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

ALLIANCE FOR NATURAL
HEALTH USA,
211 N. Union St., Suite 100,
Alexandria, VA 22314, and

MEDITREND, INC.,
4820 Eubank Blvd.,
Albuquerque, NM 87111,

Plaintiffs,

vs.

UNITED STATES OF AMERICA
c/o Attorney General of the United
States,

U.S. Department of Justice,
950 Pennsylvania Avenue, NW,
Washington, DC 20530-0001;

U.S. FOOD AND DRUG
ADMINISTRATION,
10903 New Hampshire Avenue, Silver
Spring, MD 20993; and

ROBERT M. CALIFF,
Commissioner of the
U.S. Food and Drug Administration,
10903 New Hampshire Avenue, Silver
Spring, MD 20993,

Defendants.

Civil Action No. _____

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF RE:**

**(1) VIOLATIONS OF 5 U.S.C. §
706(2)(A)(C) & 5 U.S.C. § 553(b);
AND**

**(2) VIOLATION OF THE FIFTH
AMENDMENT DUE PROCESS
CLAUSE AND 5 U.S.C. §
706(2)(B)**

1
2 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

3 **I. INTRODUCTION**

4 1. Plaintiffs Alliance for Natural Health USA (“ANH”) and Meditrend,
5 Inc. (“Plaintiffs”), by counsel, hereby submit this Complaint against Defendants
6 Robert M. Califf, Commissioner, United States Food and Drug Administration (in
7 his official capacity); the United States Food and Drug Administration (“FDA”); and
8 the United States of America.

9 2. Homeopathy is a medical art and science involving medical dilutions
10 that assist the body’s self-healing mechanisms. The United States Congress
11 recognized homeopathy as a medical art and the Food Drug and Cosmetic Act
12 (“FDCA”) includes particular provisions that uniquely protect that art. *See, e.g.*, 21
13 U.S.C. 321(g)(1)(A) (recognizing homeopathic products as “drugs”); *id.* at §§
14 351(b), 352(g) (adopting requirements of the Homoeopathic Pharmacopoeia of the
15 United States when a product is labeled and offered for sale as a homeopathic drug).
16 Similarly, the FDA has exempted homeopathic drugs from certain drug requirements
17 and has treated them differently than conventional drugs. *See* 21 C.F.R. § 211.137(e)
18 (exempting homeopathic drugs from expiration dating requirements); *id.* at §
19 211.166(c) (imposing different stability testing requirements on homeopathic
20 drugs).

21 3. Homeopathy is a widely used practice, recognized by the World Health
22 Organization,¹ dating back to the Greek physician Hippocrates, and refined
23 thereafter through hundreds of years of medical practice, prescription, and patient
24 experience. Millions of consumers use homeopathic drug products every day
25

26 ¹ WHO, 2019. "WHO Report on Traditional and Complementary Medicine",
27 2019. WHO, Geneva. Available at
28 [https://iris.who.int/bitstream/handle/10665/312342/9789241515436-
eng.pdf?sequence=1](https://iris.who.int/bitstream/handle/10665/312342/9789241515436-eng.pdf?sequence=1) (last accessed Oct. 15, 2024).

1 worldwide. Homeopathic drugs have a well-established safety record, and are
2 largely available as over-the-counter (“OTC”) preparations with very few adverse
3 event reports received by the FDA annually in stark contrast to conventional drugs.

4 4. The Federal, Food, Drug, and Cosmetic Act of 1938 included
5 homeopathic drugs in the general definition of “drug” products regulated by the
6 FDA. *See* 21 U.S.C. § 321(g).² In recognition of inherent differences between
7 homeopathic and conventional drugs and the extremely low incidence of adverse
8 events associated with homeopathics compared to conventional drugs, the FDA
9 permitted homeopathic product sales for over eighty years without requiring pre-
10 market drug approval under 21 U.S.C. § 355 as is required for conventional drugs.
11 Most homeopathic products have therefore been manufactured and marketed under
12 standards and monographs in the Homoeopathic Pharmacopoeia of the United States
13 (HPUS) for decades.

14 5. Homeopathics are not suited to meet the same standards as are applied
15 to conventional drugs because they rely on fundamentally different physico-
16 chemical and energetic properties, as well as different mechanisms of action and
17 measures of clinical usefulness. Moreover, homeopathics lack patent protection and,
18 so, cannot recoup the cost of conventional drug development and approval (now
19 estimated at between \$1-2 billion). The FDA filing fee alone for conventional drug
20 approval is a seven-figure sum, beyond the means of unpatented homeopathic
21

22 ² The primary author of the 1938 FDCA was Royal S. Copeland, a homeopathic
23 physician, ophthalmologist, former President of the American Institute of
24 Homeopathy, and President of the New York City Board of Health. *See* N.Y.
25 Medical College, Philip Capozzi, M.D., Library, Library Research Guides, NYMC
26 Biographies, Copeland, Royal S., M.D., 1868-1938,
27 <https://guides.library.nymc.edu/RoyalCopeland> (last accessed Oct. 15, 2023);
28 Eric Foxman, *History of Homeopathy, Royal Samuel Copeland, Former U.S. Senator*,
<https://theaahp.org/articles/royal-s-copeland-we-know-the-name-but-do-we-know-the-man/>
(last accessed Oct. 15, 2024). Copeland was a United States Senator from New York, and he sponsored the 1938 FDCA. *See id.* The Act formally recognized—and thus protected—homeopathic drugs.

1 products. *See* 87 Fed. Reg. 61063, 61064 (Oct. 7, 2022) (announcing Prescription
2 Drug User Fee Amendments (“PDUFA”) rates for fiscal year 2023, which includes
3 a \$1,621,013 application fee when no clinical data is required and a \$3,242,026
4 application fee when clinical data is required).

5 6. After nearly 80 years of limited regulation, the FDA recently altered its
6 policy regarding homeopathic drug products. In 2017, the FDA issued a draft
7 guidance entitled, “Drug Products Labeled as Homeopathic,” announcing the
8 agency’s shift to a so-called “risk-based approach.” *See* 82 Fed. Reg. 60403 (Dec.
9 20, 2017) (Notice of availability of Draft Guidance). Despite decades of extensive
10 and safe use of homeopathic OTCs, the FDA speculated without any proof that
11 homeopathic drugs were endemically or inherently unsafe citing rare, isolated
12 instances of mismanufacture as a basis for concluding that homeopathics posed a
13 safety risk. The FDA issued its final guidance on December 6, 2022 (hereinafter
14 “Final Guidance”),³ which coincided with FDA’s withdrawal of Compliance Policy
15 Guide (CPG) 400.400 (hereinafter “CPG 400.400”).⁴ FDA now takes the position
16 that, “absent a determination that a homeopathic drug product is not a ‘new drug’
17 under section 201(p), all homeopathic drug products are subject to the premarket
18 approval requirements in section 505 of the FD&C Act[.]” *Id.* (explaining that there
19 “are currently no homeopathic drug products that are approved by the FDA”).
20

21 ³ FDA, Center for Drug Evaluation and Research and Center for Biologics
22 Evaluation and Research. “Homeopathic Drug Products Guidance for FDA Staff
23 and Industry.” December 2022. Docket Number FDA-2017-D-6580. *Available at*
24 [https://www.fda.gov/regulatory-information/search-fda-guidance-](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/homeopathic-drug-products-guidance-fda-staff-and-industry)
25 [documents/homeopathic-drug-products-guidance-fda-staff-and-industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/homeopathic-drug-products-guidance-fda-staff-and-industry) (last
26 accessed Oct. 15, 2024).

27 ⁴ The CPG 400.400 governed U.S. sale of homeopathic drug products from 1988
28 to October 24, 2019, when it was withdrawn because it was deemed “inconsistent
with the agency’s risk-based approach to regulatory and enforcement action”; *see*
[https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-](https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-protect-patients-potentially-harmful-drugs-sold-homeopathic-products)
[protect-patients-potentially-harmful-drugs-sold-homeopathic-products](https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-protect-patients-potentially-harmful-drugs-sold-homeopathic-products) (last
accessed Oct. 15, 2024).

1 7. By concluding in the Final Guidance that all homeopathic drugs are
2 subject to premarket drug approval requirements, the FDA has foreclosed practical
3 channels to market OTC homeopathic drugs. Those products are now saleable only
4 at the whim of the FDA because the agency has provided homeopathic drugs no
5 viable regulatory pathway to lawful marketing. In other words, FDA has rendered
6 the FDCA’s provisions recognizing the legality of homeopathic drugs of no legal
7 force or effect whenever FDA agents in the exercise of unbridled discretion deem
8 any single homeopathic product deserving of enforcement. That change follows
9 decades of settled regulation and accepted pathways to market under CPG 400.400,
10 which the Final Guidance revoked.

11 8. The FDA’s latest policy conflicts with Congressional intent to relax—
12 not heighten—the regulatory burdens on homeopathic drugs, particularly OTC
13 products. Congress addressed OTC drug regulation in the Coronavirus Aid, Relief,
14 and Economic Security Act of 2020 (“CARES Act”). In the CARES Act, Congress
15 specifically and unequivocally exempted homeopathic OTC products from
16 conventional drug pre-market approval requirements based on the rationale that
17 homeopathic drugs are a “unique and separate category of drugs.” *See* CARES Act
18 § 3853 (citing and incorporating 37 Fed. Reg. at 9466 ¶25).

19 9. By treating OTC homeopathic drugs the same way as conventional
20 drugs, the FDA unlawfully merges homeopathic drug with conventional drug
21 regulation in direct contravention of the CARES Act. By regulating homeopathic
22 drugs under the same framework as conventional drugs, the FDA threatens
23 irreparable injury to the \$6.2 billion homeopathic industry in the United States. *See*
24 *Precedence Research, Homeopathic Products Market (By Product: Dilutions,*
25 *Tincture, Tablets, and Others; By Application: Analgesic and Antipyretic,*
26 *Respiratory, Neurology, Others; By Source: Animals, Plants, and Minerals) - Global*
27
28

1 *Industry Analysis, Size, Share, Growth, Trends, Regional Outlook, and Forecast*
2 *2021 – 2030* (Nov. 2021).⁵

3 10. Plaintiffs ANH, a non-profit advocacy organization that defends
4 patients' and consumers' rights of access to healthcare and health information, and
5 Meditrend, a homeopathic drug company, bring this action challenging (a) FDA's
6 denial of a Citizen Petition filed by the Americans for Homeopathy Choice
7 Foundation ("AHCF"); and (b) the agency's regulation of OTC homeopathic drugs
8 under Section 355 of the FDCA (21 U.S.C. § 355) and the Final Guidance. *See* Exh.
9 A (AHCF Petition, Dkt. No); *see also* Exh. B (FDA Guidance, "Homeopathic Drug
10 Products, Guidance for FDA Staff and Industry" (Dec. 2022)).

11 11. Under 5 U.S.C. § 706, consistent with the CARES Act, the Court should
12 hold homeopathics not subject to Section 355 drug pre-market approval. Meditrend
13 asks the Court to: (1) declare that homeopathic drugs marketed subject to an HPUS
14 monograph published prior to 1938 are not "new" drugs under 21 U.S.C. § 321(p);
15 (2) declare that OTC homeopathic drugs are exempt from "new" drug pre-market
16 approval requirements, pursuant to 21 U.S.C. § 321(p); (3) enjoin FDA from taking
17 enforcement action against OTC homeopathic products on grounds that such
18 products require pre-market drug approval under 21 U.S.C. § 355; and (4) declare
19 that FDA's Final Guidance violates the Due Process Clause of the Fifth Amendment.

20 21 **II. JURISDICTION AND VENUE**

22 12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331
23 (federal question jurisdiction) and 28 U.S.C. § 1346 (jurisdiction where the United
24 States is a defendant).

25 13. The Court has subject matter jurisdiction under 5 U.S.C. § 706(2)(A)
26 and (C).

27
28 ⁵ Available at <https://www.precedenceresearch.com/homeopathic-products-market> (last accessed Oct. 15, 2024).

1 such products presently unlawful if sold—subject only to the FDA’s “enforcement
2 discretion.” The FDA’s homeopathic policy provides no viable lawful means for the
3 continued manufacture, marketing, sale, and distribution of such products. The
4 AHCF petition, if granted, would have provided clear standards for the lawful sale
5 of OTC homeopathic products outside the context of pre-market approval used for
6 conventional drugs. Meditrend is an aggrieved party under the meaning of 5 U.S.C.
7 § 702.

8 **B. Defendants**

9 18. Defendant Robert M. Califf is the Commissioner of the United States
10 Food and Drug Administration (“FDA”) and is sued here in his official capacity.
11 The Commissioner is responsible for FDA’s administration of the federal Food,
12 Drug, and Cosmetic Act (“FDCA”).

13 19. Defendant United States created, organized, and operates the FDA as
14 an administrative agency within the executive branch of the federal government.

15 **IV. FACTS**

16 **A. FDA Regulation of Homeopathic Drugs**

17 20. Homeopathy is a medical practice that uses highly diluted substances
18 that are believed to stimulate and strengthen the body’s self-healing ability. When
19 produced by, and applied under, governing scientific principles, homeopathic drugs
20 do not treat disease or the symptoms of disease directly, they are intended to work
21 on multiple systems to help the body re-establish homeostatic norms (good health).
22

23 21. One of the central principles of homeopathy is that, when properly
24 selected and prepared, only minute amounts of a drug, or even its energetic imprint,
25 are needed to cure, treat, mitigate, and prevent various diseases.

26 22. The FDCA defines “drug” to include, *inter alia*, “articles recognized in
27 the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of
28 the United States, or official National Formulary, or any supplement to any of them.”

1 21 U.S.C. § 321(g)(1)(A). A conventional “new drug” requires an approved drug
2 application filed under Section 355(b) or 355(j) before it can be marketed, i.e.,
3 introduced or delivered for introduction into interstate commerce. *See id.* at §
4 355(a).⁶ The FDA has yet to approve a new drug application for a homeopathic
5 drug. Nor has FDA evaluated whether any homeopathic drug is generally
6 recognized as safe and effective (“GRAS/E”).

7 23. Historically, OTC drugs have had pathways to market separate from
8 “new” drugs. Those pathways include reliance on published monographs that allow
9 OTC drugs to be marketed without proceeding through the costly new drug pre-
10 market approval process. OTC monograph drugs have relaxed pre-market
11 regulatory burdens because the products present little to no risk to patient health and
12 safety in contrast to conventional prescription drugs. *See, e.g.*, 21 U.S.C. §
13 355h(a)(1)-(2) (an OTC drug satisfying the requirements of this section is deemed
14 to be generally recognized as safe and effective under section 21 U.S.C. § 321(p)(1),
15 not a “new drug” under section 321(p), and is not subject to section 353(b)(1)); 21
16 C.F.R. Part 333 (final OTC monograph establishing the conditions under which OTC
17 topical acne drug products are GRAS/E, and which was later incorporated into Final
18 Administrative Order OTC000013 on Nov. 23, 2021, OTC Monograph M006).

19 24. The FDA has a long history of exempting homeopathic drugs from
20 conventional “new” drug regulations. Beginning in 1972, the FDA made GRAS/E
21 determinations for several categories of OTC drugs pursuant to its OTC Drug
22 Review. *See* 37 Fed. Reg. 9464 (May 11, 1972); 21 C.F.R. Part 330. The FDA
23 formed advisory panels for OTC drugs under review. *See* 21 C.F.R. § 330.10; *see*
24 *also* FDA, *Over-the-Counter (OTC) Drug Review, OTC Monograph Reform in the*
25

26 ⁶ A “new drug” does not include, however, a drug that, at any time prior to June
27 25, 1938, was subject to the Food and Drug Acts of June 30, 1906, as amended, and
28 if at such time its labeling contained the same representations concerning conditions
of use. *See* 21 U.S.C. § 321(p)(1).

1 CARES Act, *Status of Existing OTC Monograph Products*.⁷ FDA published
2 advanced notices of proposed rulemaking (“ANPR”) in the Federal Register. *See*,
3 *e.g.*, 42 Fed. Reg. 35346 (July 8, 1977) (ANPR for internal analgesic drug products).
4 The ANPRs contained proposed monographs for OTC drugs, and FDA published
5 tentative and final monographs for OTC drug categories. Drugs manufactured and
6 labeled in compliance with an applicable OTC monograph were deemed GRAS/E
7 and, as a result, were not required to obtain approved “new” drug status. *See* 21
8 U.S.C. § 321(p) (the term “new drug” does not include GRAS/E drugs).

9 25. The FDA excluded homeopathic drug products from this OTC drug
10 review, deemed homeopathic drugs to be a separate category, and deferred its
11 evaluation of those products because of the “uniqueness of homeopathic
12 medicine[.]” *See* 37 Fed. Reg. at 9466 (“Because of the uniqueness of homeopathic
13 medicine, the Commissioner has decided to exclude homeopathic drugs from this
14 OTC drug review and to review them as a separate category at a later time after the
15 present OTC drug review is complete”).⁸

16 26. The FDA has stated repeatedly that homeopathic drugs, because of their
17 unique properties, were not to be regulated in the same manner as conventional
18 drugs. For example, in a 1988 article published in “FDA Consumer” magazine,⁹ the
19 agency wrote that homeopathic drugs “are exempt from the requirements of the
20 Federal Food, Drug, and Cosmetic Act that drugs must be proven safe and effective
21 before they can be marketed.” Exh. C (*FDA Consumer* article). The FDA similarly
22 explained at the time, in a related Talk Paper, that homeopathic products were
23 “exempted” from FDA review. *See* Exh. D (Sept. 15, 1988 FDA Talk Paper).

24
25 ⁷ Available at [https://www.fda.gov/drugs/over-counter-otc-nonprescription-](https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act)
26 [drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act](https://www.fda.gov/drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act) (last accessed
27 Oct. 15, 2024).

28 ⁸ The CARES Act memorialized that language when Congress ratified this
clause as part of its OTC drug legislation.

⁹ FDA Consumer was a magazine published by the FDA from 1967 through
2007.

1 27. The FDA continues to publish content for consumers online indicating
2 that homeopathic drugs are not subject to the FDA’s drug approval requirements.
3 For example, the FDA continues to host video content explaining that homeopathic
4 products are “sold without FDA review for safety or effectiveness...”¹⁰

5 28. Because homeopathic OTC drugs¹¹ were exempt from the conventional
6 OTC drug review, those products were also excluded from certain pathways to
7 market. Therefore, instead of evaluating homeopathic drugs under its OTC Drug
8 review, in 1988 the FDA exercised its enforcement discretion and issued a
9 compliance policy that established conditions under which homeopathic drugs could
10 “ordinarily” be marketed without an approved new drug application, so long as the
11 homeopathic drugs complied with certain requirements for labeling, manufacturing,
12 and registration. *See* Compliance Policy Guide 7132.15, § 400.400 (1988) (“CPG
13 400.400”).

14 29. The CPG 400.400 “specified the regulatory duties of manufacturers of
15 homeopathic drugs and thus had legal consequences[.]” *See MediNatura, Inc. v.*
16 *Food & Drug Admin.*, 496 F. Supp. 3d 416, 437-38 (D.D.C. 2020), *aff’d*, 998 F.3d
17 931 (D.C. Cir. 2021). That CPG document had the force of law thereby providing
18 homeopathic drug manufacturers with pathways to lawfully market homeopathic
19 drugs without undergoing “new drug” review reserved for conventional drugs. *See*
20 *id.* at 931 (“By its own terms, the [CPG 400.400] thus pertains to the affirmative
21 ‘regulation’ of homeopathic drugs and not just ... to the exercise of enforcement
22 discretion.”). The CPG “permitted homeopathic drug companies to market their
23

24 ¹⁰ *See* <https://www.fda.gov/drugs/information-drug-class/homeopathic-products#:~:text=On%20December%206%2C%202022%2C%20FDA,the%20great%20risk%20to%20patients> (last accessed October 15, 2024). *See* also FDA video “Homeopathic Drugs Warning” at: https://youtu.be/KJ21SpriY78?si=e3v-h11sV2_k8uou (last accessed October 15, 2024).

27 ¹¹ OTC homeopathic drugs, as compared to prescription drugs, are intended
28 solely for self-limiting disease conditions amenable to self-diagnosis of symptoms
and treatment.

1 products without premarket approval, in the ordinary course, so long as they
2 complied with the various statutory and regulatory requirements incorporated in the
3 Policy.” *Id.* at 440.¹²

4 30. As explained below, the FDA withdrew CPG 400.400 and replaced it
5 with a new “risk-based” approach to enforcement and regulatory actions concerning
6 homeopathic drugs. *See* FDA, “Homeopathic Drug Products, Guidance for FDA
7 Staff and Industry” (Dec. 2022).¹³ That “risk-based” model stripped away standards
8 in the CPG 400.400, and instead leaves homeopathic drugs in a standardless zone,
9 completely subject to the arbitrary whim or caprice of FDA regulators under vague
10 and amorphous policy language. The absence of reasonable standards capable of
11 guiding the regulated class leaves homeopathic drug manufacturers in a state of
12 complete legal uncertainty under constant threat of arbitrary FDA enforcement.

13 14 **B. CARES Act and Changes to OTC Drug Regulation**

15 31. Congress revised the OTC Drug Review process through the CARES
16 Act, Pub. L. No. 116-136. Under the CARES Act, an administrative process
17 replaced notice-and-comment rulemaking for identifying OTC drugs that FDA
18 determined to be GRAS/E, as well as issuing, revising, and amending OTC
19 monographs. *See* 21 U.S.C. §§ 352, 355g. In short, the CARES Act overhauled the
20 entire OTC drug approval pathway to market.

21 32. The CARES Act affected OTC drugs that were subject to an ongoing,
22 non-final monograph proceeding. It brought all those outstanding proceedings to a
23 close.

25 ¹² While the *MediNatura* decision mentioned the CARES Act as part of its
26 background summary of FDA regulation (*id.* at 427), the Court was not asked to rule
27 on whether the CARES Act Section 3853 affected the FDA’s authority to regulate
OTC homeopathic products. That is the question at issue in this case.

28 ¹³ Available at <https://www.fda.gov/media/163755/download> (last accessed Oct.
15, 2024).

1 33. The CARES Act also defaulted certain OTC drug products into the
2 category of “new drugs” requiring pre-market approval unless and until the
3 Administrative Order pathway created new OTC monographs under which they
4 could then be marketed without an approved new drug application. *See* 21 U.S.C. §
5 355h(b). Congress therefore streamlined the OTC drug pathway but definitively did
6 not deem drugs already subject to those pathways to be unmarketable “new drugs”
7 subject to Section 355 approval. *See id.* at § 355h(a)(5)-(6). In effect, drugs already
8 subject to those pathways were grandfathered.

9 34. In particular, Congress exempted OTC homeopathic drug products
10 from the new OTC drug pathways. The CARES Act eliminated FDA discretion to
11 recategorize homeopathic OTC drugs by exempting them from the new OTC portals
12 for conventional drugs. *See* Coronavirus Aid, Relief, and Economic Security Act,
13 Pub. L. No. 116-136, § 3853, Mar. 27, 2020, 134 Stat 281, 454 (2020). Thus, the
14 new administrative order process for recognizing GRAS/E OTC drugs does not
15 lawfully apply to homeopathic drugs.

16 35. **Section 3853 of the CARES Act reconfirms the FDA**
17 **Commissioner’s exclusion of homeopathic drugs in 1972 from the OTC drug**
18 **review and thereby memorializes the FDA’s findings at that time that**
19 **homeopathic drugs were “unique” and needed regulation “as a separate**
20 **category.”** The text of Section 3853 reads:

21
22 **SEC. 3853. DRUGS EXCLUDED FROM THE OVER-THE-**
23 **COUNTER DRUG REVIEW.**

24 (a) IN GENERAL.—Nothing in this Act (or the amendments made
25 by this Act) shall apply to any nonprescription drug (as defined in
26 section 505G(q) of the Federal Food, Drug, and Cosmetic Act, as
27 added by section 3851 of this subtitle) which was excluded by the
28 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.

1 (b) RULE OF CONSTRUCTION.—Nothing in this section shall be
2 construed to preclude or limit the applicability of any other
3 provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 301 et seq.).

5 *Id.*

6 36. Because FDA has not created a separate review process for determining
7 when an OTC homeopathic drug is marketable, OTC homeopathic drugs lack
8 regulatory standards to govern lawful marketing. Absent a rulemaking from FDA,
9 those products lack a legal avenue to market.

10 37. Under the CARES Act, Congress established that it did not intend for
11 OTC homeopathic drugs to be regulated in the same way as conventional drugs.
12 Although Congress indicated that other provisions of the FDCA can still apply (*see*
13 CARES Act § 3853(b)), the regulatory exclusion in Section 3853(a) is only
14 necessary or reasonable if Congress intended to exclude OTC homeopathic drugs
15 from the pre-market drug approval process used for conventional drugs, 21 U.S.C.
16 § 355.

17 38. The FDA has authority and flexibility to find a homeopathic drug
18 GRAS/E subject to conditions and standards appropriate to homeopathy. *See* 21
19 U.S.C. § 321(p)(1) (explaining that if experts, who are qualified by scientific training
20 and experience to evaluate the safety and effectiveness of drugs, generally recognize
21 a drug as safe and effective for use under the conditions prescribed, recommended,
22 or suggested in the labeling thereof, then the drug is not a “new drug”). In Section
23 3853, Congress plainly sought to relax regulatory burdens on homeopathic drugs by
24 preventing FDA from applying conventional GRAS/E standards to such drugs.
25 Evidence specific to the art of homeopathy, such as results of homeopathic provings
26 or compliance with an HPUS monograph, have historically been used to establish
27 that a homeopathic drug is safe and efficacious.

28 **C. AHCF’s Citizen Petition**

1 39. In response to the FDA’s 2019 Draft Guidance, the AHCF submitted a
2 Citizen Petition to FDA on June 5, 2020. *See* Exh. A (Dkt. No. FDA-2020-P-1510,
3 Document ID FDA-2020-P-1510-0002 (June 5, 2020) (“Citizen Petition”).¹⁴

4 40. AHCF’s Citizen Petition asked FDA “to establish a final rule setting
5 out regulations for the manufacture and sale in the United States of homeopathic
6 drugs and homeopathic drug products...” *Id.* at 8.

7 41. AHCF requested that the FDA: (1) adopt its proposed regulations;¹⁵ (2)
8 recognize as safe and effective homeopathic drugs that are properly manufactured
9 and labeled, and that are listed in, or are formally pending approval for listing in, the
10 HPUS and its supplements or addendums; (3) prohibit any homeopathic drug not
11 listed in, or formally pending approval for listing,¹⁶ in the HPUS or its supplements
12 and addendums from using the term homeopathic in any form that states or implies
13

14 ¹⁴ Available at <https://www.regulations.gov/document/FDA-2020-P-1510-0002>
15 (last accessed Oct. 15, 2024).

16 ¹⁵ AHCF’s proposed regulation: (1) defines terms, such as, but not limited to,
17 “homeopathic drug,” “homeopathic drug product,” “product properly labeled as
18 homeopathic,” and “product improperly labeled as homeopathic”; (2) describes the
19 conditions under which a homeopathic drug is deemed adulterated; (3) describes the
20 conditions under which a homeopathic drug labeled “homoeopathic” is deemed
21 misbranded; and (4) provides standards for homeopathic drugs and homeopathic
22 drug products. Regarding the proposed standards, they are as follows: (a) a
23 homeopathic drug must comply with applicable cGMPs and HPUS requirements;
24 (b) a homeopathic drug, when properly manufactured and labeled and evaluated
25 under an appropriate risk-based policy, is recognized as inherently safe; (c) an
26 appropriate risk-based policy requires that the risk of homeopathic drugs and
27 homeopathic drug products be evaluated in relation to risks presented by other
28 products; and (d) absent a determination that any specific homeopathic drug or any
specific homeopathic drug product is a new drug, the FDA will treat all homeopathic
drugs as generally recognized as safe and effective for their intended use (GRAS/E),
subject to compliance with the regulation’s provisions addressing adulteration,
misbranding, and cGMPs.

¹⁶ The Citizen Petition requested a two (2) year grace period for products, which
we assume means homeopathic active ingredients, to be proposed and accepted for
review for addition to the HPUS, and an additional four (4) years for the applications
to be accepted or rejected by a process certified by a recognized certifying
organization such as the International Standards Organization (ISO) or the American
National Standards Institute (ANSI).

1 the product is homeopathic; (4) ensure that any drug listed in, or formally pending
2 approval for listing in, the HPUS and its supplements and addendums is
3 manufactured in accordance with the HPUS and current good manufacturing
4 practices (“cGMPs”); (5) if the FDA applies a risk-based policy to drug products
5 labeled as homeopathic, ensure that the risk-based policy is formulated and applied
6 with generally accepted standards and procedures of risk assessment;¹⁷ and (6) hold
7 a public hearing if it denies the Citizen Petition. In other words, if the FDA granted
8 AHCF’s Citizen Petition, the FDA would cease applying new drug approval
9 (“NDA”) requirements to OTC homeopathic drugs, and would, in most
10 circumstances, recognize homeopathic drugs as low-risk products that are GRAS/E.

11 42. ANH and Meditrend supported the AHCF’s Citizen Petition and agrees
12 that FDA cannot lawfully subject OTC homeopathic drugs to conventional drug
13 approval requirements under Section 355. Rather, the FDA should recognize that
14 most, if not all, OTC homeopathic drugs are GRAS/E under homeopathic principles
15 and regulate them as such, particularly if they comply with applicable cGMP and
16 HPUS standards. Meditrend filed a comment to the AHCF petition expressing those
17 positions in the docket. *See* Dkt. No. FDA-2020-P-1510-0002, Comment ID FDA-
18 2020-P-1510-29462.¹⁸

19 43. Meditrend requested that FDA allow marketing and sale of OTC
20 homeopathic drugs without insisting on Section 355 pre-market drug approval if the
21 active homeopathic ingredients are included or recognized within the HPUS
22 (individually or as a class), and are manufactured consistent with homeopathic
23 principles, HPUS guidelines, and cGMP requirements.

25 ¹⁷ The Citizen Petition describes in detail what AHCF considers to be an
26 appropriate risk-based policy. In general, the Citizen Petition describes homeopathic
27 drug products as low risk compared to other products and encourages the FDA to
regulate them as such.

28 ¹⁸ Available at <https://www.regulations.gov/comment/FDA-2020-P-1510-29462> (last accessed Oct. 15, 2024).

1 **D. FDA Final Guidance Document**

2 44. The FDA published its final guidance regarding homeopathic drug
3 products in December 2022. *See* 87 Fed. Reg. 75054 (Dec. 7, 2022) (announcing
4 the availability of the final guidance). The agency declared its intention “to prioritize
5 enforcement and regulatory actions for homeopathic drug products marketed in the
6 United States without the required FDA approval.” *See* Exh. B (“Homeopathic Drug
7 Products, Guidance for FDA Staff and Industry”) (Dec. 2022) (“Final Guidance”).¹⁹
8 The agency finalized its “risk-based approach” to homeopathic drugs. *Id.* at 1.

9 45. The FDA explained that a homeopathic drug could be subject to
10 enforcement even if it “conforms to the HPUS dilution standards” published in the
11 HPUS monographs. *Id.* at 1 n.3.

12 46. By classifying all homeopathic drugs—including OTC
13 homeopathics—as unapproved new drugs subject to Section 355 pre-market drug
14 approval, the FDA increased the regulatory burdens on OTC homeopathic drugs to
15 levels much higher than those applied to conventional OTC drugs. Under the FDA’s
16 vague “risk-based approach” to homeopathic regulation, the FDA causes all such
17 products to be subject to enforcement without notice. *Id.* at 4.

18 47. The FDA also concluded erroneously as a matter of law that the
19 CARES Act requires a heightened regulatory threshold for homeopathic drug
20 products:

21 Prior to enactment of CARES, FDA had not reviewed any
22 homeopathic drug products under the OTC Drug Review, because
23 the Agency had placed homeopathic drug products in a separate
24 category and deferred consideration of them. Subsequent to
25 enactment of CARES, no GRAS/E determinations will be made for
26 homeopathic drug products under section 505G, because section
27 505G does not apply to homeopathic drug products. Because at this
28 time no homeopathic drug products have been determined by FDA

¹⁹ Available at <https://www.fda.gov/media/163755/download> (last accessed Oct. 15, 2024).

1 to be GRAS/E, all homeopathic drug products remain subject to the
2 premarket approval requirements.

3 *Id.* at 2-3. Thus, the FDA improperly construed the CARES Act to require
4 conventional drug approval requirements be met for homeopathic drugs when the
5 CARES Act plainly disallows imposition of those requirements. Meditrend
6 challenges FDA’s final order, asking the Court to rule that Congress intended to
7 protect the homeopathic OTC market from imposition of the conventional “new
8 drug” pre-market approval requirements of 21 U.S.C. § 355.

9 48. The FDA’s primary justification for increasing the burdens on OTC
10 homeopathic drugs was its speculative assertion (void of evidentiary support) that
11 homeopathics created a heightened risk of harm to patients. FDA stated: “Since the
12 issuance of CPG 400.400, the Agency has encountered multiple situations in which
13 homeopathic drug products posed a significant risk to patients.” *Id.* at 3. But the
14 agency identified no evidence to support the conclusion that homeopathic products
15 are unsafe or that drug approval under Section 355 of the FDCA is required to
16 prevent manufacturing errors.

17 49. The Final Guidance removed the clear standards that existed under
18 CPG 400.400, leaving the industry without essential guidance on how to lawfully
19 market homeopathic products.

20 **E. FDA Denial Letter**

21 50. Contemporaneous with the agency’s publication of the Final Guidance,
22 the FDA denied AHCF’s petition on December 6, 2022. *See* Exh. E (Dkt. No. FDA-
23 2020-P-1510, Document ID FDA-2020-P-1510-29367) (Dec. 6, 2022) (“Denial
24 Letter”).²⁰ The agency rejected all of AHCF’s requested regulatory reforms,
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28 ²⁰ Available at <https://www.regulations.gov/document/FDA-2020-P-1510-29367>
(last accessed Oct. 15, 2024).

1 including its request to publish regulations fostering the continued marketing and
2 sale of homeopathic drugs.

3 51. The FDA repeated its erroneous conclusion that the CARES Act
4 imposed new drug approval requirements on homeopathic drugs. *Id.* at 3.

5 52. The FDA reiterated its concern over the safety of homeopathic
6 products. *Id.* at 4. However, to the extent FDA identified purported safety concerns,
7 the agency's analysis focused only on isolated instances involving manufacturing
8 errors, not on problems endemic to homeopathic drugs themselves. *Id.* For example,
9 the FDA acknowledged that safety concerns related to instances where the
10 homeopathic ingredients contained in the final product "far exceeded the labeled
11 amounts..." *Id.*

12 53. The FDA denied the AHCF's proposal to permit continued sale of
13 homeopathic drugs subject to long-standing HPUS monographs. *See id.* at 6-7, 13-
14 14. FDA therefore rejected AHCF's position that homeopathic drugs which had
15 been sold for over eighty years are not "new" drugs under 21 U.S.C. § 321(p). Most
16 homeopathic drug products are now defined as "new." Those products have been
17 manufactured and marketed for decades under standards and monographs provided
18 in the HPUS. Under 21 U.S.C. § 321(p)(1), products marketed under the HPUS are
19 generally recognized, among experts qualified in homeopathic practice, as safe and
20 clinically effective for their homeopathic uses. Describing a product that has been
21 marketed and sold to consumers for generations as a "new" drug conflicts with the
22 plain and intended meaning of the statute.

23 54. The FDA also rejected AHCF's proposal to permit evaluation of
24 homeopathic drugs under homeopathic—rather than conventional—standards of
25 review. *See Denial Letter* at 7-8, 11-12.

26
27 **F. Meditrend's Comments**
28

1 (holding that agency interpretation violated CARES Act and thus 5 U.S.C. §
2 706(2)(C) where CARES Act spoke directly to the issue).

3 59. Regulating OTC homeopathic drugs under the same standards as
4 conventional “new” drugs violates the CARES Act and contradicts its legislative
5 intent.

6 60. Agency action in excess of, or in conflict with, statutory command is
7 unlawful under the Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2)(A)
8 and (C) and is entitled to no judicial deference; indeed, even were there some degree
9 of statutory ambiguity arguably present, *Loper Bright Enterprises v. Raimondo*, 603
10 U.S. ____ (2024), makes it emphatically the duty of the Court, not the FDA, to
11 determine the statutory meaning in line with the canons of statutory construction.

12 61. Under Section 3853(a) of the CARES Act, products “excluded” by
13 FDA in 1972 are OTC homeopathic drugs. That statutory note is unambiguous.
14 Congress intended through this exclusion to relax—not heighten—the premarket
15 burdens on OTC homeopathic drugs and did not intend homeopathic drugs to be
16 subjected to increased “new drug” pre-market approval requirements under 21
17 U.C.S. § 355.

18 62. By exempting OTC homeopathic drugs from pre-market approval
19 requirements, Congress intended to permit the continued marketing and sale of OTC
20 homeopathic drugs subject to the conditions defined in CPG 400.400. That
21 interpretation is supported by Congressional intent.

22 63. Congress expressly adopted and ratified the FDA’s language from 1972
23 wherein the FDA excluded OTC homeopathic drugs from premarket requirements
24 “[b]ecause of the uniqueness of homeopathic medicine...” *See* 37 Fed. Reg. 9466
25 (¶25). Following that FDA-issued exemption in 1972, the FDA then permitted
26 homeopathic products to be marketed without premarket approval for nearly fifty
27 (50) years. By adopting the FDA’s language from the Federal Register, Congress
28 expressly acknowledged that OTC homeopathics should not be regulated the same

1 as conventional drugs but, instead, under a different regulatory scheme. Requiring
2 homeopathic drugs to meet stricter standards, i.e., by eliminating the marketing
3 pathway permitted under the CPG 400.400, FDA rejected the plain and intended
4 meaning of the CARES Act, thus violating it.

5 64. Congress's language in the CARES Act is consistent with other
6 provisions of the FDCA, including 21 U.S.C. § 360eee(13), which expressly
7 excludes "homeopathic drugs marketed in accordance with applicable guidance
8 under this chapter" from significant obligations imposed on conventional drugs,
9 which are found in Section 360eee-1. Those requirements include, *inter alia*,
10 product identifiers, manufacturing requirements, wholesale distributor requirements,
11 dispenser requirements, repackager requirements, enhanced drug distribution
12 requirements, and guidance documents. *See* 21 U.S.C. § 360eee-1. *See* Drug
13 Quality and Security Act, Pub. L. 113-54 (Nov. 27, 2013), 127 Stat 587. Thus, here
14 again, Congress chose to relax (not heighten) the regulatory requirements applicable
15 to homeopathic drug products. Congress referenced the FDA's "applicable
16 guidance" related to homeopathic drugs in existence at that time in 2013, i.e., CPG
17 400.400. Congress intended for homeopathic drug regulation to proceed in
18 accordance with CPG 400.400.

19 65. The FDA's recognition that homeopathic drugs are not "new drugs"
20 within the meaning of the FDCA for nearly eighty (80) years undermines the
21 agency's assertion that such products must now be regulated as "new drugs" under
22 Section 355.

23 66. Under the major questions doctrine, the FDA lacks a clear statutory
24 command to increase regulatory burdens to the point of destroying the entire
25 consumer market in homeopathic OTC drugs by imposing on it burdensome new
26 drug regulatory requirements and the associated typical billions of dollars of cost per
27 drug.

1 67. Members of Congress provided direct evidence of congressional intent
2 in a letter to the FDA in September 2021 signed by twenty-four congresspersons.
3 *See* Congressional Ltr. to FDA (Sep. 3, 2021).²² Members of Congress encouraged
4 FDA to protect homeopathic drugs consistent with the CARES Act:

5 Since 1938 until 2017, the FDA consistently recognized the
6 distinction between conventional and homeopathic drugs, and
7 Congress has repeatedly reaffirmed this distinction as set forth in
8 the Food, Drug, and Cosmetic Act. As discussed above, **most**
9 **recently in 2020, Congress passed the CARES Act, which**
10 **exempts homeopathic drugs from review under its provisions**
11 **regarding pharmaceutical drugs.** In 1938, the FDA supported the
12 decision to recognize the HPUS and its supplements as the official
13 compendium of standards and monographs for homeopathic drug
14 ingredients giving the Agency the tools to regulate homeopathic
15 drugs as a unique and separate category of drugs. On several
16 occasions, the FDA has commented on this distinction as set forth
17 by Congress, and the Agency’s policies have been in adherence with
18 the law which, as the FDA stated in 1988, “gives no premarket
19 review of true homeopathic dilutions.”

20 68. *See id.* (emphasis added). Of the representatives who submitted that
21 letter to the FDA, seventeen (17) cast votes in favor of the final CARES Act
22 legislation.²³ The September 2021 letter represents direct evidence of congressional
23 intent concerning the legislative text of the CARES Act. *See id.*

24 69. Requiring all homeopathic drugs to secure approval under Section 355
25 will destroy the OTC homeopathic market. Two estimates for the cost of clinical
26 trials needed for New Drug Approvals have been estimated to average \$498.9
27 million and \$456.7 million per drug, respectively. *See*, DiMasi, J, et al., “Innovation
28 in the pharmaceutical industry: New estimates of R&D costs,” Journal of Health

25 ²² Available at, <https://homeopathychoice.org/wp-content/uploads/2021/09/9.3-Letter-to-the-FDA-regarding-Homeopathic-Guidelines.pdf> (last accessed Oct. 15,
26 2024).

27 ²³ An additional member, Gus Bilirakis, cast a vote for the same statutory
28 language when it was introduced earlier under separate legislation in H.R. 7328
(Housing Innovation Act) and H.R. 269 (Pandemic and All-Hazards Preparedness
and Advancing Innovation Act of 2019).

1 Economics, 2016;47:20-23 and Wouters, O.J, et al. “Estimated research and
2 development investment needed to bring a new medicine to market, 2009-
3 2018.” JAMA. 2020;323(9):844-853. Clinical trials required to support FDA drug
4 approvals have a median cost of \$19 million. Multiple such trials are required to
5 satisfy the FDA’s rigorous standards. Unlike conventional drugs, however,
6 homeopathic drugs lack market exclusivity provided by patent protections, in part,
7 because those products have been generally marketed unencumbered by the FDA
8 for decades. The absence of barriers to market entry, coupled with widespread use
9 of homeopathic products standardized under the HPUS, eliminate financial
10 incentives to pursue drug approval over such products.

11 70. Homeopathic products are also unsuited for FDA’s conventional new
12 drug pre-market approval because new drug approval is designed for novel synthetic
13 pharmacologically active ingredients with substantially higher safety risks non-
14 existent with homeopathic dilutions.²⁴

15 71. The FDA thus acts contrary to its authority, limitations, and/or statutory
16 right. The FDA’s policy regarding homeopathic OTC drugs under Section 355(a) is
17 not in accordance with the CARES Act. *See* 5 U.S.C. § 706(2)(A), (C).

18 72. The Court should enjoin the FDA from taking enforcement action
19 against any OTC homeopathic drug products on the basis that such products lack
20 pre-market new drug approval under 21 U.S.C. § 355(a).

21
22 ²⁴ The FDCA was passed in 1938 primarily to address drug safety concerns in
23 the wake of prominent drug safety failures. *See, e.g.,* FDA, *Part II: 1938, Food,*
24 *Drug, Cosmetic Act*, <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act#:~:text=FDR%20signed%20the%20Food%2C%20Drug,adequate%20directions%20for%20safe%20use> (last accessed Oct. 15, 2024) (explaining how the 1938 amendment to the FDCA was “enhanced and passed in the wake of a therapeutic disaster in 1937,” which involved over 100 people dying after consuming a “sulfa wonder drug” that contained a “highly toxic analogue of antifreeze,” and how the 1938 law required, *inter alia*, drugs to be labeled with adequate directions for safe use and for new drugs to be FDA approved as safe before they could be lawfully marketed).

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COUNT TWO

**FDA Violated 5 U.S.C. 706(2)(A) and 5 U.S.C. 553(b) by Denying AHCF's
Request for a Rulemaking Regarding Homeopathic Drugs**

73. Plaintiffs incorporate by reference all allegations contained in Paragraph 1 through Paragraph 72.

74. FDA erred in denying AHCF's request for regulation concerning homeopathic drug products.

75. After Congress exempted OTC homeopathic drugs from OTC drug approval pathways in the CARES Act, OTC homeopathic drugs were left without a pathway to market. Regulation of homeopathic drugs under Section 355 is legally and scientifically inappropriate.

76. Absent regulatory standards, homeopathic manufacturers lack legal protections for homeopathic products. Those manufacturers also lack recourse if the agency moves to act against them on a case-by-case basis.

77. Because homeopathic drugs are unique and function differently from conventional drugs—a fact Congress has affirmed—requiring OTC homeopathic drugs to proceed through conventional new drug pre-market approval pathways is infeasible and would destroy the homeopathic industry in the United States, an industry that Congress did not intend to destroy, but to preserve.

78. The Court has authority to overturn an agency's decision not to initiate a rulemaking where the agency has committed an error of law or incorrectly evaluated fundamental factual premises. *See, e.g., WildEarth Guardians v. U.S. E.P.A.*, 751 F.3d 649, 653 (D.C. Cir. 2014); *see also New York v. Env't Prot. Agency*, 921 F.3d 257, 261 (D.C. Cir. 2019) (the Court may set aside the agency's judgment where the agency "had not adequately explained the facts and policy concerns it relied on or that those facts did not have some basis in the record").

1 81. Plaintiffs incorporate by reference all allegations contained in
2 Paragraph 1 through Paragraph 80.

3 82. FDA acted arbitrarily and capriciously by imposing heightened
4 regulatory requirements on homeopathic drug products based on hypothesized safety
5 concerns where the administrative record instead shows homeopathic drugs pose no
6 cognizable safety risks to consumers.

7 83. Based on unsupported safety concerns, FDA arbitrarily and
8 capriciously took adverse action against an entire industry. FDA's conclusions
9 regarding homeopathic drug safety were unsupported by fact, and contradicted the
10 evidence available to FDA at the time. *See* Exh. B at 3-4; Exh. E at 4. Homeopathic
11 OTCs are much safer than conventional medicines; homeopathics are already
12 deemed GRAS/E by the FDA.

13 84. In December 2022, FDA published the Final Guidance. In that
14 guidance document, FDA stated that it “developed a risk-based approach under
15 which the Agency intends to prioritize enforcement and regulatory actions involving
16 certain categories of such products that *potentially* pose a higher risk to public
17 health.” Final Guidance at 1 (emphasis added). FDA ascribed generalized and
18 hypothesized safety risks to an unspecified number of products. *See* Exh. B at 3.

19 85. FDA presumed homeopathic OTC drugs carry a heightened safety risk,
20 contrary to the evidence. FDA claims that since issuance of CPG 400.400, the
21 Agency has encountered “multiple situations” in which homeopathic drug products
22 posed a significant risk to patients. *Id.* at 3. FDA alleged that such products either
23 caused or “could have caused” significant harm. *See id.* at 3 (quotations added). For
24 proof, FDA cited to the teething and Zicam products also referenced in the denial
25 letter, and discussed by AFHC's citizen petition. *See id.* at 3 n.12; Exh. E at 4; Exh.
26 A at 11-12.

27 86. FDA acknowledges that homeopathic drugs are distinct from other
28 drugs. *See* Exh. E at 11. The only two examples offered by FDA of safety concerns

1 in relation to homeopathic OTCs involved labeling and manufacturing issues related
2 to baby teething products and nasal sprays, and the quality of the data on which the
3 FDA relied has been challenged.²⁵ However, the FDA identified no evidence that
4 homeopathic products were inherently or intrinsically unsafe when manufactured or
5 used as intended, citing instead to specific isolated instances of manufacturer error
6 having nothing to do with endemic or intrinsic characteristics of homeopathic
7 products. *See generally* Exh B; Exh. E.

8 87. The AHCF petition generated over 54,000 comments, almost
9 exclusively in support of AHCF's request to foster continued sales of homeopathic
10 drugs through reasonable regulation. Those comments included those from the
11 medical community reciting detailed experiences with homeopathic product safety.
12 *See, e.g.*, Dkt. Nos. FDA-2020-P-1510-20392 (medical doctor explaining that
13 homeopathy is "the safest category of drugs"); -9213 (explaining that 200-year
14 history of homeopathic use supports safety); -16385 (explaining the impracticality
15 of proposed homeopathic regulation and highlighting the record of homeopathic
16 safety); -19987 (homeopathic history of safe use); -2444 (Registered Nurse
17 explaining that homeopathic drugs are "the safest and most non-toxic medicine"); -
18 27937 ("The safety and effectiveness of homeopathy is also backed by thousands of
19 research studies"); -10465 (safety of homeopathy compared to safety risks with
20 conventional drugs); -23435 (homeopathy lacks side effects present with
21 conventional drugs); -2120 (describing 200+ year history of safe homeopathic use);
22 -26093 (describing "nontoxic and inherently safe" use of homeopathics); -54013
23 (explaining that homeopathic medications are safe when properly manufactured and
24 labeled); -9154 (same); -20237 (same); -9200 (same).

25 88. The World Health Organization concluded that "Adverse events
26 occurring during homeopathic treatment are rarely attributed to the homeopathic

27 ²⁵ Lennihan, B. "Food and Drug Administration Action Against Homeopathic
28 Teething Tablets Lacked Evidence Base." *Alt. Compl. Therapy*. 2018:24(1):19-28.

1 medicine itself.” See FDA-2020-P-1510-2120 (quoting *Safety Issues in the*
2 *preparation of Homeopathic Medicines*, World Health Organization (2009)). The
3 WHO therefore determined that, where safety issues for homeopathic products arise,
4 those are generally related to impurities in the source material or failures of good
5 manufacturing practices. *Id.*

6 89. According to testimony provided to the FDA regarding the National
7 Poison Data System (NPDS) and the American Association of Poison Control
8 Centers (AAPCC), exposure reports to “homeopathic” products account for 1% or
9 less of all calls to Poison Control Centers. See Exh. A app. 13 at 1²⁶ (citing 2015-
10 N-0540-4429, presentation from Edward P. Krenzelok, Rocky Mountain Poison and
11 Drug Center²⁷). Moreover, because the NPDS reports group together dietary
12 supplements, herbals and homeopathics, and there is often identity confusion
13 between these three product categories, the limited reports on homeopathic products
14 are likely overestimated and mis-attributed. See *id.* The overwhelming majority
15 (98%) of “homeopathic” reports are nonetheless categorized as either having minor
16 or no adverse effects, and those incidents are typically managed without the need for
17 any medical referral. See *id.*; see also Exh. A app. 13 at 4 (“[I]nvestigations into
18 homeopathic treatment including randomized controlled trials, observational
19 studies, experimental studies, case reports, systematic reviews, worldwide literature
20 searches, consultation with regulating authorities, and conversations with
21 homeopathic practitioners reveal that homeopathy is an extremely safe and effective
22 form of medicine.”)

23 90. FDA’s concerns over *potential* safety issues are, based on the evidence
24 it cites, speculative and inflated, drawn from isolated manufacturing practices and
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26 ²⁶ Available at [https://homeopathychoice.org/app/uploads/2019/03/The-Safety-](https://homeopathychoice.org/app/uploads/2019/03/The-Safety-of-Homeopathic-Medicine-AFHC-Citizen-Petition-Supporting-Document-1.pdf)
27 [of-Homeopathic-Medicine-AFHC-Citizen-Petition-Supporting-Document-1.pdf](https://homeopathychoice.org/app/uploads/2019/03/The-Safety-of-Homeopathic-Medicine-AFHC-Citizen-Petition-Supporting-Document-1.pdf)
(last accessed Oct. 15, 2024).

28 ²⁷ Available at <https://www.regulations.gov/document/FDA-2015-N-0540-4429>
(last accessed Oct. 15, 2024).

1 labeling concerns. Pre-market drug approval under Section 355 would not have
2 prevented cGMP-related deviations. Requiring drug approval for safety and efficacy
3 does not address failures in good manufacturing practices. The FDA's regulation of
4 homeopathics under the withdrawn CPG 400.400 included the requirement that
5 homeopathic drugs meet drug GMP standards. A risk of *potential* (and
6 demonstrably rare) GMP failures was therefore not a factually supported basis to
7 *increase* regulatory requirements on the entire homeopathic industry when the
8 existing CPG 400.400 had already required compliance with GMP standards.

9 91. FDA's imposition of heightened regulatory requirements because of
10 alleged safety concerns was arbitrary and capricious and unsupported by the facts
11 available to the agency at the time. Regarding the two examples cited by the FDA
12 in both the Denial Letter and Final Guidance document cited *supra* (Exh. E and Exh.
13 B, respectively), the FDA was unable to determine if any of the baby teething
14 products actually caused harm, and FDA only found that belladonna alkaloids in
15 some of the products exceeded the labeled amounts. *See* Exh. A at 11.

16 92. FDA's records show that homeopathic OTCs are substantially safer
17 than conventional drug counterparts. For instance, between 1999 and 2024
18 (October), the FDA received a total of 1,285 adverse events in the FDA Adverse
19 Events Reporting System (FAERS) related to homeopathic drug products. *See*
20 *Homeopathics*, FDA Adverse Events Reporting System (FAERS) (current as of June
21 30, 2024).²⁸ By comparison, between the 5-year period 2019 to 2023 inclusive, the
22 FDA received 64,664 reports for suspected adverse events linked to use of the drug
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27 ²⁸ Available at <https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis> (last
28 accessed Oct. 15, 2024).

1 acetaminophen (the active ingredient in Tylenol®) (data current as of June 30,
2 2024).²⁹

3 93. For the same 5-year period, the FDA received just 169 reports for all
4 homeopathic products.³⁰ These data, from the FDA’s own database, show that
5 reports for all homeopathic drugs represented just 0.26% of the number for a single
6 drug, namely acetaminophen (i.e., 383 times fewer reports).

7 94. The FDA’s concerns over homeopathic drug safety are exaggerated and
8 speculative. The FDA has speculatively observed that, “[w]hile products labeled as
9 homeopathic are generally labeled as highly diluted, some of these products have
10 been found to contain measurable amounts of active ingredients and therefore could
11 cause significant harm.”³¹ But, as noted, the FDA has no evidence that homeopathic
12 products have caused “significant harm” when properly manufactured and used as
13 directed.

14 95. The FDA simply has no evidence that OTC homeopathic drugs are
15 high-risk. There is no evidence that the use of homeopathic products results in a
16 need for pre-market applications for products that have been in use for hundreds of
17 years and are documented to be safer than conventional medicines. The FDA’s
18 elimination of the marketing pathway for homeopathic drugs in CPG 400.400, and
19 its subsequent increased regulation of homeopathic drugs, are therefore arbitrary and
20 capricious agency actions void of a reasonable evidentiary foundation. The FDA
21 largely ignored, and failed to consider, the overwhelming evidence of homeopathic
22 drug safety in the record.

23 ²⁹ Available at <https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis> (last
24 accessed Oct. 15, 2024).

25 ³⁰ Available at <https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis>.

26 ³¹ See <https://www.fda.gov/drugs/information-drug-class/homeopathic-products#:~:text=On%20December%206%2C%202022%2C%20FDA,the%20great%20risk%20to%20patients> (last accessed Oct. 15, 2024).

1 to provide the regulated class with fair notice of what conduct is prohibited. *See*
2 FDA, “Homeopathic Drug Products, Guidance for FDA Staff and Industry” (Dec.
3 2022).³²

4 101. Unlike the withdrawn CPG 400.400, the Final Guidance includes no
5 standards for the lawful sale of homeopathic drug products. Instead, the FDA
6 replaced those standards with a standardless “risk-based approach” giving its
7 regulators unbridled discretion to dictate conditions for “manufacturing, distribution
8 and marketing of homeopathic drug products[.]” *Id.* at 4.

9 102. CPG 400.400 provided definitions applicable to homeopathic drugs and
10 rules governing the lawful manufacturing, labeling, and sale of same. *See* Ex. G
11 (CPG 400.400). Those rules included compliance with “standards for strength,
12 quality, and purity set forth in the [HPUS].” *Id.* It included reference to the types
13 of claims that could be made on homeopathic labeling. *Id.* (citing “A Dictionary of
14 Practical Material Medica by John Henry Clark, M.D.”). The CPG 400.400 included
15 labeling polices and provisions, including, e.g., (1) directions for use; (b) statement
16 of ingredients; (c) documentation that must be maintained to support recognition in
17 the HPUS; (d) the product’s established name; (e) labeling exemptions for small
18 containers; (f) language requirements; (g) net quantity of contents; (h) statement of
19 identity; and more. *Id.* The CPG 400.400 also included provisions for both
20 prescription and OTC homeopathic drugs. That CPG included standards for
21 compliance with current good manufacturing practices (with certain exceptions).

22 103. The FDA also explained in the CPG 400.400 that firms “not in
23 compliance with the conditions described above will be considered for regulatory
24 follow-up.” *Id.* As noted, *supra*, the CPG 400.400 imposed binding obligations and
25 clear standards on the industry. *See MediNatura*, 496 F. Supp. 3d at 437-38. The
26 FDA’s substitute of a standardless and entirely subjective “risk-based approach”

27 ³² Available at <https://www.fda.gov/media/163755/download> (last accessed Oct.
28 15, 2024).

1 deprives the regulated class of guidance sufficient to discern a reliable way to
2 lawfully market homeopathic products, leaving the regulated class to guess as to
3 what requirements apply, they being entirely what agency regulators select moment
4 by moment at their whim or caprice. That void leaves Meditrend and the entire
5 regulated class unable to determine at present and in future which homeopathic
6 products, if any, are lawful to manufacture, distribute, and sell.

7 104. Although the Final Guidance cites examples of “risky” products that
8 may have enforcement priority, the FDA reserves the right to take enforcement
9 action against any homeopathic product without providing prior notice: “FDA is not
10 required, and generally does not expect, to give special notice that a drug product
11 may be subject to enforcement action.” Final Guidance at 4. Critically, the FDA
12 reserves unto itself unlimited discretion to act against any homeopathic drug product
13 for any reason: “[T]his guidance is intended to provide notice that any homeopathic
14 drug product that is being marketed illegally is subject to FDA enforcement action
15 at any time.” *Id.* at 5. FDA has also taken the position that all homeopathic drug
16 products are “being marketed illegally,” because the FDA now requires all
17 homeopathic drugs to achieve new drug pre-market approval under Section 355. No
18 homeopathic drug product has achieved that, and none will likely do so given the
19 enormous new drug filing fees and the extraordinary multi-billion dollar cost of
20 achieving market access for each new drug. *See id.* at 3.

21 105. In short, the Final Guidance deems all homeopathic drugs unlawful, and
22 FDA fails to provide the regulated class, including Meditrend, with any standards
23 by which homeopathic drugs can be manufactured, distributed, and sold lawfully
24 other than through the Section 355 pre-market new drug approval requirements—
25 the standard Congress meant to apply exclusively to drugs other than homeopathic
26 drugs. Thus, FDA declares that it will use enforcement discretion for “risky”
27 products that are very broadly defined. For example, these include products “that
28 contain or purport to contain ingredients associated with potentially significant

1 safety concerns”, those “used for the prevention of treatment of serious...diseases
2 and conditions”, and “products for vulnerable populations.”³³ Although the FDA
3 provides certain examples of risky homeopathic drugs, the FDA does not limit
4 enforcement to those specific products. Moreover, unlike CPG 400.400, the FDA
5 provides no reasonable method for homeopathic drug manufacturers to determine
6 whether their product is lawfully or properly labeled. The FDA’s Final Guidance
7 therefore violates the Due Process Clause of the Fifth Amendment because it fails
8 to give the regulated class, including Meditrend, any, let alone, reasonable, notice of
9 the applicable legal standards governing lawful versus unlawful sales of
10 homeopathic products.

11 106. Homeopathic drug companies face potential criminal penalties under
12 the FDCA for selling products the FDA deems unapproved new drugs. *See, e.g.*, 21
13 U.S.C. §§ 331(a),(d), 333(a).

14 107. Where a regulation carries the potential for criminal enforcement,
15 courts undertake a comparatively stricter vagueness review under the Due Process
16 Clause. *See, e.g., All. for Nat. Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 131
17 (D.D.C. 2011).

18 108. “A fundamental principle in our legal system is that laws which regulate
19 persons or entities must give fair notice of conduct that is forbidden or required.”
20 *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (“This requirement
21 of clarity in regulation is essential to the protections provided by
22 the Due Process Clause of the Fifth Amendment.”)

23 109. A regulation or ordinance may be unconstitutionally vague because it
24 fails to provide fair notice of prohibited conduct, or it fails to establish minimal
25

26 ³³ “Final Guidance”, “Homeopathic Drug Products Guidance for FDA Staff and
27 Industry,” p. 5. Available at [https://www.fda.gov/regulatory-information/search-
28 fda-guidance-documents/homeopathic-drug-products-guidance-fda-staff-and-
industry](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/homeopathic-drug-products-guidance-fda-staff-and-industry) (last accessed Oct. 15, 2024).

1 guidelines to govern enforcement. *See U.S. v. Regan*, 93 F. Supp. 2d 82, 87 (D.
2 Mass. 2000) (citing *City of Chicago v. Morales*, 527 U.S. 41, 57 (1999)). Vague
3 regulations violate due process rights because they “neither give a party fair notice
4 of the type of activity the regulation proscribes nor sets the standards by which
5 government officials will enforce the regulation, permitting arbitrary and
6 discriminatory enforcement.” *See Jacobsen v. Rensink*, No. C 96-4074 MWB, 1997
7 WL 33833742, at *16 (N.D. Iowa Mar. 15, 1997).

8 110. The FDA’s Final Guidance neither provides homeopathic drug
9 manufacturers with fair notice of the standards by which OTC homeopathic drugs
10 can be lawfully marketed, nor sets standards to govern when FDA officials will deem
11 homeopathic drugs unsaleable.

12 111. The FDA had reasonable alternatives that would have avoided Due
13 Process concerns. For more than thirty years, the FDA regulated the industry under
14 the CPG 400.400 using standards that gave fair notice.

15
16 **VI. RELIEF REQUESTED**

17 WHEREFORE, Plaintiffs respectfully request that this Court,

18 (2) Declare that homeopathic drugs marketed subject to an HPUS
19 monograph published prior to 1938 are not “new” drugs under 21 U.S.C. § 321(p);

20 (3) Declare that OTC homeopathic drugs are exempted by the CARES Act
21 from pre-market new drug approval requirements under 21 U.S.C. § 355(a);

22 (4) Enjoin FDA from taking enforcement action against OTC homeopathic
23 products on grounds that such products require pre-market new drug approval under
24 21 U.S.C. § 355; and

25 (5) Reverse and remand the FDA’s final action in its Final Guidance
26 consistent with the Court’s order, thereby necessitating that FDA maintain the status
27 quo ante (before adoption of its Final Guidance) until such time as FDA initiates a
28 rulemaking under 5 U.S.C. 553(b) to provide a practical pathway, consistent with

1 the CARES Act, for market clearance of OTC homeopathic drugs that mirrors
2 conditions for sale stated in the now-rescinded CPG 400.400.

3 (6) Declare that FDA's Final Guidance violates the Due Process Clause of
4 the Fifth Amendment and the APA's prohibition on unconstitutional agency action
5 and against arbitrary and capricious agency action by failing to provide clear
6 standards for homeopathic drug manufacturers.

7
8
9 DATED: October 21, 2024.

10 Respectfully submitted,

11
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Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2024, the foregoing COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF was electronically filed using the Court's CM/ECF system and served* via that system on the following Defendants:

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* Upon the Clerk's execution of summonses, each Defendant shall be served a copy of the summons and the complaint.

/s/ Jonathan W. Emord
Jonathan W. Emord