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ANH Petitions FDA to Restore Safe Harbor for Homeopathic Medicines

Citizen Petition calls for reinstatement of CPG 400.400, formal rulemaking, and a science-based “traffic-light” enforcement framework

ALEXANDRIA, VA., October 1, 2026 — The Alliance for Natural Health USA (ANH-USA), together with homeopathic manufacturer Meditrend Inc., has filed a Citizen Petition calling on the U.S. Food and Drug Administration (FDA) to restore its longstanding safe harbor for homeopathic medicines and halt implementation of its current framework pending formal public rulemaking.

For 31 years, FDA’s Compliance Policy Guide 400.400 provided a clear framework under which homeopathic products meeting specified standards could be marketed without being treated as enforcement targets solely because they lacked new drug approval. FDA withdrew that policy in 2019 and later finalized a risk-based enforcement guidance in December 2022.

ANH-USA and Meditrend argue that FDA’s replacement framework leaves responsible manufacturers unable to know what steps will protect compliant products from enforcement—even where products meet established homeopathic labeling, and quality standards. The petition further argues that FDA failed to adequately account for decades of industry reliance on CPG 400.400 or undertake the notice-and-comment rulemaking required before adopting a policy with such significant impact on the industry.

“The Administrative Procedure Act prohibits FDA from abruptly ending an industry safe harbor without evaluating the reliance interests of the industry,” said Jonathan W. Emord, General Counsel to ANH-USA. “The agency did not do that, and it also did not provide the regulated class with reasonable parameters to know whether any particular homeopathic drug on the market will be the subject of enforcement action. It should restore CPG 400.400 and engage in proper rulemaking to define those parameters so manufacturers, suppliers, retailers, practitioners, and consumers know what products may safely be sold and purchased.”

Restore clear rules and protect consumer access

The petition asks FDA to take four actions pending completion of formal notice-and-comment rulemaking:

1. Revoke its 2019 withdrawal of Compliance Policy Guide 400.400.
2. Reinstatement CPG 400.400 and its conditions for marketing homeopathic medicines.

3. Cease implementation of the enforcement framework adopted in the December 2022 homeopathic drug guidance.
4. Commence a rulemaking to define precisely what kinds of homeopathic products may be safely sold in the United States without threat of FDA enforcement.

Focus enforcement on demonstrated product risks

The petition's scientific exhibit examines 2,068 adverse event reports associated with homeopathic or purportedly homeopathic products. The analysis concludes that FDA's own adverse event records do not justify treating properly manufactured, HPUS-compliant, correctly labeled homeopathic medicines as a broad public health risk.

The exhibit argues that FDA has relied heavily on isolated, unrepresentative examples involving improperly manufactured, mislabeled, contaminated, pharmacologically dosed, or otherwise non-compliant products. Such products were never entitled to the protections of CPG 400.400. Their defects support targeted enforcement against specific bad actors or risky products—not withdrawal of the clear compliance framework for responsible manufacturers.

"FDA's own adverse event record fails to show any evidence of a class-wide safety problem with properly manufactured, correctly labeled, HPUS-compliant homeopathic medicines," said Robert Verkerk, Ph.D., Executive and Scientific Director of ANH-USA. "The science points to a very different conclusion: enforce against adulteration, mislabeling, contamination, inappropriate routes, and genuinely risky products—but do not use those outliers to threaten the entire category. The FDA's current stance on homeopathics works in direct opposition to this administration's MAHA agenda."

Regulatory uncertainty has concrete consequences

In a sworn declaration accompanying the petition, Meditrend President Seneca Savage describes lost investor support, difficulty sourcing ingredients, and manufacturing disruptions following FDA's policy change.

ANH-USA warns that this uncertainty threatens consumer access to long-standing homeopathic products. The petition calls for a transparent, enforceable framework that preserves FDA's authority to act against adulteration, misbranding, and genuine safety concerns while giving responsible manufacturers predictable conditions under which to operate.

The accompanying scientific exhibit proposes a practical "traffic-light" approach. Green products—those meeting defined homeopathic, labeling, manufacturing, and low-risk criteria—would be treated as lowest enforcement priority. Amber products raising unresolved concerns would be subject to additional scrutiny. Red products presenting clear risks, such as adulteration, contamination, misbranding, pharmacologically active exposure, or causally supported serious adverse events, would be prioritized for enforcement.

“FDA should focus its resources where the real risks are,” Verkerk added. “A clear Green-Amber-Red framework would protect consumers, preserve access, and give responsible companies the certainty they need to operate.”

ANH-USA is urging FDA to act without delay and to establish a transparent public process for defining the boundaries of lawful, responsible homeopathic drug marketing.

ENDS.

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