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.

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