy on health fraud would apply." *Id*. at 29 (Ex. A).

CPG 400.400 did, however, specify various other requirements for marketing homeopathic drugs. Most notably, CPG 400.400 stated that all homeopathic drugs "must comply with the labeling provisions" found in the FFDCA and relevant FDA regulations. *Id*. at 31 (Ex. A). Under the general labeling requirements set forth in the Policy, homeopathic drug labels were required to include a name and place of business associated with manufacturing, packing, or distribution, directions for use, a statement of ingredients, and an established name. *Id*. at 31–32 (Ex. A). Because many homeopathic drugs at that time bore Latin names, and because the FFDCA and FDA regulations require drug labeling to be in English, CPG 400.400 mandated that "the industry is required to translate these names from Latin to their common English names as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first." *Id*. at 32 (Ex. A). In addition, CPG 400.400 included more specific labeling requirements

for drugs depending on their prescription or OTC status, which was to be determined in accordance with the FFDCA. *Id*. at 32–34 (Ex. A).

CPG 400.400 went on to list requirements for homeopathic drugs beyond labeling. It required that firms that "manufacture, prepare, propagate, compound, or otherwise process homeopathic drugs must register as drug establishments" in accordance with the FFDCA. *Id*. at 34 (Ex. A). The Policy also required that homeopathic drugs "be packaged" and "be manufactured" as specified in the FFDCA, except for certain carveouts for homeopathic drugs that the FDA had promulgated in previous regulations. *Id*. CPG 400.400 thus expressly subjected homeopathic drugs to many of the requirements of the FFDCA, including for manufacturing, packaging, and labeling, but it did not expressly require that homeopathic drugs demonstrate their safety and efficacy through the NDA process or otherwise, even though doing so is required under the FFDCA. In a section titled "Regulatory Action Guidance," the Policy concluded by stating that "[t]hose firms marketing homeopathic drugs which are not in compliance with the conditions described above will be considered for regulatory follow-up." *Id*.

At a hearing that the FDA hosted on April 21, 2015, on the topic of "Homeopathic Product Regulation," Daniel Michels, the director of the Office of Compliance within the FDA's Center for Drug Evaluation and Research at the time the Policy was issued and one of its primary authors, addressed the question of "why . . . a CPG [was] needed in the first place, and why . . . it ha[s] this particular construct." *See* Transcript at 261–62, *Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter Century*, FDA (2015), available at https://www.fda.gov/media/92580/download (hereinafter "Hearing on Homeopathic Product Regulation"). Michels explained that before the 1980s, "[w]e

in the compliance area thought that this was something we'd never have to worry about" because the practice of homeopathy was "was dying, forget it, it'll be gone by the time we retire." *Id.* at 263. But that assumption turned out to be "[n]ot true" because of "new growth in homeopathy." *Id*. And the FDA was particularly concerned about homeopathic drugs that "were being offered for clearly health fraud conditions, cure your cancer, fix your broken leg." *Id.* at 264. But the FDA had a "knowledge gap" because it "didn't know what homeopathic products were." *Id.* at 265. In Michels's telling, FDA officials "didn't know" how homeopathic drugs were manufactured, how they were labeled, how to distinguish between prescription and OTC homeopathic drugs, or even where to find a copy of the HPUS. *Id.* at 265–66. Through extensive research into the industry, the FDA concluded that it "could not, in the 1980s, treat homeopathic products with the same regulatory construct that we applied to the other 'traditional, pharmaceutical products.'" *Id.* at 266.

Based on that realization, Michels explained, the FDA created CPG 400.400 as an alternative regulatory framework, which applied all of the FFDCA's requirements for drugs to homeopathic products, with the notable exception of "final product testing"—that is, the NDA process. *Id.* at 268. With respect to the various labeling requirements that CPG 400.400 applied directly to homeopathic products for the first time, Michel said that "the industry and the community took on that challenge." *Id.* at 269. As to the standards for manufacturing homeopathic drugs, Michels said that, because the HPUS was out of date at the time the Policy was published, the FDA included "other reference materials [that] are cited there as dispositive in terms of the regulatory status and standards for these products." *Id*. In sum, Michels explained that CPG 400.400 "enhanced FDA's ability to take regulatory action when necessary,

against products containing or alleged to contain homeopathic ingredients" by establishing a "line in the sand" beyond which "outliers" would face enforcement action. *Id.* at 270.

Although Congress has never codified CPG 400.400 in a law exempting homeopathic drugs from the NDA process, it has on occasion included in legislation references to the FDA's accommodation of the homeopathic drug industry. When Congress enacted new requirements for tracking prescription drugs through the supply chain as part of the Drug Quality and Security Act in 2013, for instance, it exempted homeopathic prescription drugs from those provisions by excluding from the definition of "product" any "homeopathic drugs marketed in accordance with applicable guidance under this chapter." *See* 21 U.S.C. § 360eee(13). Likewise, when amending the OTC Drug Review program in the CARES Act, Congress exempted from its new regulatory scheme "any nonprescription drug . . . which was excluded by the Food and Drug Administration from the Over-the-Counter Drug Review in accordance with the paragraph numbered 25 on page 9466 of volume 37 of the Federal Register, published on May 11, 1972," which incorporates by reference the original exclusion of homeopathic drugs from the FDA's OTC Drug Review. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3853, 134 Stat. 281, 454 (2020).[2]

[2] MediNatura also refers in its briefing to certain correspondence between members of Congress and the FDA regarding the impact of legislation on CPG 400.400. Dkt. 15 at 26 n.6. In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012). That statute gave the FDA greater authority to regulate the importation of drugs. Dkt. 23 at 22 n.6; *see also* 21 U.S.C. § 381(r). In a letter, Jeanne Ireland, then-Assistant Commissioner for Legislation at FDA, wrote to Senator Tom Harkin, Chairman of the Committee on Health, Education, Labor, and Pensions, that the new legislation "will not affect FDA's implementation of CPG 400.400 with regard to the importation of homeopathic drugs." *See* Letter from Jeanne Ireland, Assistant Comm'r for Legislation, Food & Drug Admin., to Sen. Tom Harkin, Chairman, Comm. on Health, Educ., Labor, and Pensions (Aug. 10, 2012), available at https://www.theaahp.org/wp-content/uploads/2014/01/harkin-response.pdf; Dkt. 15 at 26 n.6.

4. *The FDA's Efforts to Rescind and Replace CPG 400.400*

In 2015, the FDA announced that it was reconsidering its regulation of homeopathic drugs and invited the public to attend a hearing, described above, and to submit comments. *See* Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century, 80 Fed. Reg. 16,327 (March 27, 2015). In the hearing notice, the FDA explained that since 1988, under CPG 400.400, "prescription and nonprescription drug products labeled as homeopathic have been manufactured and distributed without FDA approval." *Id*. at 16,328. The agency noted the continued "upward growth trajectory" in homeopathic drug sales, going from a multimillion-dollar industry in 1988 to one with about $2.9 billion in sales as of 2007. *Id*. The FDA also discussed adverse health effects related to "[h]omeopathic [a]gents." *Id*. And, CPG 400.400 notwithstanding, the notice emphasized that "nothing" in the FFDCA "exempts drugs labeled as homeopathic from any of the requirements related to approval" and therefore, insofar as "a drug labeled as homeopathic is a new drug" within the meaning of the FFDCA, that product "is subject to the same premarket approval requirements and the same standards for safety and efficacy as all new drugs." *Id*.

In December 2017, the FDA issued a draft guidance titled "Drug Products Labeled as Homeopathic," in which the agency announced its intention to replace the more categorical provisions of CPG 400.400 with a "risk-based approach." Dkt. 1 at 40 (Ex. B). The draft guidance, like the hearing notice, explains that, under the FFDCA, homeopathic drugs are subject to the same regulatory requirements as all other drugs, including the same premarket approval requirements. *Id*. at 41 (Ex. B). Because premarket approval, whether through an NDA, Biologics License Application, or the OTC Drug Review plays "an essential role in ensuring that drugs are both safe and effective," the FDA cautioned that "[d]rugs marketed

without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling." *Id*. Unlike the mandatory "must" phrasing of Section 400.400, the 2017 draft guidance included boilerplate language that, when finalized, it would "not establish any rights for any person" and will "not [be] binding on FDA or the public." *Id*. at 40 (Ex. B).

In light of the growth of homeopathic medicine and attendant safety concerns, the FDA proposed in the 2017 draft guidance that it would "apply a risk-based enforcement approach to the manufacturing, distribution, and marketing of drug products labeled as homeopathic." *Id*. at 42 (Ex. B). Under that risk-based approach, the FDA would prioritize enforcement actions against certain classes of homeopathic medicines, including "[p]roducts with reported safety concerns," "[p]roducts intended to be used for the prevention or treatment of serious and/or life threatening diseases and conditions," and, as relevant here, "[p]roducts for routes of administration other than oral and topical." *Id*. at 43–44 (Ex. B). The draft guidance observed that "unapproved injectable drug products and unapproved ophthalmic drug products pose a greater risk of harm to users due to their routes of administration (e.g., bypassing some of the body's natural defenses, differences in absorption) and the potential risk of harm from contamination." *Id*. at 43 (Ex. B).

Notwithstanding those priorities, the FDA stated that the draft guidance, when finalized, will "provide notice that *any* product labeled as homeopathic that is being marketed illegally is subject to FDA enforcement action at any time." *Id.* at 43 (Ex. B) (emphasis added). And because no homeopathic product is marketed in accordance with the FFDCA, that will render every homeopathic product subject to enforcement at any time. Finally, the 2017 draft guidance signaled FDA's plan to rescind Section 400.400 "[s]imultaneous[ly] with the issuance of the final guidance." *Id*. at 40 (Ex. B).

The FDA received thousands of comments on the 2017 draft guidance, including from manufacturers, prescribers, and patients of homeopathic medicine, many of whom requested that aspects of CPG 400.400 be retained, arguing that the new guidance provided the industry with "an incomplete list of what it probably cannot market and no guidance as to what can be marketed." Dkt. 1 at 6–7 (Compl. ¶ 23) (citing comments from the American Association of Homeopathic Pharmacists and the Homoeopathic Pharmacopoeia Convention of the United States). Commenters also "challenged [the] FDA's position that injectable products raise inherent safety concerns." *Id*. at 6 (Compl. ¶ 23) (citing comments from the American Association of Homeopathic Pharmacists, National Health Freedom Action, and the Consumer Healthcare Products Association). And the comments highlighted the reliance interests of homeopathic drug manufacturers who had made significant investments on the understanding that they would be able to market their products in accordance with CPG 400.400. *Id*. at 8 (Compl. ¶ 27) (citing comment from the American Association of Homeopathic Pharmacists).

Several months after the release of the 2017 draft guidance, the FDA received a citizen petition from Americans for Homeopathy Choice.[3] Dkt. 12-12 (Ex. K). The petition requested that the FDA establish an expert advisory committee on homeopathy, convert CPG 400.400 into a regulation (with slight modifications), withdraw the 2017 draft guidance, and, in the interim, leave CPG 400.400 in place. *Id*. at 2–3 (Ex. K). The petition argued (1) that although homeopathic medicines qualify as drugs under the statute, they should not be considered new drugs because they had been in continuous use in the United States since 1825, and (2) that

[3] Drug manufacturers or others can request administrative action from the FDA through a citizen petition process. *See* 21 C.F.R. §§ 10.25, 10.30. Any "interested person" may petition the FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." *Id*. § 10.25.

medicines recognized in the Homeopathic Pharmacopoeia of the United States are "bona fide" under the law "as long as they are manufactured according to their 'expected identity, strength, quality, and purity.'" *Id*. at 3 (Ex. K). The petition posited that these proposals would "create a system that allows homeopathy to continue to be a safely utilized, effectively regulated and accessible choice for consumers." *Id*. at 23 (Ex. K). And it further asserted that retaining essential elements of CPG 400.400 would honor reliance interests by allowing "consumers represented by Petitioner[], Americans for Homeopathy Choice, and the professionals they consult, continued access and use of these medicines." *Id*. at 14 (Ex. K).

In October 2019, the FDA did three things at roughly the same time. First, it issued a revised version of the 2017 draft guidance for further public comment. Dkt. 1 at 46 (Ex. C). The updated 2019 draft guidance was substantially similar to the 2017 draft. The FDA added a definition of "homeopathic drug product" and clarified that the agency "anticipates that many homeopathic drug products will fall outside the categories of drug products that FDA intends to prioritize for enforcement and regulatory action." *Id*. at 49 (Ex. C). The FDA also elaborated on its safety concerns by detailing "multiple situations in which homeopathic drug products posed a significant risk to patients." *Id*. at 51 (Ex. C). The agency focused primarily on two examples of safety concerns related to homeopathic drugs. *Id.* First, a 2016 search of the FDA Adverse Event Reporting System revealed 99 adverse events "consistent with belladonna toxicity, including reports of infant deaths and seizures, possibly related to teething products." *Id*. "Further investigation revealed that the poisonous belladonna alkaloids in some of the [homeopathic] products far exceeded the labeled amounts . . . ." *Id*. Second, "by 2009," the FDA had received more than 130 reports of Zicam homeopathic intranasal zinc products causing

users to lose their sense of smell. *Id*. The revised guidance continued to identify injectable products as posing a particularly high risk. *Id*. at 53 (Ex. C).

At the same time, the FDA withdrew CPG 400.400—not waiting until it was ready to publish the final guidance, as the agency had indicated it would do in the 2017 draft. *See* Compliance Policy Guide Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed; Withdrawal of Guidance, 84 Fed. Reg. 57,439, 57,440 (Oct. 25, 2019). In the Federal Register notice accompanying the withdrawal, the FDA discussed the "broad misconception that all homeopathic products are highly diluted and generally composed of 'natural' ingredients, and that they are therefore incapable of causing harm." *Id*. On the contrary, the agency cautioned, the "FDA has encountered situations in which homeopathic products either caused or could have caused significant harm, even though the products, as labeled, appeared to meet the conditions described in CPG 400.400." *Id*. The growth of the homeopathic drug industry, which led to "increased population exposure," contributed to the "FDA's enhanced focus on the safety of homeopathic drugs in recent years" and led it to rethink the 30-year-old CPG 400.400. *Id*. The FDA decided to rescind CPG 400.400 immediately, rather than waiting until the final replacement guidance was ready, because of "the recent growth of safety concerns associated with homeopathic drug products" and the agency's conclusion that "CPG 400.400 is inconsistent with the [FDA's] risk-based approach to enforcement generally." *Id*. Finally, the FDA noted that the withdrawal of the guidance does not change the legal obligations of homeopathic drug manufacturers, which were always subject under the FFDCA to the FDA's premarket approval process, even if (consistent with CPG 400.400) no homeopathic medicine had ever been approved through that process. *Id*.

Along with the revised draft guidance and the withdrawal of CPG 400.400, the FDA also denied the citizen petition filed by Americans for Homeopathy Choice. Dkt. 12-13 (Ex. L). The denial letter retread much of the same ground covered in the draft guidance and the notice of withdrawal. Near the end of the letter, the FDA included a section addressing "Alleged Reliance on CPG 400.400." *Id*. at 15–16 (Ex. L). The agency asserted that any claims of reliance were based on "the incorrect belief that withdrawing CPG 400.400 represents a change in the legal obligations that apply to homeopathic drugs under the statutes FDA administers." *Id* at 15 (Ex. L). Because the FFDCA requires premarket review and approval of all new drugs, CPG 400.400 "did not, and legally could not, provide a path for legal marketing of unapproved homeopathic drug products." *Id*. The agency, the letter further explained, "does not have authority to exempt a product or class of products that are new drugs from the new drug approval requirements." *Id*. And, in any event, even if homeopathic drug manufacturers, prescribers, and users could state valid reliance interests, the FDA concluded that "there is substantial justification [for] overcoming any such . . . interest." *Id*. at 15 (Ex. L). The agency gave four reasons: (1) homeopathic drugs are not exempt from statutory premarket review and approval requirements; (2) the recent growth of safety concerns associated with homeopathic products; (3) the continued expansion of the homeopathic drug industry, which increases consumer exposures; and (4) the FDA's interest in its general risk-based approach to enforcement. *Id*. at 15–16 (Ex. L). For those reasons, the FDA denied the petition. *Id*. at 16 (Ex. L).

B. Factual and Procedural Background

Plaintiff MediNatura manufactures, imports, and distributes both over-the-counter and prescription homeopathic drugs. Dkt. 1 at 9 (Compl. ¶ 31). MediNatura began as the U.S. subsidiary of Biologische Heilmittel Heel GmbH ("Heel"), the world's second largest

homeopathic drug company, based in Germany. *Id.* (Compl. ¶ 33). In 2014, MediNatura spun off as an independent U.S. company, with its headquarters in Pennsylvania and a manufacturing facility in New Mexico. *Id*. (Compl. ¶ 33); *id*. at 2 (Compl. ¶ 6); *id.* at 10 (Compl. ¶ 37).

Among MediNatura's portfolio of products are six injectable prescription drugs, which it still imports from Germany. Dkt. 5-1 at 8. Five of those drugs—sold under the trade names Zeel, Traumeel, Neuralgo Rheum, Lymphomyosot X, and Spascupreel—are "prescribed explicitly for pain management." Dkt. 5-1 at 8 n.2. The sixth, Engystol, is used "as an immunity booster to help reduce the severity and duration of symptoms in viral infections—which may include pain—particularly in the early stages of colds and influenza-like illnesses." *Id.* Over the past 18 years, MediNatura has distributed more than 5 million prescription injectables in the United States. Dkt. 1 at 9 (Compl. ¶ 32). The revenue derived from those sales—about $50 million—represents 41% of the company's total business. *Id*. The other 59% of its revenue is derived from the sales of about 70 over-the-counter products, which MediNatura manufactures domestically. *Id*.; *id.* at 10 (Compl. ¶ 37).

MediNatura alleges that its "mission is to provide effective medicines without serious or lethal side effects, thus offering medical practitioners and patients safe remedies that reduce suffering and save lives." *Id.* (Compl. ¶ 34). MediNatura promotes its injectable drugs as safer alternatives to opioids and corticosteroids—painkillers that carry well-known risks. Dkt. 5-1 at 14. The company asserts that its injectable products have caused one reported adverse drug reaction ("ADR") within the past 18 years, compared to more than 86,000 ADRs and more than 14,000 deaths from corticosteroids. Dkt. 1 at 13–14 (Compl. ¶¶ 51–52).

MediNatura's products are monographed in the HPUS, which imposes certain safety and other requirements on homeopathic drugs. Dkt. 1 at 10 (Compl. ¶ 36). In accordance with

homeopathy's less-is-more ethos, MediNatura's drugs include extremely small traces of their active ingredients. In homeopathic terms, a "1X" dilution contains one part of the active ingredient and nine parts diluent. *Id.* at 15 n.12 (Compl. ¶ 54). A "2X" dilution comprises one part "1X" dilution and nine parts diluent, meaning it is only 1/100th of the active ingredient. *Id.* The concentration of the active ingredient continues to decrease exponentially from there. *Id.* Taking one example from MediNatura's complaint, the company's Traumeel product contains a 9.3X dilution of "mercurius solubilis," which works out to 0.00099 micrograms of the active ingredient, "well below" the "[p]ermitted [d]aily [e]xposure" level of 3 micrograms of mercury for a 50-kilogram person. *Id.* at 14 (Compl. ¶ 54). MediNatura draws a comparison with the seasonal flu vaccine, which can contain as much as 25 micrograms of mercury (as a preservative), or more than 25,000 times more mercury than a dose of Traumeel. *Id.* at 15 (Compl. ¶ 55). As another example, MediNatura's Zeel product contains 0.002 micrograms of "embryo suis" (or porcine embryos), which is well below the 0.15-microgram permitted daily exposure (and Zeel's 9X final dilution is 10 million times less concentrated than the 2X dilution that the HPUS permits for embryo suis). *Id.* at 16 (Compl. ¶ 56).

The products also comply with FDA regulations for manufacturing and labeling, including those referenced in CPG 400.400. Dkt. 1 at 9–10 (Compl. ¶¶ 35, 37). MediNatura professes its compliance "with FDA's current Good Manufacturing Practices, drug establishment registration and drug product listing regulations, and, if imported, import requirements that require inspection and release by both FDA and the U.S. Customs and Border Protection." *Id.* (Compl. ¶ 35). Those current Good Manufacturing Practices "assure, among other things, dose-to-dose content uniformity and production under sterile conditions." *Id.* at 16 (Compl. ¶ 57). In addition, the FDA regularly inspects MediNatura's manufacturing facilities in both New Mexico

and Germany, with the latter "also being inspected by the relevant German authorities." *Id.* at 10 (Compl. ¶ 37).

MediNatura asserts that it has made various investments in reliance on CPG 400.400. As permitted by that regulatory framework, the homeopathic drug industry has grown substantially in recent years and now claims more than 6 million "patients and consumers" annually in the United States. *Id.* at 11 (Compl. ¶ 41). MediNatura asserts that demand for its prescription injectable products has also increased—as "[p]atients have come to rely on" them "to treat their symptoms in a safe manner"—as an alternative to corticosteroids or opioids. *Id*. (Compl. ¶ 42). To meet demand, MediNatura expanded product lines and upgraded its manufacturing facilities, incurring production and marketing costs in the process. *Id.* (Compl. ¶ 43). MediNatura has also incurred costs to comply with the labeling and manufacturing requirements listed in CPG 400.400. *Id.* at 11–12 (Compl. ¶ 43).

On June 11, 2020, several months after the withdrawal of CPG 400.400, the FDA sent MediNatura a warning letter regarding its six prescription injectable homeopathic drugs. *See* Dkt. 1 at 210–14 (Ex. I). The letter asserted that MediNatura's "injectable products are unapproved new drugs under" the FFDCA and that, as a result, "[i]ntroducing or delivering these products for introduction into interstate commerce violates" the FFDCA. *Id.* at 210 (Ex. I). The FDA, according to the letter, singled out these particular products for two reasons. First, "injectable drug products can pose risks of serious harm to users" because they "are delivered directly into the body, sometimes directly into the bloodstream, and therefore, bypass some of the body's key defenses against toxins and microorganisms that can lead to serious and life-threatening conditions." *Id.* Second, MediNatura's products "are labeled to contain potentially toxic or otherwise harmful ingredients, such as 'mercurius solubilis' (mercury) and 'embryo

totalis suis,' thereby presenting additional risk of serious harm to patients when delivered directly into the body." *Id.*

The letter further explained that the FDA had determined (1) that MediNatura's prescription injectables are "drugs" within the meaning of the FFDCA because they "are intended to cure, mitigate, treat, or prevent disease and/or intended to affect the structure or function of the body of man or other animals" and (2) that they are "new drugs" within the meaning of the Act because they "are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling." *Id.* at 212 (Ex. I). And as new drugs, MediNatura's products could not be sold in interstate commerce without prior approval from the FDA, which MediNatura has neither sought nor received. *Id.* at 212–13 (Ex. I).

The letter recognized that MediNatura's products "are labeled as homeopathic drugs with active ingredients measured in homeopathic strengths." *Id.* at 213 (Ex. I). But the letter explained that the FFDCA's definition of "drug" includes articles recognized in the HPUS, such that "[h]omeopathic drugs are subject to the same regulatory requirements as other drugs." *Id.* Without any mention of the withdrawal of CPG 400.400, the letter stated that "nothing in the [FFDCA] exempts homeopathic drugs from any of the requirements related to adulteration, misbranding, or approval." *Id.* The letter warned that failure to correct the identified violations "may result in legal action without further notice," including "refusal of admission into the United States, and such products may be subject to detention without physical examination." *Id.*

Six days later, on June 17, 2020, the FDA added MediNatura's six prescription injectable products to an Import Alert, which spans 349 pages. Dkt. 1 at 216–564 (Ex. J). A note at the top of the Import Alert, which is titled "Detention Without Physical Examination of Unapproved

New Drugs Promoted [i]n [t]he U.S.," explains that "[t]his import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue" but "does not create or confer any rights for or on any person, and does not operate to bind FDA or the public." *Id.* at 216 (Ex. J).

On July 29, 2020, MediNatura filed this lawsuit, *id.* at 1, and, on August 1, 2020, it filed a motion for a preliminary injunction, Dkt. 5. The company challenges both the rescission of CPG 400.400 and issuance of the Import Alert. Dkt. 1 at 2 (Compl. ¶¶ 3–4). MediNatura asserts four claims: (1) "FDA's withdrawal of CPG 400.400 and the Import Alert both entirely fail to consider the reliance interests of the homeopathic drug industry, medical practitioners, and patients—all of [which] were upended by FDA's dramatic change in policy;" (2) "the Import Alert places binding, prospective requirements on a group of distributors and importers of homeopathic drugs, despite the fact that it was not promulgated through notice-and-comment rulemaking;" (3) "the Import Alert is arbitrary and capricious because it provides no reasoned explanation for detaining the Products—which have a long and proven record of safety;" and (4) the "FDA's actions are arbitrary and inconsistent with the FFDCA because they together leave no realistic pathway for the marketing of homeopathic drugs." Dkt. 5-1 at 11–13.

The FDA opposes Plaintiff's motion for preliminary injunction and counters with a motion to dismiss. Dkt. 11. The FDA first argues that MediNatura's claims are neither ripe for judicial review nor cognizable under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq*., because the withdrawal of CPG 400.400 and the addition of MediNatura's products to the Import Alert do not constitute final agency action. Dkt. 11-1 at 24–31. The agency further maintains that the withdrawal of CPG 400.400 is unreviewable under the APA, because the Policy merely reflects the FDA's enforcement priorities, which are committed to the agency's

discretion. *Id.* at 31–33. As to MediNatura's fourth claim, the FDA asserts that MediNatura lacks standing and has not exhausted its administrative remedies. *Id.* at 33–36. MediNatura filed a combined reply in support of its motion for summary judgment and opposition to the FDA's motion to dismiss, Dkt. 15, and the FDA filed a final reply brief, Dkt. 23. The Court held oral argument on the motions on September 3, 2020.

In response to questions raised at oral argument, MediNatura filed a supplemental brief updating the Court on its efforts to import its injectable products. Dkt. 25. The company reported that on August 12, 2020, it ordered two shipments of Engystol. Dkt. 25-1 at 1 (Clive Decl. ¶ 4). One shipment, which arrived at the Los Angeles International Airport, was allowed to proceed into the country, while the other, which arrived at the Houston Intercontinental Airport, was detained. *Id.* at 1–2 (Clive Decl. ¶¶ 5–10).

The motions are now fully briefed and ripe for decision.

II. LEGAL STANDARD

A. Motion to Dismiss

A motion to dismiss under Rule 12(b)(1) challenges the Court's jurisdiction to hear a claim and may raise a "facial" or a "factual" challenge to the Court's jurisdiction. *See Hale v. United States*, No. 13-1390 (RDM), 2015 WL 7760161, at *3 (D.D.C. Dec. 2, 2015). A facial challenge to the Court's jurisdiction contests the legal sufficiency of the jurisdictional allegations contained in the complaint. *See Erby v. United States*, 424 F. Supp. 2d 180, 182 (D.D.C. 2006). For a facial challenge, the Court must accept the allegations of the complaint as true and must construe "the complaint in the light most favorable to the non-moving party." *Id.*; *see I.T. Consultants, Inc. v. Republic of Pakistan*, 351 F.3d 1184, 1188 (D.C. Cir. 2003). In this sense, the Court must resolve the motion in a manner similar to a motion to dismiss under Rule

12(b)(6). *See Price v. Socialist People's Libyan Arab Jamahiriya*, 294 F.3d 82, 93 (D.C. Cir. 2002).

Alternatively, a Rule 12(b)(1) motion may pose a "factual" challenge to the Court's jurisdiction. *Erby*, 424 F. Supp. 2d at 182–83. For factual challenges, the Court "'may not deny the motion to dismiss merely by assuming the truth of the facts alleged by the plaintiff and disputed by the defendant,' but 'must go beyond the pleadings and resolve any disputed issues of fact the resolution of which is necessary to a ruling upon the motion to dismiss.'" *Id*. (quoting *Phoenix Consulting Inc. v. Republic of Angola*, 216 F.3d 36, 40 (D.C. Cir. 2000)). In this context, the factual allegations of the complaint are not entitled to a presumption of validity, and the Court is required to resolve factual disputes between the parties. *Id*. at 183. The Court may consider the complaint, any undisputed facts, and "'the [C]ourt's resolution of disputed facts.'" *Id*. (quoting *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992)).

A motion to dismiss for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6) "tests the legal sufficiency of a complaint." *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). In evaluating a Rule 12(b)(6) motion, the Court "must first 'tak[e] note of the elements a plaintiff must plead to state [the] claim to relief,' and then determine whether the plaintiff has pleaded those elements with adequate factual support to 'state a claim to relief that is plausible on its face.'" *Blue v. District of Columbia*, 811 F.3d 14, 20 (D.C. Cir. 2015) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675, 678 (2009)) (alterations in original) (internal citation omitted). The complaint, however, need not include "detailed factual allegations" to withstand a Rule 12(b)(6) motion. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff may survive a Rule 12(b)(6) motion even if "recovery is very remote and unlikely," so long as the facts alleged in the complaint are "enough to raise a right to relief above

the speculative level." *Id.* at 555–56 (internal quotation marks omitted). In assessing a Rule 12(b)(6) motion, a court may consider only "the facts contained within the four corners of the complaint," *Nat'l Postal Prof'l Nurses v. U.S. Postal Serv.*, 461 F. Supp. 2d 24, 28 (D.D.C. 2006), along with "any documents attached to or incorporated into the complaint, matters of which the court may take judicial notice, and matters of public record," *United States ex rel. Head v. Kane Co.*, 798 F. Supp. 2d 186, 193 (D.D.C. 2011).

B. Motion for Preliminary Injunction

"A preliminary injunction is an extraordinary remedy never awarded as of right," *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008), but "only when the party seeking the relief, by a clear showing, carries the burden of persuasion," *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004). To secure a preliminary injunction, a plaintiff "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter*, 555 U.S. at 20. "The last two factors 'merge when the Government is the opposing party.'" *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 10 (D.C. Cir. 2019) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

Before the Supreme Court's decision in *Winter*, courts in this circuit applied a "sliding-scale" approach to the preliminary injunction analysis under which "a strong showing on one factor could make up for a weaker showing on another." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011). Since *Winter*, the D.C. Circuit has hinted on several occasions that "a likelihood of success is an independent, free-standing requirement for a preliminary injunction." *Id*. at 393 (quoting *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh, J., concurring)); *see also Archdiocese of Wash. v. Wash. Metro. Area Transit Auth.*,

897 F.3d 314, 334 (D.C. Cir. 2018) (observing that *Winter* may be "properly read to suggest a 'sliding scale' approach to weighing the four factors be abandoned"). But, to date, the court of appeals has declined to decide the issue. *See, e.g.*, *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 7 (D.C. Cir. 2016); *see also Am. Meat Inst. v. U.S. Dep't of Agric.*, 746 F.3d 1065, 1074 (D.C. Cir. 2014), *reinstated in relevant part by* 760 F.3d 18 (D.C. Cir. 2014) (en banc); *Sherley*, 644 F.3d at 393.

III. ANALYSIS

The Court begins with the FDA's motion to dismiss, before turning to MediNatura's motion for preliminary injunction.

A. Motion to Dismiss

The FDA moves to dismiss all four of MediNatura's claims. It argues that MediNatura's first claim, challenging the rescission of CPG 400.000, must be dismissed because the withdrawal did not constitute final agency action. Dkt. 11-1 at 24–27. In the absence of final agency action, the FDA contends, MediNatura's claim is both unripe for judicial review and not cognizable under the APA. *Id.* at 24. The FDA seeks dismissal of MediNatura's second and third claims, which challenge the addition of MediNatura's products to the import alert, on similar grounds. *Id.* at 27–29. Finally, the FDA seeks dismissal of MediNatura's fourth claim on several grounds, including that MediNatura lacks standing, that MediNatura failed to exhaust administrative remedies, and that the FDA did not fail to take any discrete and legally required action. *Id.* at 29–30, 33–36. The Court takes these arguments in turn.

1. *Count I: Withdrawal of CPG 400.400*

a. Final Agency Action

The FDA first argues that the withdrawal of CPG 400.400 did not constitute final agency action, rendering MediNatura's claims both unfit for judicial review and barred by the APA. *Id.* at 24–27. The FDA is correct that the presence of final agency action is relevant both to whether a claim is ripe for review, *see Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002), and whether the plaintiff has a cause of action under the APA, *see* 5 U.S.C. § 704; *Holistic Candlers and Consumers Ass'n v. FDA*, 664 F.3d 940, 943 (D.C. Cir. 2012).

With respect to ripeness, there is little doubt that MediNatura's first claim is constitutionally ripe, but the Court must also consider whether there are "prudential reasons for refusing to exercise jurisdiction," *Nat'l Park Hosp. Ass'n v. DOI*, 538 U.S. 803, 808 (2003) (internal quotation marks omitted). To determine whether a case is prudentially ripe for judicial review, the Court looks to "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967). Under the fitness prong of the test, the Court considers whether the issue is "purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *Devia v. Nuclear Regulatory Comm'n*, 492 F.3d 421, 424 (D.C. Cir. 2007) (internal quotation marks omitted). Under the hardship prong, courts must consider whether the challenged administrative action is likely to have a direct and immediate effect on the "primary conduct" of the plaintiff. *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164 (1967); *see also Nat'l Park Hosp. Ass'n*, 538 U.S. at 810. In the context of APA challenges, however, if the court determines that "an issue is clearly fit for review, there is no need to consider 'the hardship to the parties of withholding court consideration,' because there

would be no advantage to be had from delaying review." *Action for Children's Television v. FCC*, 59 F.3d 1249, 1258 (D.C. Cir. 1995) (internal citation omitted); *see also Cohen v. United States*, 650 F.3d 717, 735 (D.C. Cir. 2011); *Garcia v. Acosta*, 393 F. Supp. 3d 93, 107 (D.D.C. 2019).

The APA, in turn, limits judicial review to "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. An agency action is final if two conditions are met. First, the action "must mark the consummation of the agency's decisionmaking process" and "must not be of a merely tentative or interlocutory nature." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal quotation marks and citation omitted). "And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 178 (internal quotation marks and citations omitted).

Here, because the FDA argues that MediNatura's claim is unripe solely on the ground that the withdrawal of CPG 400.400 does not constitute final agency action, the inquiries merge. If the Court determines that the withdrawal constituted final agency action, then MediNatura has a cause of action under the APA, and its claim is ripe. Moreover, because prudential ripeness does not implicate the Court's subject-matter jurisdiction, the Court need not consider ripeness before considering whether MediNatura can satisfy the APA's final-agency-action requirement. *See Holistic Candlers*, 664 F.3d at 943 n.4 ("[A]lthough the parties focus considerable attention on whether the case is ripe for judicial review, [the court's] conclusion that [FDA] warning letters do not constitute final agency action makes it unnecessary . . . to consider the remainder of the ripeness inquiry.").

The FDA argues that CPG 400.400 was a nonbinding policy statement that merely "described the Agency's enforcement priorities for homeopathic drugs." Dkt. 11-1 at 26. As the

FDA sees it, CPG 400.400 neither conferred rights nor imposed obligations, and, in particular, "did not purport to exempt homeopathic drugs from statutory premarket approval requirements." *Id.* at 26–27. And "[j]ust as *issuing* a non-binding policy statement is not final agency action," the FDA asserts that "*withdrawing* a non-binding policy statement is not final agency action either." *Id.* at 26 (emphasis in original).

MediNatura responds that what matters is not whether FDA labels CPG 400.400 as "guidance" or "non-binding" but, rather, how the FDA applied CPG 400.400 in practice. Dkt. 15 at 20–21. MediNatura argues that, under the two-part test from *Bennett*, the withdrawal constituted the consummation of the agency's decision-making process, ending a regulatory regime that had governed the homeopathic drug industry for more than thirty years and that CPG 400.400 created both legal obligations and rights. *Id.* at 21. As to obligations, MediNatura asserts that CPG 400.400 required homeopathic drug manufacturers to "comply with detailed labeling requirements," including by mandating "an alternative measure for expressing the potency of homeopathic drugs." *Id.* With respect to rights and legal consequences, MediNatura contends that CPG 400.400 "established that homeopathic drugs consistent with the guidance 'may ordinarily be marketed in the U.S.'" *Id.* (emphasis omitted) (quoting Dkt. 1 at 29 (Ex. A)). The withdrawal, in turn, "removed that assurance and subjected homeopathic drugs to import alerts and potential enforcement actions." *Id.* at 22.

Because the FDA does not contest that the withdrawal of CPG 400.400 constituted the culmination of its decision-making process, the dispute between the parties centers on whether the withdrawal constituted an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett*, 520 U.S. at 178 (internal quotation marks omitted). The D.C. Circuit has held that even when an agency labels a document as non-binding

guidance, that document can constitute final agency action if the language of the document indicates that it is binding or if the agency administers it with binding effect. *See Gen. Elec. Co.*, 290 F.3d at 382–84; *Appalachian Power Co.*, 208 F.3d at 1023. The Court thus looks to the text of CPG 400.400 and to the FDA's implementation of the Policy.

Although properly characterizing the Policy presents a close and difficult question, the language of CPG 400.400 indicates that it specified the regulatory duties of manufacturers of homeopathic drugs and thus had legal consequences, and the FDA's application of the guidance confirms that understanding. Starting with the text, the title of the document is "Conditions Under Which Homeopathic Drugs May [B]e Marketed." Dkt. 1 at 29 (Ex. A). The body of CPG 400.400 states its purpose as "provid[ing] guidance on the regulation of OTC and prescription homeopathic drugs and delineat[ing] those conditions under which homeopathic drugs may ordinarily be marketed in the U.S." *Id*. By its own terms, the document thus pertains to the affirmative "regulation" of homeopathic drugs and not just, as the FDA claims, to the exercise of enforcement discretion. And that makes sense when one considers how the Policy altered the status quo when the FDA issued it in 1988. As Michels explained at the hearing that led to CPG 400.400's withdrawal, the FDA had not been regulating the sale of homeopathic products at all prior to issuing the Policy. *See Hearing on Homeopathic Product Regulation* at 263. The Policy thus represented a compromise between the FDA and the homeopathic drug industry, through which the industry would come into partial compliance with the FFDCA in exchange for the FDA's permission to market their products.

To be sure, this key sentence of CPG 400.400 is qualified; it did not grant categorical authorization to market any homeopathic drug that satisfies the conditions set forth in the Policy. But the sole qualification was not as sweeping as the FDA suggests. Rather, the FDA added a

single adverb that did not fundamentally alter the compromise embodied in the Policy: "This document . . . delineates those conditions under which homeopathic drugs may *ordinarily* be marketed in the U.S." Dkt. 1 at 29 (Ex. A) (emphasis added). The word "ordinarily," as used in this context, means "[i]n the ordinary or usual course of events or state of things; in most cases; usually, commonly." *Ordinarily*, *Oxford English Dictionary* (3d Ed. 2004). That CPG 400.400 permitted the marketing of homeopathic drugs "in the ordinary or usual course," while also preserving the FDA's discretion to bring enforcement actions in extraordinary or unusual circumstances, is no surprise. Of course, if a homeopathic drug proved to be unsafe or was marketed as the cure for cancer or a broken leg, the FDA could enforce the FFDCA against those violations. As Michels explained, the FDA would still enforce the law against "outliers." *See Hearing on Homeopathic Product Regulation* at 270. But the mere fact that the privilege conferred by the Policy was less than absolute—just like most privileges—does not mean the Policy had no legal consequences. Other portions of the text confirm this understanding. CPG 400.400 instructed that "compliance personnel should particularly consider whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy," in which case "priorities and procedures concerning the agency's policy on health fraud would apply." Dkt. 1 at 29 (Ex. A).

In exchange for forbearance in the usual course, the text of CPG 400.400 also imposed obligations on the marketers of homeopathic drugs. Under the heading of "Policy," the document set out several pages of labeling requirements for homeopathic drugs, each using mandatory language, dictating what a company "must" do to comply. *Id.* at 31–34 (Ex. A). For example, CPG 400.400 imposed six general labeling requirements, including:

> Statement of Ingredients: Ingredient information shall appear in accord with Section 502(e) of the Act and 21 CFR 201.10. Labeling must bear a statement

> of the quantity and amount of ingredient(s) in the product in conformance with Section 502(b) of the Act, as well as 21 CFR 201.10, expressed in homeopathic terms, e.g., lx, 2x.
>
> Documentation must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients.
>
> Established Name: The product must be in conformance with Section 502(e)(1) of the Act and must bear an established name in accord with Section 502(e)(3) of the Act and 21 CFR 201.10. Many homeopathic products bear Latin names which correspond to listings in the HPUS. Since Section 502(c) of the Act and 21 CFR 201.15(c)(1) require that all labeling be in English, the industry is required to translate these names from Latin to their common English names as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first. It is permissible for industry to include in the labeling both English and Latin names.

Id. at 32 (Ex. A). The Policy provided additional labeling requirements specific to prescription and OTC homeopathic drugs. *Id.* at 32–34 (Ex. A). CPG 400.400 further set out requirements for registration with the FDA and for manufacturing practices. *Id.* at 34 (Ex. A). With respect to registration, CPG 400.400 provided that "[a]ll firms which manufacture, prepare, propagate, compound, or otherwise process homeopathic drugs must register as drug establishments in conformance with Section 510 of the Act and 21 CFR 207." *Id*. And, as for manufacturing, the Policy directed: "Homeopathic drug products must be manufactured in conformance with current good manufacturing practice, Section 501(a)(2)(B) of the Act and 21 CFR 211." *Id*. At the same time, moreover, the Policy exempted homeopathic drugs from certain testing and expiration dating requirements, "due to the unique nature of these drug products" and in light of a "pending" regulation at the time that would "exempt homeopathic drug products from the requirement for laboratory determination of identity and strength of each active ingredient prior to release for distribution." *Id.* In all, the document used the word "must" more than two dozen times. *Id*. at 29–34 (Ex. A).

Notably absent from this list of "musts," however, was compliance with the NDA process or any other requirement for showing that the drugs were safe and effective for their intended use, as required by the FFDCA. As to safety and efficacy, CPG 400.400 merely noted that "[a] product's compliance with requirements of the" HPUS, the United States Pharmacopœia, or the National Formulary "does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use." *Id*. at 31 (Ex. A). But the Policy said nothing further about the FFDCA's NDA requirement. Instead, it referred its audience to Dr. John Henry Clarke's *A Dictionary of Practical Materia Medica* as a "guide to the use of homeopathic drugs (including potencies, dosing, and other parameters)." *Id.* That tome, written at the end of the 19th century, includes expansive descriptions of the qualities and uses of each homeopathic substance. For instance, with respect to mercurius, Dr. Clarke's Dictionary notes that "[i]t antidotes . . . [b]ad effects of sugar; stings of insects; ailments from Arsenic or Copper vapours." *See* "Mercurius," John Henry Clarke, *A Dictionary of Practical Materia Medica* (1900), available at http://www.homeoint.org/clarke/m/merc.htm. According to the dictionary, among the mental side effects of mercurius are "[g]reat anguish, restlessness (is constantly changing from place to place), and agitation, with fear of losing the reason, or with excessive internal torment, principally in evening, or in bed at night, as if conscious of having committed some crime." *Id*. Whatever the qualities of Dr. Clarke's extensive reference guide, it does not approximate the FDA's NDA process. CPG 400.400's reliance on *A Dictionary of Practical Materia Medica*, without referencing any contemporary standards for assessing the safety and effectiveness of the drugs at issue, further signals the Policy's tradeoffs: homeopathic drug companies were permitted to market their products without premarket approval in exchange for

complying with the various statutory and regulatory requirements for labeling, manufacturing, and registration.

In the final section of the document, under the heading "Regulatory Action Guidance," the FDA warns: "Those firms marketing homeopathic drugs which are not in compliance with the conditions described above will be considered for regulatory follow-up." Dkt. 1 at 34 (Ex. A). Although CPG 400.400 may not "read[] like a ukase," as the supposed "guidance" document at issue in *Appalachian Power Co.* did, CPG 400.400 "commands, it requires, it orders, it dictates." *Appalachian Power Co.*, 208 F.3d at 1023. The Policy gave the homeopathic drug industry its "marching orders," and the FDA expected the industry "to fall in line." *Id.* (internal quotation marks omitted). As Michels put it, "the industry and the community took on that challenge." *Hearing on Homeopathic Product Regulation* at 269. CPG 400.400 therefore permitted homeopathic drug companies to market their products without premarket approval, in the ordinary course, so long as they complied with the various statutory and regulatory requirements incorporated in the Policy. That regulatory framework had legal consequences.

Turning from text to practice, the parties each cite to warning letters that the FDA sent to homeopathic drug companies during the years when CPG 400.400 was in effect to show how the agency implemented the Policy. Although the letters do not paint an entirely consistent picture, when taken together and read in conjunction with the text, they confirm that the Policy constituted final agency action for purposes of the APA. On several occasions, the FDA sent warning letters to homeopathic drug companies citing them for failures to comply with CPG 400.400, which MediaNatura points to as proof of the Policy's binding effect. *See, e.g.*, FDA Warning Letter to HomeopathyStore.com (Jul. 6, 2015), available at

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/homeopathystorecom-07062015 ("Letter to HomeopathyStore.com"); FDA Warning Letter to Nutri-Dyn Midwest, Inc. (Jan. 15, 2016), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/nutri-dyn-midwest-inc-461006-01152016 ("Letter to Nutri-Dyn"); FDA Warning Letter to Dae Young Foods Co., Ltd. (Nov. 20, 2017), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dae-young-foods-co-ltd-527505-11202017 ("Letter to Dae Young Foods").

In all three letters, FDA "acknowledge[d] that many homeopathic drugs are manufactured and distributed without FDA approval under enforcement policies set out in" CPG 400.400. *Id*. The FDA explained that, "[a]s its title suggests, the CPG identifies specific conditions under which homeopathic drugs may ordinarily be marketed." *Id*. But, the FDA warned, "in order to fall under the enforcement policies set forth in [CPG 400.400], a homeopathic product must meet the conditions set forth in [CPG 400.400]." *Id*. The letters then went on to explain how the recipients had failed to comply with CPG 400.400. *See, e.g.*, Letter to HomeopathyStore.com ("Under the CPG, only homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed over-the-counter . . . ."). The language from these letters, accordingly, supports the conclusion that the FDA treated CPG 400.400 in practice as a document with legal consequences.

Within one of those same letters, however, the FDA also included a section titled "Unapproved New Drugs," in which the agency alleged that the products in question directly violated the FFDCA because the products met the statute's definitions of "drug" and "new drug" and therefore could not be marketed "without prior approval from FDA." Letter to Nutri-Dyn.

This language subjecting homeopathic drugs to the NDA requirement is, at least arguably, at odds with MediNatura's contention that CPG 400.400 itself carried direct legal consequences. But the Court concludes that, when read in its entirety, the Nutri-Dyn letter still suggests that CPG 400.400 carried legal consequences. The letter explained, for instance, that two of the active ingredients in the products at issue "are not established homeopathic active ingredients in the HPUS or any of its addenda or supplements" and thus "the policies set forth in CPG [400.400] for the marketing of homeopathic drug products do not apply to these products." *Id*. In that passage, the agency applied CPG 400.400 as a basis for taking enforcement action and treated the Policy as a legally operative document. *See Am. Mining Cong. v. Mine Safety & Health Admin*., 995 F.2d 1106, 1112 (D.C. Cir. 1993).

In arguing that CPG 400.400 did not establish any legal rights or duties—and was merely a statement of the FDA's unconstrained enforcement priorities—the FDA points to a different set of warning letters, which it characterizes as initiating enforcement actions against homeopathic drug companies even though they were in compliance with CPG 400.400. *See, e.g.*, Dkt. 11-10 (Ex. H) (FDA Warning Letter to Matrixx Initiatives, Inc. (June 16, 2009)); Dkt. 11-11 (Ex. I) (FDA Warning Letter to Homeopathy for Health (June 8, 2010)); Dkt 11-15 (Ex. M) (FDA Warning Letter to King Bio Inc.) (Jan. 11, 2018)); Dkt. 11-16 (Ex. N) (FDA Warning Letter to GUNA, Inc. (Jan. 11, 2018)); Dkt. 11-17 (Ex. O) (FDA Warning Letter to Nutra Pharma (March 11, 2019)). In the warning letter to King Bio Inc., to take one representative example, the FDA asserted that "[h]omeopathic drugs products are subject to the same regulatory requirements as other drug products; nothing in the Act exempts homeopathic drug products from any of the requirements related to adulteration, labeling, misbranding, or approval." Dkt. 11-15 at 4 (Ex. M). The FDA acknowledged that "many drug products labeled as homeopathic are

manufactured and distributed without FDA approval under enforcement policies set out in [CPG 400.400],” but emphasized that “the enforcement policies set forth in the CPG are not unlimited.” *Id*. Indeed, the FDA further explained, the inclusion of the word “ordinarily” in the Policy “indicates that the CPG specifically contemplates that there may be circumstances where a product that otherwise may meet the conditions set forth in the CPG may nevertheless be subject to enforcement action.” *Id*.; *see also* Dkt. 11-10 at 2-3 (Ex. H) (including the same language); Dkt. 11-16 at 4 (Ex. N) (same); Dkt. 11-17 at 4 (Ex. O) (same). And the FDA concluded that the products in question were unapproved new drugs that violated the FFDCA. Dkt. 11-15 at 3 (Ex. M).

Although these letters present another close question in this difficult case, the Court disagrees with the FDA’s contention that they show that CPG 400.400 did not bind either the industry or the agency. Instead, the letters are consistent with the view that the Policy’s general rule created privileges and obligations but that the rule was subject to certain exceptions. Indeed, far from conflicting with CPG 400.400, these letters apply the Policy—including the limitation discussed above. As the FDA observed, the Policy’s use of the word “ordinarily” contemplated that its waiver of the FFDCA’s premarket approval requirements would not apply if an exceptional circumstance required enforcement. Dkt. 1 at 29 (Ex. A); Dkt. 11-15 at 4 (Ex. M). What’s more, CPG 400.400 directed that “compliance personnel should particularly consider whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy.” Dkt. 1 at 29 (Ex. A). The FDA thus retained discretion to bring enforcement actions when public health required, such as during a public health crisis or when a homeopathic product presented a substantial safety concern. The letters that FDA cites came in exactly those types of circumstances. The letter to King Bio Inc., for

example, explained that the company's AddictaPlex "product is intended to diagnose, mitigate, prevent, treat or cure opioid addiction." Dkt. 11-15 at 3 (Ex. M); *see also* Dkt. 11-16 at 4 (Ex. N) (targeting homeopathic product advertised as treating opioid addiction); Dkt. 11-17 at 4 (Ex. O) (same). Such application is certainly "beyond recognized or customary practice of homeopathy." Dkt. 1 at 29 (Ex. A). Likewise, another letter addressed a product marketed during the swine flu epidemic as treating that virus, Dkt. 11-11 (Ex. I), while yet another addressed the safety concerns associated with Zicam, one of the two incidents that FDA avers led the agency to replace CPG 400.400. Dkt. 11-10 (Ex. H); Dkt. 1 at 51 (Ex. C). These enforcement actions were consistent with CPG 400.400 and did not treat the Policy as merely a non-binding description of the FDA's enforcement priorities.

The Court is unpersuaded, therefore, that the FDA's retention of enforcement discretion under CPG 400.400 meant that the document had no legal consequences. Many general agency policies are subject to exceptions and limitations, but that does not mean those policies do not constitute final agency action. Even setting aside what one can deduce from the parties' dueling citations to warning letters, the fact that millions of unapproved homeopathic products were sold over a three-decade period pursuant to CPG 400.400, with the homeopathic drug industry growing to $2.9 billion in annual sales, provides compelling evidence that the Policy had legal consequences. And the agency's inspections of homeopathic drug facilities to ensure compliance with current Good Manufacturing Practices, as required in CPG 400.400, further confirms that the Policy had legal consequences. Dkt. 1 at 16 (Compl. ¶ 59); *id.* at 34 (Ex. A).

In reply, the FDA argues that CPG 400.400 "did not create or impose any requirements" for labeling or manufacturing. Dkt. 23 at 10–11. Rather, the document "simply listed requirements under the [FFDCA] and regulations that were already applicable to drugs

distributed in interstate commerce." *Id.* at 11. As an initial matter, it is not clear to the Court that this argument is factually correct. To be sure, CPG 400.400 is full of cross-references to statutory provisions and regulations, but its requirements are tailored in various ways to homeopathic drugs. For instance, CPG 400.400 required homeopathic drug labels to list ingredients "in homeopathic terms" and provided a grace period for translating labels from Latin to English. Dkt. 1 at 32 (Ex. A). And the Policy specified that a certain regulatory "testing requirement will not be enforced for homeopathic drug products." *Id.* at 34 (Ex. A). But, in any event, this argument misses the point. Just as important as what CPG 400.400 requires is what it omits: CPG 400.400 imposes or cross-references a host of regulatory requirements but never says that manufacturers of homeopathic drugs must submit and obtain approval for an NDA (or meet the GRAS/E requirements) before going to market. That is significant because the FDA has never approved an NDA for a homeopathic drug, nor has it ever recognized a homeopathic drug as GRAS/E. As such, every sale of a homeopathic drug in interstate commerce is made in violation of the statute—or, put less delicately, every sale of a homeopathic drug is unlawful.

In the absence of CPG 400.400, moreover, homeopathic drug manufacturers would have had little incentive to comply with the FFDCA's labeling and manufacturing requirements because compliance would have been futile, doing nothing to remove the barrier to marketing posed by the NDA requirement. It would have made little sense for a drug manufacturer to notify the FDA of its plan to market an unapproved drug, to comply with FDA labeling requirements, and to invite an FDA inspection of its facilities for compliance with good manufacturing practices. Nor is this observation hypothetical. Before the FDA issued CPG 400.400, homeopathic drug companies did not comply with these labeling, manufacturing, and registration requirements, meaning that CPG 400.400 caused a substantial change to the status

quo. CPG 400.400 induced homeopathic drug manufacturers to come into compliance with the FDA's many labeling, manufacturing, and registration requirements, with the assurance that they would "ordinarily" be allowed to market their products without satisfying the standard FDA premarket approval process. Regardless of whether it is characterized as exercising enforcement discretion or granting a right, CPG 400.400 provided a regulatory framework within which millions of homeopathic products were (partially) regulated and sold, and the rescission of that framework carries legal consequences.

As a point of comparison to which the parties make frequent reference, the Department of Homeland Security retained substantial discretion under the Deferred Action for Childhood Arrivals ("DACA") program. *See* Memorandum from Janet Napolitano, Sec'y of Homeland Sec., "Exercising Prosecutorial Discretion with Respect to Individuals Who Came to the United States as Children" (June 15, 2020), available at https://www.dhs.gov/xlibrary/assets/s1-exercising-prosecutorial-discretion-individuals-who-came-to-us-as-children.pdf. The DACA memorandum listed five requirements that an applicant needed to meet to participate in the program but noted that "requests for relief pursuant to this memorandum are to be decided on a case by case basis" and that "DHS cannot provide any assurance that relief will be granted in all cases." *Id.* at 1–2. Despite that discretion, none of the parties or courts addressing the APA challenges to the government's effort to rescind the DACA program made even passing reference to the final agency action requirement; the parties (including the government) evidently took it as a given that the rescission constituted final agency action. *See generally Dep't of Homeland Sec. v. Regents of the Univ. of Calif.*, 140 S. Ct. 1891 (2020); *Casa De Maryland v. U.S. Dep't of Homeland Sec.*, 924 F.3d 684 (4th Cir. 2019); *Regents of the Univ. of California v. U.S. Dep't of Homeland Sec.*, 908 F.3d 476 (9th Cir. 2018) ("*Regents I*"); *Nat'l Ass'n for the*

Advancement of Colored People v. Trump, 298 F. Supp. 3d 209 (D.D.C. 2018); *Batalla Vidal v. Duke*, 295 F. Supp. 3d 127 (E.D.N.Y. 2017). The Court is satisfied that CPG 400.400 had legal consequences for the homeopathic drug industry.

Finally, the FDA argues that CPG 400.400 could not possibly have conferred any legal status on homeopathic drug makers because the agency has no authority to override the FFDCA's premarket approval requirements. *See* Dkt. 23 at 11–12. But whether the FDA had the authority to delineate conditions under which homeopathic drugs may "ordinarily" be marketed is an entirely different question from whether the FDA actually did delineate those conditions. CPG 400.400 purported to set out such conditions, and the FDA allowed the sales of millions of unapproved homeopathic products over a thirty-year period within the framework that CPG 400.400 established. It is entirely possible, maybe even probable, that CPG 400.400 failed to give full effect to the FFDCA. But it is untenable to suggest that an agency that abdicates its enforcement responsibility is insulated from judicial review on the theory that the arguably *ultra vires* nature of the policy deprives it of legal consequence. As a general matter, judicial review under the APA would serve little purpose if only lawful agency policies were reviewable, on the theory that unlawful policies are null and void to begin with and thus do not carry legal consequences. Even *ultra vires* agency policies carry the force of law until invalidated by a court. The withdrawal of CPG 400.400 constitutes final agency action because it removed the set of regulatory conditions under which unapproved homeopathic drugs were marketed for three decades. The APA's final agency action requirement is, accordingly, satisfied with respect to MediNatura's challenge to the rescission of CPG 400.400, and that claim is ripe for judicial review.

b. Decision Committed to Agency Discretion

FDA next argues that the withdrawal of CPG 400.400 is unreviewable under the APA because the decision was committed to the agency's discretion. Dkt. 11-1 at 31–33.

The APA precludes judicial review of "agency action [that] is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). Because the APA creates a "basic presumption of judicial review [for] one 'suffering legal wrong because of agency action,'" *Abbott Laboratories*, 387 U.S. at 140 (quoting 5 U.S.C. § 702), the Supreme Court has "read the exception in § 701(a)(2) quite narrowly," *Weyerhaeuser Co. v. U.S. Fish and Wildlife Serv.*, 139 S. Ct. 361, 370 (2018). An agency's decision not to institute enforcement proceedings in a given case, however, is "presumptively unreviewable." *Heckler v. Chaney*, 470 U.S. 821, 832 (1985).

In arguing that the withdrawal of CPG 400.400 was committed to agency discretion, the FDA relies exclusively on *Heckler v. Chaney*. In that case, a group of death row inmates petitioned the FDA to institute enforcement proceedings to prevent the "unapproved use of an approved drug" for executions by means of lethal injection. *Id.* at 823–24. The FDA refused. *Id.* at 824. In a letter responding to the inmates' request, the FDA Commissioner observed that the agency's jurisdiction over the use of drugs for human executions was unclear. *Id*. But even "[w]ere FDA clearly to have jurisdiction in the area," the Commissioner asserted, he would not exercise that authority pursuant to the agency's "inherent discretion to decline to pursue certain enforcement matters" because executions by lethal injection are "duly authorized statutory enactments in furtherance of proper State functions." *Id.* at 824–25.

The Supreme Court held that the APA precluded review of the Commissioner's decision and gave four reasons for the "general unsuitability for judicial review of agency decisions to refuse enforcement." *Id.* at 831. First, such decisions "often involve[] a complicated balancing

of a number of factors which are peculiarly within [the agency's] expertise," including the allocation of the agency's scarce enforcement resources and the ordering of the agency's enforcement priorities. *Id.* at 831–32. Second, "when an agency refuses to act it generally does not exercise its coercive power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." *Id*. at 832 (emphasis omitted). Third, unlike enforcement actions, which provide a "focus for judicial review," a failure to enforce is less likely to come with a built-in administrative record. *Id*. And fourth, an agency's decision not to enforce mirrors a prosecutor's decision not to bring charges, the latter of which has long been regarded as a matter of unreviewable discretion. *Id.*

In a footnote, the *Chaney* Court acknowledged possible exceptions to the rule that refusals to enforce are presumptively unreviewable. *Id.* at 833 n.4. First, a refusal to enforce might be reviewable when an agency premises the decision "solely on the belief that it lacks jurisdiction." *Id*. Second, judicial review might be appropriate if "the agency has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities." *Id.* (internal quotation marks omitted). But the Court ultimately "express[ed] no opinion on whether such decisions would be unreviewable." *Id*. In a concurrence, Justice Brennan rephrased the second possible exception as covering situations in which "an agency engages in a pattern of nonenforcement of clear statutory language." *Id*. at 839.

The FDA argues that its "setting of enforcement priorities" in CPG 400.400 "is unreviewable for the same reasons [*Chaney*] held that individual non-enforcement decisions are unreviewable." Dkt. 11-1 at 32. According to the FDA, a general enforcement policy involves the discretionary balancing of factors within the agency's expertise, just like an individual

decision not to enforce. *Id*. And the "FDA's decision to withdraw an enforcement policy is akin to changes in policy as to criminal prosecutorial discretion." *Id*. The FDA thus contends (1) that a general policy of non-enforcement is equally committed to an agency's discretion as an individual decision not to enforce and (2) that the withdrawal of a non-enforcement policy, which exposes regulated parties to enforcement, is just as unreviewable as the initiation of such a policy.

In response, MediNatura also relies almost exclusively on a single case—the Supreme Court's recent decision in *DHS v. Regents of the University of California*, which held that the Department of Homeland Security's rescission of the DACA program violated the APA. Dkt. 15 at 24–27. In that case, the government presented the same argument that the FDA advances here:

> The Government contends that a general non-enforcement policy is equivalent to the individual non-enforcement decision at issue in *Chaney*. In each case, the Government argues, the agency must balance factors peculiarly within its expertise, and does so in a manner akin to a criminal prosecutor. Building on that premise, the Government argues that the rescission of a non-enforcement policy is no different—for purposes of reviewability—from the adoption of that policy. While the rescission may lead to increased enforcement, it does not, by itself, constitute a particular enforcement action. Applying this logic to the facts here, the Government submits that DACA is a non-enforcement policy and that its rescission is therefore unreviewable.

Regents, 140 S. Ct. at 1906. The Supreme Court had no need to "test this chain of reasoning," however, because it determined that DACA was "not simply a non-enforcement policy." *Id*. Under the DACA program, the Department of Homeland Security had "solicited applications from eligible aliens, instituted a standardized review process, and sent formal notices indicating whether the alien would receive the two-year forbearance." *Id*. That made DACA less a generalized non-enforcement policy and more a system of individual adjudications. *Id*. And successful applicants received a tangible benefit—deferred action—that constituted "an

'affirmative act of approval,' the very opposite of a 'refus[al] to act.'" *Id.* (quoting *Chaney*, 470 U.S. at 831–32). Further, a grant of deferred action in the DACA program came with other attendant benefits, including work authorization and access to public benefits like Social Security and Medicare, which "provide[d] further confirmation" of the Supreme Court's conclusion that "DACA is more than simply a non-enforcement policy." *Id*. Indeed, "[u]nlike an agency's refusal to take requested enforcement action, access to these types of benefits is an interest 'courts often are called upon to protect.'" *Id.* (quoting *Chaney*, 470 U.S. at 832).

MediNatura argues that the rescission of CPG 400.400 was just like the rescission of DACA. Dkt. 15 at 24–27. MediNatura asserts that, like DACA, CPG 400.400 was "more than just a non-enforcement decision" because "it embodied a whole regulatory scheme for three decades." *Id.* at 25. And like DACA, "CPG 400.400 absolutely did confer benefits, and obligations, on the intended recipients." *Id.* With respect to benefits, CPG 400.400 permitted homeopathic drugs to be marketed in the United States without premarket approval. *Id*. And it also, MediNatura contends, lent regulatory legitimacy to homeopathic drugs, such that "physicians who prescribed homeopathic drugs and patients who used them could be assured that those drugs complied with the labeling requirements and were manufactured according to FDA's cGMPs." *Id.* Even more to the point, MediNatura argues that CPG 400.400 established "a detailed regulatory program" under which "[m]anufacturers [had to] comply with . . . requirements or be subject to enforcement action, just as DACA recipients needed to comply with administrative requirements to be eligible for relief." *Id*.

Although the Court is unpersuaded that either *Chaney* or *Regents* controls this case, the Court concludes that the withdrawal of CPG 400.400 is more akin to the withdrawal of DACA in *Regents* than to the non-enforcement decision at issue in *Chaney*. Given the strong presumption

in favor of review and the Supreme Court's narrow reading of Section 701(a)(2), the Court holds that the rescission of the policy was not committed to agency discretion by law for the following reasons.

To start, *Chaney* is distinguishable with respect to two key links in the "chain of reasoning" required to get from the holding of that case to the FDA's position here. *Regents*, 140 S. Ct. at 1906. The FDA argues both that a general non-enforcement policy is no more reviewable than an individualized non-enforcement policy and that the rescission of a non-enforcement policy is no more reviewable than the issuance of that policy. Although the Supreme Court left both questions unanswered in *Regents*, with respect to the first, the D.C. Circuit has held that at least some general non-enforcement policies are reviewable. *See OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812 (D.C. Cir. 1998); *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676–77 (D.C. Cir. 1994); *see also Kenney v. Glickman*, 96 F.3d 1118, 1123 (8th Cir. 1996). And, with respect to the second, the rescission of a three-decade-old non-enforcement policy implicates the agency's "coercive power over an individual's . . . property rights" in a manner that the exercise of prosecutorial discretion does not. *Chaney*, 470 U.S. at 832 (emphasis omitted).

In *Crowley*, the D.C. Circuit denied review of a "single-shot non-enforcement decision," but in so doing, the court of appeals distinguished prior cases which it read as holding that "an agency's statement of a general enforcement policy may be reviewable." *Crowley*, 37 F.3d at 676 (emphasis omitted). The court explained why the justifications for withholding review of individual non-enforcement decisions, as expressed in *Chaney*, do not apply to general non-enforcement policies. *Id.* at 677. First, "[b]y definition, expressions of broad enforcement policies are abstracted from the particular combinations of facts the agency would encounter in

individual enforcement proceedings" and "are more likely to be direct interpretations of the commands of the substantive statute." *Id*. Such general policies therefore are less likely to involve the "mingled assessments of fact, policy, and law" that *Chaney* recognized as particularly suited to an agency's expertise and discretion. *Id*. Next, "an agency's pronouncement of a broad policy against enforcement poses special risks that it 'has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities.'" *Id.* (quoting *Chaney*, 470 U.S. at 833 n.4). Finally, with respect to whether the agency's action provides a focus for review, the *Crowley* court observed that "an agency will generally present a clearer (and more easily reviewable) statement of its reasons for acting when formally articulating a broadly applicable enforcement policy, whereas such statements in the context of individual decisions to forego enforcement tend to be cursory, ad hoc, or post hoc." *Id*.

The D.C. Circuit had occasion to apply this distinction between individual non-enforcement decisions and general non-enforcement policies in *OSG Bulk Ships*. In that case, the court of appeals considered a challenge to a policy of the Maritime Administration that permitted certain vessels, which were built using government subsidies and are limited to service in foreign trade, to "enter domestic trade after the statutorily defined economic life of the vessel expires." *OSG Bulk Ships*, 132 F.3d at 809. The court made quick work of the Maritime Administration's argument that the APA precluded judicial review, holding unequivocally that "an agency's adoption of a general enforcement policy is subject to review." *Id.* at 812.

Reading these passages expansively, one could understand *Crowley* and *OSG Bulk Ships* as establishing that generalized non-enforcement policies are *always* reviewable, notwithstanding *Chaney*. Such a broad rule would likely suffice to show that the rescission of CPG 400.400 is

subject to review. But *Crowley* and *OSG Bulk Ships* are also susceptible to a narrower reading, as adopted by this Court in the DACA litigation, because both cases "involved nonenforcement decisions based solely on agency statutory interpretation." *NAACP*, 298 F. Supp. 3d at 231. The court in *Crowley* observed, for example, that review of generalized non-enforcement policies is appropriate, in part, because such policies "are more likely to be direct interpretations of the commands of the substantive statute." 37 F.3d at 677. Generalized non-enforcement policies that are premised on interpretation of a statute, moreover, fit more neatly within one of the exceptions recognized in *Chaney* itself—situations in which an agency bases its refusal to initiate enforcement "solely on the belief that it lacks jurisdiction." 470 U.S. at 833 n.4. Because the non-enforcement policy at issue in CPG 400.400 was at least arguably less tied to statutory interpretation than those at issue in *Crowley* and *OSG Bulk Ships*, the Court will look to the factors underlying the *Chaney* decision, as the D.C. Circuit did in *Crowley*, to determine whether *Chaney*'s reasoning precludes judicial review in this case.

As noted above, *Chaney* held that non-enforcement decisions are unreviewable for four reasons. 470 U.S. at 832. The generalized nature of CPG 400.400 undermines at least the first and third of those considerations. First, the Supreme Court in *Chaney* observed that individual non-enforcement policies "often involve[] a complicated balancing of a number of factors which are peculiarly within its expertise." *Id.* at 831. Such factors include "whether a violation has occurred, . . . whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all." *Id*. As a broadly applicable, prospective policy, CPG 400.400 did not involve case-by-case factual considerations with respect to whether a violation occurred in a particular

circumstance, whether the agency would succeed in an action against that violation, or whether "the particular enforcement action" fits the agency's priorities. Indeed, as explained further below, the Policy marked a shift from the agency's non-regulation of the homeopathic drug industry to a partial regulatory regime that "delineate[d] those conditions under which homeopathic drugs may ordinarily be marketed in the U.S." Dkt. 1 at 29 (Ex. A). As such, CPG 400.400 was about far more than how to preserve or allocate scarce enforcement resources; it represented a decades-long compromise designed to induce homeopathic drug manufacturers to submit to regulation of their labeling, manufacturing practices, and the like in exchange for the FDA's affirmation that those manufacturers could "ordinarily" market their products in the United States.

To be sure, that compromise turned on the FDA's policy judgment and, presumably, its assessment of the relative risks posed by homeopathic drugs. But that type of policy judgment is different from the typical exercise of prosecutorial discretion, and the broader policy considerations at issue are better suited to judicial review than the fact-bound considerations that typically underlie the decision not to enforce in an individual case. The fact that the agency's judgment was policy-based, moreover, does not preclude judicial review; to the contrary, the APA often requires courts to review agency policy decisions for rationality.
5 U.S.C. § 706(2)(A); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *Nat'l Tire Dealers & Retreaders Ass'n, Inc. v. Brinegar*, 491 F.2d 31, 35 (D.C. Cir. 1974); *see also Massachusetts v. E.P.A.*, 549 U.S. 497, 533–34 (2007). The first factor in *Chaney*, accordingly, does not support the FDA's argument that its decision to withdraw the Policy was committed to agency discretion.

The general nature of CPG 400.400 is also relevant to the third factor—whether the non-enforcement action "provides a focus for judicial review." 470 U.S. at 832. Here, this factor weighs in favor of reviewability. Although an agency's decision not to bring an enforcement action in an individual case often produces no record of any kind, both the issuance and withdrawal of CPG 400.400 came with substantial documentation. CPG 400.400 is a seven-page document with "Background," "Discussion," "Policy," and even "Definitions" sections. See Dkt. 1 at 29–35 (Ex. A). When the FDA rescinded the policy, it explained that decision in the Federal Register, *see* 84 Fed. Reg. 57,439, and in a 15-page letter denying a citizen petition from Americans for Homeopathy Choice, *see* Dkt. 11-14 (Ex. L), which the FDA itself contends should be part of the administrative record in this case, Dkt. 11-1 at 38–39. These documents are neither cursory nor ad hoc; the withdrawal notice includes substantial, detailed legal and policy analysis, review of which is well within a court's competency in applying the APA. The legal reasoning and policy judgments expressed in those documents create a focus for judicial review. The third consideration supporting the Supreme Court's holding in *Chaney* therefore does not apply to the rescission of CPG 400.400. The Policy's general nature therefore distinguishes it from the individualized non-enforcement decision at issue in *Chaney*, at least with respect to the first and third factors supporting that decision.

Consideration of the second and fourth factors addressed in *Chaney*, meanwhile, undermines the other link in the FDA's chain of reasoning—that withdrawal of a non-enforcement policy is just as unreviewable as the original promulgation of such a policy. *Chaney* noted (1) that "when an agency refuses to act it generally does not exercise its coercive power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect" and (2) "that an agency's refusal to institute proceedings

shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch." 470 U.S. at 832 (emphasis omitted). In analyzing these two factors, the lower courts in the DACA litigation were split on the question of whether the rule established in *Chaney* applies to the rescission of non-enforcement policies (a question the Supreme Court did not reach). In the *NAACP* case, this Court found "unpersuasive" the challengers' argument based on a distinction between the issuance and withdrawal of a non-enforcement policy. *NAACP*, 298 F. Supp. 3d at 230. Observing that "the rescission of DACA does not actually require the Department to initiate removal proceedings against any specific alien" and that "an agency's decision to revoke a nonenforcement policy involves the same prioritization and resource-allocation considerations as its decision to implement such a policy," the Court had "little difficulty concluding that *Chaney* extends to the revocation of nonenforcement decisions." *Id.* at 230–31.

The Eastern District of New York, however, disagreed. *See Batalla Vidal*, 295 F. Supp. 3d at 149–50. The decision to rescind DACA was unlike the decision to institute a non-enforcement policy, that court held, because withdrawal "curtails (if it does not eliminate outright) DHS's ability to exercise prosecutorial discretion with respect to individuals previously eligible to request deferred action." *Id*. *Chaney*'s analogy to a prosecutor's discretion not to bring charges in a given case thus breaks down where "the rescission of the DACA program subjects individuals who previously enjoyed some protection from removal to coercive state authority." *Id.* at 150. The Ninth Circuit in reviewing the DACA rescission did not reach this question but did observe in a footnote that "a literal reading of *Chaney*'s language would not even encompass the decision to rescind DACA, since *Chaney* by its own terms applies only to

'agency decisions not to undertake enforcement action.'" *Regents I*, 908 F.3d at 499 n.13 (emphasis omitted) (quoting *Chaney*, 470 U.S. at 832). "Nowhere does the [*Chaney*] opinion suggest the broader proposition that any decision simply related to enforcement should be presumed unreviewable." *Id*.

Here, MediNatura's lawsuit is the opposite of a challenge to a non-enforcement policy. MediNatura sues to stop the withdrawal of such a policy, and that withdrawal, if anything, makes enforcement more likely. Furthermore, given that CPG 400.400 imposed requirements on companies in exchange for forbearance—including inspections by the FDA of homeopathic drug manufacturing facilities, *see* Dkt. 15 at 13—the analogy to a prosecutor's decision not to bring charges is strained. The FDA argues that both the issuance of CPG 400.400 and its withdrawal "involve choices of which [FFDCA] violations to prioritize, and those choices rest on a complicated balancing of factors within FDA's expertise, including determining how the agency's resources are best spent in light of its overall priorities." Dkt. 11-1 at 32 (internal quotation marks omitted). But even assuming that the FDA's decision was based (at least in part) on these considerations, the agency still fails to address whether its rescission of a thirty-year-old policy that "ordinarily" allowed manufacturers to market homeopathic drugs, subject to the conditions specified in CPG 400.400—without a replacement policy or any similar assurances in place—represented the agency's exercise of "its coercive power over an individual's liberty or property rights," *Chaney*, 470 U.S. at 832 (emphasis omitted). It would be difficult to fault a manufacturer for viewing this action as an exercise of the FDA's "coercive power," not at all akin to a decision whether to initiate a prosecution in a particular case. The reasoning of *Chaney* with respect to these factors, therefore, is not controlling.

Stepping back for a moment, it is not clear that CPG 400.400 is best characterized as a non-enforcement policy at all. Total non-enforcement against homeopathic drugs was the status quo at the time CPG 400.400 was instituted. The change that the Policy made in the regulatory landscape was to bring the industry into partial compliance with the FFDCA with respect to labeling, manufacturing, and registration, in exchange for reducing the agency's non-enforcement policy to writing. As Michels put it, CPG 400.400 "enhanced FDA's ability to take regulatory action when necessary, against products containing or alleged to contain homeopathic ingredients" by establishing a "line in the sand" beyond which "outliers" would face enforcement action. *Hearing on Homeopathic Product Regulation* at 270. As such, CPG 400.400 was as much an enforcement decision as a non-enforcement decision. *Chaney* is therefore distinguishable at every step of the analysis.

Regents is not a perfect fit for the facts of this case, either, but the rescission of DACA provides a closer analogy to the withdrawal of CPG 400.400. The Supreme Court rested its holding that the DACA rescission was reviewable on the program's provision of affirmative immigration benefits, which the agency distributed through a process resembling individual adjudications. *Regents*, 140 S. Ct. at 1906. And the Court found additional support for its reviewability holding in the additional benefits attendant to a grant of deferred action, such as eligibility for Social Security and Medicare. *Id*. The distinction between the absence of disapproval and the presence of approval is a slippery one, but CPG 400.400 provided at least some affirmative benefits to homeopathic drug companies. Principally, the Policy gave companies peace of mind that if they complied with the labeling, manufacturing, and registration requirements (and marketed their homeopathic products for traditional uses), they would not be subject to enforcement actions despite their lack of premarket approval. And that lack of

enforcement came with attendant benefits, although none as concrete as eligibility for Social Security. By complying with CPG 400.400, homeopathic drug companies enjoyed a level of FDA imprimatur. Although their products were not FDA approved, they could warrant to customers that their products complied with FDA labeling and manufacturing requirements, signaling some measure of their safety. The FDA's inspections of homeopathic drug production facilities, through CPG 400.400 and the current Good Manufacturing Practices program, Dkt. 1 at 16 (Compl. ¶ 57); *id*. at 34 (Ex. A), for example, gave homeopathic drug companies the sheen of legitimacy. (And those inspections, by the way, bear a resemblance to individual adjudications, to draw one more parallel with the *Regents* decision.) In short, CPG 400.400 was a closer cousin to the broad regulatory scheme at issue in *Regents* than the decision not to bring a particular enforcement action in *Chaney*.

The parties have each rested their hopes on a single Supreme Court case, and the facts of this case fall somewhere in between. But for the reasons explained above, the Court is satisfied that the withdrawal of CPG 400.400 was not committed to agency discretion by law, especially in light of how narrowly the Supreme Court has read Section 701(a)(2). The FDA's motion to dismiss with respect to MediNatura's first claim is therefore denied.

2. *Counts II & III: Addition of MediNatura's Products to the Import Alert*

MediNatura's second and third claims both challenge the FDA's addition of its six injectable products to the Import Alert. MediNatura argues that the Import Alert was procedurally invalid for failing to comply with the APA's notice-and-comment requirements, Dkt. 5-1 at 35–39, and substantively invalid for arbitrarily determining that MediNatura's products are unsafe, *id.* at 39–42. The FDA moves to dismiss these claims on the ground that the Import Alert does not constitute a final agency action, rendering these claims unfit for judicial

review and barred by the APA. Dkt. 11-1 at 27–29. Applying the two-part test for final agency action under the APA, the FDA argues that the Import Alert "did not represent the consummation of FDA's decisionmaking process, and it did not determine MediNatura's rights or obligations or have legal consequences." *Id.* at 27 (citing *Bennett*, 520 U.S. at 177–78). The FDA argues that the Import Alert provides only "non-binding guidance" to FDA field offices for determining which products to detain. *Id*. And even if the Import Alert were binding, it is only interlocutory, because detention is an interim step that leads to a hearing before a final decision on admissibility. *Id.* at 27–28.

MediNatura responds that "given FDA's unequivocal statement that MediNatura's injectable products are unapproved new drugs, there is no indication that FDA district offices would view themselves as free to allow shipments of those products." Dkt. 15 at 16. The company asserts that contesting the detention of its productions would be futile. *Id.* at 18. And the Import Alert, accordingly, has legal consequences for MediNatura because the agency "reached the end of its decision-making process," *id.* at 18, and "nothing is gained by waiting for further administrative process," *id.* at 19.

The Court agrees with the FDA that the Import Alert is not final agency action. First, the Import Alert does not represent the culmination of the agency's decision-making process. The placement of a product on the Import Alert must be followed by two additional steps—detention and final refusal of admission—during which the agency's position remains unsettled. Although MediNatura cites to a press release in which the FDA expressed its plans to "stop these drugs from entering the U.S.," Dkt. 15 at 18 (emphasis omitted), the Court is unconvinced, on the record before it, that the FDA is so set in its position about the safety of MediNatura's products that it would be unwilling to consider arguments to the contrary. MediNatura has

presented substantial evidence to the Court about the safety of its products (although comparatively little information about their effectiveness), and it can present that same evidence to the FDA in a hearing challenging the detention of its shipment to Houston. Dkt. 25-1 at 1–2 (Clive Decl. ¶¶ 5–10).

MediNatura relies on *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 68 n.7 (D.D.C. 2010), for the proposition that "further resort to the administrative process would be futile," but that case is inapposite. The Plaintiffs in *Smoking Everywhere, Inc*. were two makers of electronic cigarettes, Smoking Everywhere and NJOY. *Id.* at 65–66. At the time of the suit, Smoking Everywhere's products had already been refused admission, while NJOY's had only been detained. *Id.* The Court held that the detention of NJOY's products was final agency action because there was "no reason to believe that FDA would treat NJOY's products any differently than Smoking Everywhere's products" and because "FDA has already refused entry to as many as thirty-five shipments of electronic cigarettes from twenty manufacturers." *Id.* at 68 n.7. MediNatura has not presented any evidence that the FDA has already made a final decision to refuse admission to any of its own products or those of its competitors, and the Court has no basis to conclude that the FDA's decision to exclude MediNatura's products is set in stone, especially given that the agency allowed the company's shipment to Los Angeles to proceed. Dkt. 25-1 at 1–2 (Clive Decl. ¶¶ 5–10).

Nor does the Supreme Court's decision in *Army Corps of Engineers v. Hawkes Co.*, 136 S. Ct. 1807, 1814 (2016), require a different result. In *Hawkes*, the Supreme Court held that an interlocutory administrative decision may nevertheless count as final agency action when it has immediate legal consequences. *Id*. The case involved a Jurisdictional Determination ("JD") as to whether property constituted waters of the United States for purposes of the Clean Water Act.

Id. at 1811. A negative JD granted a five-year safe harbor from civil enforcement proceedings. *Id.* at 1814. A positive JD did not carry immediate penalties, which depended on later enforcement action, but the Supreme Court concluded that a positive JD was nevertheless final agency action because the denial of a safe harbor is a legal consequence. *Id*. Here, in contrast, placement on the Import Alert does not carry immediate legal consequences. FDA field agents are empowered to inspect and to detain drugs even if they do not appear on the Import Alert, and they are also free to allow drugs listed on the Import Alert to proceed if the circumstances warrant.

The Court also agrees with the FDA, on the second prong of the *Bennett* test, that the Import Alert is non-binding and therefore does not determine legal rights or obligations. As explained above, in considering whether agency "guidance" documents have legal consequences, courts look to both the language of the document and how the document is applied in practice. Here, both factors indicate that the Import Alert is non-binding. The Import Alert states that it "does not operate to bind [the] FDA" but, rather, instructs FDA field offices on which drugs "should be considered for detention without physical examination." Dkt. 1 at 216 (Ex. J). This differs from the Import Alert at issue in *Bellarno International Ltd. v. FDA*, 678 F. Supp. 410, 415 (E.D.N.Y. 1988), on which MediNatura relies. That Import Alert used mandatory language, providing that products would be detained "automatically," without any qualification, and using "'shall' rather than 'may.'" *Id*. As for how the Import Alert is implemented in practice, MediNatura's experience since filing its motion for preliminary injunction undercuts its own argument. The company ordered two shipments of 4,800 vials of its Engystol product. Dkt. 25-1 at 1 (Clive Decl. ¶¶ 4–5). One shipment was allowed to proceed into the country, while the other was detained. *Id*. at 1–2 (Clive Decl. ¶¶ 5–10). The Court concludes that the

Import Alert does not carry immediate legal consequences and thus does not constitute final agency action.

MediNatura therefore lacks a cause of action under the APA to challenge the Import Alert, and the Court will, accordingly, dismiss Counts II and III.

3. *Count IV: Failure to Create Separate Approval Process for Homeopathic Drugs*

The Court need not linger long over the FDA's motion to dismiss MediNatura's fourth claim, which alleges that the agency acted in an arbitrary and capricious manner by failing to consider whether homeopathic drugs are GRAS/E and by failing to create an appropriate NDA process for homeopathic drugs. Dkt. 5-1 at 42–47.

The FDA moves to dismiss this claim on numerous grounds. First, the FDA argues that MediNatura cannot force it to create a pathway to premarket approval for homeopathic drugs. Dkt.11-1 at 30. As the FDA points out, the APA permits a court to "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1), only when the action in question is a discrete duty that the agency was lawfully required to take, Dkt. 11-1 at 30 (citing *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004)). And the FDA argues it has no statutory duty—nor even statutory authority—to make special accommodations for homeopathic drugs. *Id*. Second, the FDA argues that MediNatura does not have standing to bring this claim. *Id.* at 33. By asking that the Court enjoin only (1) the rescission of CPG 400.400 and (2) the addition of MediNatura's products to the Import Alert, MediNatura "does not ask this Court for relief that would likely redress this alleged injury," given that neither requested remedy would create a pathway to premarket approval for homeopathic drugs. *Id.* Finally, the FDA argues that, insofar as MediNatura seeks a determination that its injectable products are GRAS/E, the

company has "not exhausted its administrative remedies," because it neglected to "file a citizen petition requesting that FDA determine whether its injectable drugs are GRAS/E." *Id.* at 34.

In opposing the motion to dismiss, MediNatura contends that the FDA "misconstrues" its fourth claim, which it frames as alleging that the "FDA's actions were arbitrary because it withdrew CPG 400.400 and issued the Import Alert without using its existing authority under the FFDCA to allow a realistic way for homeopathic drugs to continue to be marketed in the United States." Dkt. 15 at 36–37. As such, MediNatura's fourth claim is not, in fact, a separate *claim*; instead, it merely offers a separate *reason* that the withdrawal of CPG 400.400 (and issuance of the Import Alert) was arbitrary and capricious. That is, MediNatura alleges that the withdrawal of CPG 400.400 violated the APA not only because the agency failed adequately to consider reliance interests, but also because the agency failed to consider possible alternatives. Based on this clarification, the Court will dismiss Count IV on the ground that it does not state a separate claim but will consider MediNatura's argument that the agency should have considered alternative accommodations for homeopathic drugs in the context of the company's challenge to the rescission of CPG 400.400 in Count I.

Accordingly, the Court will deny the FDA's motion to dismiss as to Count I and grant the motion to dismiss as to Counts II, III, and IV.

B. Preliminary Injunction

The Court next considers MediNatura's motion for a preliminary injunction. Dkt. 5. As explained above, a party seeking a preliminary injunction "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter*, 555 U.S. at 20. On the present record, the Court is unpersuaded that

MediNatura has shown that it is entitled to the "extraordinary remedy" of a preliminary injunction. *Id.* at 24.

1. *Likelihood of Success on the Merits*

To start, MediNatura cannot show a likelihood of success on the merits on Claims II, III, and IV, given the Court's decision on the FDA's motion to dismiss. The Court "has not only already concluded that [MediNatura] is unlikely to prevail on the merits" of those claims but has already rejected the claims on the merits. *Amgen Inc. v. Azar*, No. 17-1006 (RDM), 2018 WL 1990521, at *1 (D.D.C. Feb. 22, 2018) (internal quotation marks omitted); *see also Nat'l Ass'n for Fixed Annuities v. Perez*, 219 F. Supp. 3d 10, 13–14 (D.D.C. 2016) (When "the Court has already held that [the movant's] challenges fail on the merits," the movant "faces a particularly heavy burden" in seeking preliminary relief).

That leaves Count I. Although framed in different ways, MediNatura's challenges to the FDA's withdrawal of CPG 400.400 all posit that the agency acted precipitously.
First, MediNatura alleges that the FDA failed to consider adequately the reliance interests of manufacturers, prescribers, and consumers of homeopathic drugs. Dkt. 5-1 at 31. The company maintains that it has made substantial investments both to comply with CPG 400.400 and to expand its business, all on the assumption that the Policy would shield it from enforcement action. *Id.* at 31–32. But the FDA, according to MediNatura, completely failed to address those reliance interests in its withdrawal of CPG 400.400. *Id.* at 32–33. Second, MediNatura argues that the FDA failed to consider alternatives to an abrupt end to thirty years of non-enforcement of the FFDCA's premarket approval requirements. *Id.* at 34, 42–47. MediNatura maintains, for example, that the FDA could have created an alternative NDA process for homeopathic drugs, could have devised a specific procedure for recognizing homeopathic drugs as GRAS/E, or could

have at least provided some adjustment period for homeopathic drug manufacturers to come into compliance with the agency's new policy, rather than suddenly withdrawing the old policy before the new one was ready. *Id.* at 34–35.

The FDA responds that it was not required to consider any reliance that CPG 400.400 may have engendered because any such reliance was premised on the "simply wrong" notion that CPG 400.400 conferred lawful status on homeopathic drugs or exempted them from the FFDCA's premarket approval requirements. Dkt. 11-1 at 37. And even if the FDA had been required to consider reliance interests, it did so adequately in a letter responding to the citizen petition from Americans for Homeopathy Choice, which the agency issued at the same time as the CPG 400.400 withdrawal. *Id.* at 38. With respect to alternatives, the FDA sings a similar tune, arguing that the FFDCA does not grant the agency discretion to give homeopathic drug producers any special treatment, and "an agency need not consider policy alternatives that are beyond the scope of the agency's authority to implement in the first place." *Id.* at 39.

Both of MediNatura's contentions have some merit, but they overstate what the FDA has done, what it failed to do, and what it is permitted to do. The Court addresses reliance interests and alternatives in turn.

a. Failure to Consider Reliance Interests

MediNatura claims that CPG 400.400 engendered substantial reliance interests. For instance, "MediNatura has worked to develop significant importing, manufacturing, and distribution infrastructure to meet the increasing demand for homeopathic drug products, including homeopathic injectable products." Dkt. 5-1 at 31. The company has also made investments to come into compliance with the Policy's labeling, manufacturing, and registration requirements. *Id.* at 31–32. And not only homeopathic drug companies but also their customers

relied on the Policy: "Medical practitioners and patients also have come to rely on MediNatura's products to manage pain and other symptoms safely." *Id.* at 32.

An agency that "changes course" must "'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account,'" *Regents*, 140 S. Ct. at 1913 (quoting *Encino Motorcars, LLC v. Navarro,* 136 S. Ct. 2117, 2126 (2016)) (additional internal quotation marks omitted). "In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *FCC. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009). An agency changing policies must therefore "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 140 S. Ct. at 1915. "It would be arbitrary and capricious to ignore such matters." *Id.* at 1913 (internal quotation marks omitted).

The FDA's contention that it "was not required to consider MediNatura's alleged reliance interests because they were not reasonably incurred" is unpersuasive. Dkt. 11-1 at 37. The agency argues that because it lacks authority to exempt homeopathic drugs from the FFDCA's premarket approval requirements, MediNatura's "understanding that [CPG 400.400] permitted MediNatura to distribute its unapproved injectable drugs in violation of the [FFDCA] . . . is simply wrong." *Id*. This amounts to another version of the argument that the Court rejected above in denying the FDA's motion to dismiss as to Count I. Regardless of the scope of the FDA's statutory authority, CPG 400.400 did permit the sale of millions of unapproved homeopathic drugs over a thirty-year period, and MediNatura was justified in taking the agency

at its word when it said that CPG 400.400 set out "conditions under which homeopathic drugs may ordinarily be marketed in the U.S." Dkt. 1 at 29 (Ex. A).

The Supreme Court in *Regents* considered and rejected an argument like the one the FDA presses here. In that case, the government argued that it did not need to consider reliance interests because DACA recipients' reliance on that program was not "legally cognizable." 140 S. Ct. at 1913. The government premised this argument on the DACA Memorandum's statement that the program "conferred no substantive rights" and DHS's subsequent determination that the benefits provided by the program were unlawful. *Id.* at 1913–14. The Supreme Court held that the policy's "disclaimers" about its lack of binding effect "are surely pertinent in considering the strength of any reliance interests, but that consideration must be undertaken by the agency in the first instance, subject to normal APA review." *Id*. Further, the agency was free to "conclude that reliance interests in benefits that it views as unlawful are entitled to no or diminished weight." *Id.* at 1914. But *considering* the alleged reliance interests and whether they were reasonable "was the agency's job," and "the agency failed to do it." *Id*.

The FDA's citation to *Solenex, LLC v. Bernhardt*, 962 F.3d 520, 529 (D.C. Cir. 2020), does not require a different result. The Court in that case held that the plaintiff did not have any reliance interests based on the unique facts of the case, but first emphasized that "the reliance interests that [the plaintiff] flag[ged] were, in fact, specifically considered and addressed by the [agency]." *Id*. The D.C. Circuit's opinion in *Solenex* is thus consistent with the Supreme Court's decision in *Regents*. When an agency changes policy, it must consider any alleged reliance interests, even if it ultimately finds that the asserted reliance interests are weak or outweighed by other factors.

That brings the Court to the FDA's alternative argument—that its consideration of reliance interests was sufficient. "Deciding whether agency action was adequately explained requires, first, knowing where to look for the agency's explanation." *Regents*, 140 S. Ct. at 1907. Although the FDA did not address reliance interests in its memorandum withdrawing CPG 400.400, the agency did consider reliance interests (albeit briefly) in its response to the citizen petition from Americans for Homeopathy Choice. Dkt. 11-14 at 15–16 (Ex. L). As a general matter, a court would not look for an agency's explanation of one administrative action in its decision explaining a separate action. The record suggests, however, that the FDA treated the Federal Register notice rescinding the Policy and its response to the citizen petition as interrelated parts of a single administrative action. The FDA issued its response to the citizen petition, Dkt. 11-14 (Ex. L), on October 24, 2019, one day before the agency published its withdrawal of CPG 400.400, 84 Fed. Reg. 57,439. The nearly simultaneous issuance of the two documents eliminates any possible concern that the more fulsome explanation in the citizen petition response might represent an impermissible "*post hoc* rationalization." *Regents*, 140 S. Ct. at 1908 (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)). The response to the citizen petition, moreover, directly addresses the decision to withdraw CPG 400.400 and evinces the FDA's intention that its consideration of the petition go hand in hand with the rescission. *See* Dkt. 11-14 at 5 (Ex. L) ("FDA believes that it is appropriate to withdraw CPG 400.400 at this time, rather than waiting for the issuance of the final guidance."). An internal FDA memorandum addressing safety concerns related to homeopathic drugs, sent on October 22, 2019, confirms this understanding. Dkt. 11-12 (Ex. J). The memorandum explains that "[a]s part of [the] process" of withdrawing CPG 400.400 and replacing it with a risk-based approach, the "FDA has also taken into consideration the citizen

petition filed by Americans for Homeopathy Choice," Dkt. 11-12 at 3 (Ex. J). The memorandum also expresses the FDA's intention to "respond to the Petition simultaneous with withdrawal of CPG 400.400." *Id*. The citizen petition response, accordingly, is likely part of the administrative record for the withdrawal of CPG 400.400.

In its response to the citizen petition, the FDA includes a section titled "Alleged Reliance on CPG 400.400," which acknowledges the concern raised by the homeopathic drug industry about its thirty years of reliance on CPG 400.400 and briefly addresses that concern. Dkt. 11-14 at 15-16 (Ex. L). The response starts by taking issue yet again with the premise that withdrawing CPG 400.400 "represents a change in the legal obligations that apply to homeopathic drugs under the statutes FDA administers." *Id.* at 15. As the FDA explains, it "does not have authority to exempt a product or class of products that are new drugs from the new drug approval requirements." *Id.* Rather, CPG 400.400 "merely described an enforcement policy regarding homeopathic drug products," and thus the withdrawal of the Policy did not, in the FDA's view, "represent a change in the legal status of homeopathic drug products." *Id.* As explained above, the Court is unpersuaded by this argument. Regardless of the scope of the FDA's statutory authority, CPG 400.400 permitted unapproved homeopathic drugs, in the ordinary course, to be sold in the United States, and the industry did in fact rely on that regulatory framework—at its peril, as things have turned out. Even in withdrawing a non-enforcement program that arguably conflicts with statutory directives, an agency must explain its "policy choices." *Regents*, 140 S. Ct. at 1910.

The FDA does explain its rationale, at least briefly. After noting that the FFDCA requires premarket approval for all new drugs and that no homeopathic drug has cleared that hurdle, the FDA goes on to conclude that there was "substantial justification" for overriding the

interests of those "homeopathic professionals . . . or consumers [who] may have relied on the prior enforcement policy." Dkt. 11-14 at 15 (Ex. L). The agency then identifies four considerations that outweighed the industry's reliance interests and, in the FDA's view, necessitate immediate withdrawal of CPG 400.400:

> (1) the fact that the [FFDCA] and [Public Health Service] Act include premarket review and approval requirements from which homeopathic drug products are not exempt . . . ; (2) the recent growth of safety concerns associated with homeopathic drug products (including concerns regarding products associated with serious adverse events and otherwise presenting significant safety risks and egregious violations of CGMP requirements); (3) the continued expansion of the homeopathic industry since issuance of CPG 400.400, resulting in an increasing number of consumer exposures; and (4) the agency's interest in its general risk-based approach to enforcement.

Id. at 15–16 (Ex. L). The first of these considerations adds little, if anything, to the FDA's observation that it lacks statutory authority to exempt homeopathic drugs from the dictates of the FFDCA, and the Court need not explain why that argument is unavailing for the fourth time in this opinion. The remaining considerations, in contrast, are material. The agency's brief discussion of those issues, moreover, must be understood in the context of its much more extensive analysis of each factor in the earlier sections of the petition response and in the notice withdrawing CPG 400.400.

MediNatura argues that the agency's safety concerns are misplaced with respect to its products, given their track record of safety. But CPG 400.400 did not apply only to MediNatura; it applied to every homeopathic drug company. And when directed at the industry as a whole, the FDA's safety concerns and attendant interest in moving to a risk-based approach are compelling. In the withdrawal notice, the FDA focuses primarily on two examples of safety concerns associated with homeopathic drugs, which together affected fewer than 250 people. 84 Fed. Reg. at 57,440. But those incidents had serious consequences, including "infant deaths"

and the "loss of the sense of smell." *Id*. And the FDA contends that these are "only two examples among many." *Id*. Where the public health is concerned, the Court owes the FDA's scientific and medical judgment great deference.

The Supreme Court precedent requiring the consideration of reliance interests before agencies shift policies, moreover, does not set a high bar. The agency in *Regents* failed to consider reliance interests at all, 140 S. Ct. at 1913–15, and in *Encino Motorcars*, the agency's change in policy could not overcome significant reliance interests where it "gave almost no reasons at all" justifying its new policy, 136 S. Ct. at 2126–27. Albeit in somewhat cursory fashion, the FDA here "assess[ed] whether there were reliance interests, determine[d] whether they were significant, and weigh[ed] any such interests against competing policy concerns." *Regents*, 140 S. Ct. at 1915. MediNatura has not shown a likelihood of success on this question.

b. Failure to Consider Alternatives

MediNatura also argues that the FDA did not adequately consider alternatives to the withdrawal of CPG 400.400. In the company's view, the FDA "could have instead created an NDA pathway for approval of homeopathic drugs" that would take into consideration "Congress's intent to regulate these products differently from" traditional medicine, "FDA's own determination regarding the uniqueness of these products," and "evidence by experts in the field of homeopathy." Dkt. 5-1 at 34. Or the FDA "could have created a process that would review the [GRAS/E] status of drugs like MediNatura's that would consider the same types of homeopathic evidence." *Id*. Or finally, the FDA could have "provided an adequate period of time for MediNatura and other homeopathic drug manufacturers and distributors to adjust and comply before banning importation of homeopathic injectable drugs that have been safely and widely used in this country for decades." *Id*. at 34–35.

In order to make rational decisions, agencies must keep in mind options other than their chosen course. But an agency is not required to "consider all policy alternatives," *State Farm*, 463 U.S. at 51, or "every alternative device and thought conceivable by the mind of man," *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 551 (1978). Rather, it must consider alternatives that are "within the ambit of the existing standard." *State Farm*, 463 U.S. at 51. Thus, in *State Farm*, the agency could not scrap an automatic-seatbelts-plus-airbags rule on the basis that the automatic seatbelts did not work, without first considering an airbags-only option. *Id*. Likewise, in *Regents*, the agency could not withdraw a forbearance-plus-benefits policy on the basis that the benefits were unlawful, without first considering a forbearance-only option. 140 S. Ct. at 1912.

MediNatura's first two suggestions for the FDA—that it create NDA or GRAS/E processes specifically tailored to homeopathic drugs—are not within the ambit of the existing policy. They are the equivalent of asking the agency in *Regents* to grant amnesty to every DACA recipient or the agency in *State Farm* to require manufacturers to install speed governors on all new cars. The FDA argues (without persuasive rebuttal) that it does not have statutory authority to tailor its premarket approval procedures for homeopathic drugs. Dkt. 11-1 at 39. MediNatura's arguments seem premised on the notion that the agency must leave open some avenue for the legal marketing of homeopathic drugs, but if it is not possible for the industry to comply with the requirements of the FFDCA, that is a problem to take up with Congress.

MediNatura's third argument is stronger. The FDA did not provide any grace period for homeopathic drug companies to attempt to come into compliance with premarket approval requirements before rescinding the policy, and in fact withdrew CPG 400.400 earlier than planned, after initially proposing not to rescind it until the final replacement guidance was ready.

Dkt. 1 at 40 (Ex. B). But MediNatura's challenge to the abrupt withdrawal of the Policy, without an alternative policy tailormade to regulate homeopathic medicines in place, overstates what has happened. First, the FDA made clear that it was working toward withdrawing CPG 400.400 starting in 2015 or perhaps even earlier. *See* 80 Fed. Reg. 16,327. To the extent that homeopathic product manufacturers wanted to protect themselves from the possibility that the Policy would be withdrawn, they could have petitioned for GRAS/E status or filed an NDA in the years between the FDA's initial announcement of its intentions and the eventual withdrawal. As MediNatura itself admits, however, the NDA process is "prohibitively expensive" and "impossible" for homeopathic drugs. Dkt. 5-1 at 43. As such, it is unclear what a grace period, without any additional accommodations for homeopathic drugs, would accomplish.

Moreover, the FDA's change of policy in withdrawing CPG 400.400 in favor of a risk-based approach is not the sort of seismic shift for the homeopathic drug industry that MediNatura suggests. Before the FDA withdrew the policy, homeopathic drug manufacturers could "ordinarily" market their drugs without premarket approval—but the agency retained authority to address unusual risks or concerns. Dkt. 1 at 29 (Ex. A). Since withdrawing the Policy, the FDA has yet to launch an all-out offensive directed at homeopathic drugs. Although the agency has cast the net somewhat more broadly, it continues to focus on the drugs that it believes pose the greatest risk to the public. With respect to MediNatura's injectable products, the FDA prioritized enforcement because "drugs with routes of administration other than oral or topical, like injectables, are of higher risk." Dkt. 11-12 at 9–10 (Ex. J). Unlike drugs administered orally, which are filtered through the liver, or drugs administered topically, which are filtered through the skin, "injectable drugs are delivered directly into the bloodstream and bypass these types of natural defenses against toxic ingredients, toxins, or dangerous organisms that can lead to serious

and life-threatening conditions such as septicemia or sepsis." *Id*. Those safety concerns are unique to injectable drugs. As the FDA argues in its reply, although "MediNatura and its amici at various points suggest that the withdrawal of [CPG 400.400] threatens the entire homeopathic drug industry," that "suggestion dramatically exaggerates the stakes of [the] FDA's actions" because the agency "did not abandon a policy of enforcement discretion vis-à-vis homeopathic drugs." Dkt. 23 at 10 n.1. At least at this early stage of the litigation, MediNatura has not shown a likelihood of success on the merits of its claim that the FDA acted arbitrarily and capriciously by not considering alternatives to the withdrawal of CPG 400.400.

2. *Irreparable Injury*

"[A] showing that irreparable injury is 'likely' is the *sine qua non* for obtaining a preliminary injunction—it is what justifies the extraordinary remedy of granting relief before the parties have had the opportunity fully to develop the evidence and fully to present their respective cases." *Achagzai v. Broad. Bd. of Governors*, No. 14-768 (RDM), 2016 WL 471274, at *3 (D.D.C. Feb. 8, 2016); *see also Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) ("A movant's failure to show any irreparable harm is therefore grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief."); *Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 241–42 (D.D.C. 2014); *Trudeau v. FTC*, 384 F. Supp. 2d 281, 296–97 (D.D.C. 2005), *aff'd*, 456 F.3d 178 (D.C. Cir. 2006).

MediNatura alleges that it is likely to suffer irreparable harm in three ways. First, MediNatura argues that because it cannot obtain money damages from the FDA, an injunction is the only possible remedy for the economic losses the company will suffer if it is unable to import its products. Dkt. 5-1 at 47–48. Second, the detention of MediNatura's products would

"threaten the viability of MediNatura's business" because its imported injectable drugs represent roughly 40% of the company's revenue. *Id.* at 48. And third, the "FDA's actions 'directly conflict with [MediNatura's] mission' to bring natural remedies to its customers, reduce the suffering of thousands, and save lives." *Id.* at 49 (citing *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016) (brackets in original).

The FDA responds that "'the fact that economic losses may be unrecoverable does not absolve [MediNatura] from its considerable burden of proving that those losses are certain, great and actual.'" Dkt. 11-1 at 47 (additional internal quotation marks omitted) (quoting *Nat'l Mining Ass'n v. Jackson*, 768 F. Supp. 2d 34, 52 (D.D.C. 2011)). The FDA further asserts that MediNatura's theory of irreparable harm is "conclusory and speculative and therefore cannot satisfy the high irreparable harm standard." *Id.* at 48. Specifically, the FDA challenges MediNatura's assertion that detention of its injectable drugs would threaten its business, arguing that MediNatura has not offered information about its overall financial position; has not specified which of its injectable products would run out when, even though the sales volumes of its various products differ substantially; has not explained how its contracts and relationships with medical providers would be disrupted; and has failed to substantiate how many customers it might lose. Dkt. 11-1 at 48.

The Court is persuaded that losing 41% of its revenue, Dkt. 1 at 9 (Compl. ¶ 32), would likely constitute a crippling blow to MediNatura, and little conjecture is required to understand that the company would lose customers if it is unable to offer its products for an extended period. But the Court concludes that MediNatura has nevertheless failed to carry its burden of demonstrating that it is likely to suffer irreparable harm for two additional reasons. First, at this stage, MediNatura has reported only that one shipment of one of its products, Engystol, was

detained, while another shipment of that same product was permitted to proceed into the country. It is unclear, based on the current record, whether MediNatura has attempted to import its other five products since the FDA added them to the Import Alert, and if so, whether the FDA has detained or will detain those shipments. MediNatura has not shown the sort of systematic detention and denial of admission that was at issue in *Smoking Everywhere*, on which MediNatura relies. *See* 680 F. Supp. at 68 n.7.

Second, even assuming that MediNatura would suffer irreparable harm from the detention of its products, the Court is unconvinced that MediNatura has demonstrated that such harm would be directly traceable to the withdrawal of CPG 400.400. In its motion, MediNatura premised its theory of irreparable harm on both the withdrawal of the Policy and the Import Alert, but the Court has now dismissed the company's claims based on the Import Alert, leaving only the withdrawal of CPG 400.400. As explained above, CPG 400.400 set forth "conditions under which homeopathic drugs may ordinarily be marketed," but the FDA maintained discretion to enforce the FFDCA against homeopathic drugs that it determined posed exceptional safety risks. Dkt. 1 at 29 (Ex. A). Here, in the FDA's warning letter to MediNatura, the FDA explained that it had singled out the company's "especially concerning" products for enforcement, stressing that "injectable drug products can pose risks of serious harm to users" because they "are delivered directly into the body, sometimes directly into the bloodstream, and therefore, bypass some of the body's key defenses against toxins and microorganisms that can lead to serious and life-threatening conditions." Dkt. 1 at 210 (Ex. I). Given that concern, the Court cannot conclude that MediNatura has shown a likelihood that the company will suffer an irreparable injury in the near-term due to the FDA's withdrawal of CPG 400.400—as opposed to the agency's arguably independent decisions to issue the warning letter and Import Alert.

At least for now, the Court is unpersuaded that MediNatura has carried its burden of showing that it is likely to suffer irreparable harm in the absence of a preliminary injunction.

3. *Balance of Equities and the Public Interest*

Because the Court has already concluded that MediNatura has not shown that it is likely to succeed on the merits or to suffer irreparable harm, the Court need not devote many words to the balance of equities and the public interest. MediNatura argues that a preliminary injunction is in the public interest because, in the absence of an injunction, "the public will lose access to a set of widely used homeopathic treatments proven to be safe alternatives to riskier treatments like corticosteroids." Dkt. 5-1 at 49. The FDA responds that "[i]t is patently unreasonable to suggest that removal of illegally-distributed unapproved drugs from the market will harm public health by driving people to lawfully distributed alternatives." Dkt. 11-1 at 50–51 (emphasis omitted). On the contrary, the FDA asserts that the public has a strong interest "in FDA's efficient enforcement of the [FFDCA]." *Id.* at 50.

The Court credits the FDA's argument. The public has a strong interest in the FDA's enforcement of the FFDCA, which protects public health and safety. Especially during a pandemic, it is important for the FDA to have flexibility to bring enforcement actions against drug companies that make claims about their products that science does not support. Even a safe drug can pose risks to public health if it is not effective. A patient who takes that ineffective drug instead of an effective alternative loses out on the better treatment. It is in the public interest for the FDA to have wide latitude to enforce the law against unapproved drugs that the agency deems unsafe or ineffective.

CONCLUSION

For the foregoing reasons, the Court **GRANTS** in part and **DENIES** in part the FDA's motion to dismiss, Dkt. 11. The motion is **GRANTED** and the complaint is **DISMISSED** as to Counts II, III, and IV. The motion is **DENIED** as to Count I. The Court further **DENIES** MediNatura's motion for preliminary injunction, Dkt. 5.

SO ORDERED.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: October 23, 2020