

FDA Draft Guidance Proposes Risk-Based Regulatory Scheme for Drug Products Labeled as Homeopathic

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PRACTICES Healthcare Transactions and Regulatory, FDA Regulatory and Compliance, Healthcare and Life Sciences

More than two and a half years after the U.S. Food and Drug Administration (FDA) announced that it was re-evaluating its regulatory framework for homeopathic products, the FDA released its [Draft Guidance on Drug Products Labeled as Homeopathic](#). The Draft Guidance summarizes the FDA's current enforcement perspective on homeopathic products and provides a list of the FDA's enforcement priorities.

History of Homeopathic Remedies and Regulation in the United States

Homeopathy has been used around the world since the late 1700s. Generally, it is based on two principles: (1) a substance that *causes* symptoms in a healthy person can be used in a diluted form to *treat* symptoms and illnesses (referred to as “like-cures-like”); and (2) the more diluted a substance, the greater its potency.

The first federal food and drug statute, the Food and Drugs Act of 1906, did not reference homeopathy and instead recognized the U.S. Pharmacopeia (USP) and the National Formulary (NF) as the country's exclusive drug compendia, meaning that only preparations listed in those two publications were defined as “drugs.” Preparations that did not conform to the publications' standards could be deemed “adulterated,” rendering their manufacture unlawful. At the time, this included preparations listed in the Homeopathic Pharmacopoeia of the United States (HPUS), a recognized compilation of homeopathic medicines published in 1897.

In 1938, the federal Food, Drug, and Cosmetic Act of 1938 (FDCA) included the HPUS as an official compendium alongside the USP and NF and brought homeopathic medicines under the federal law's definition of “drug.” Still, homeopathic drugs continued to be informally regulated until the FDA and industry members began working together in the early 1980s to develop a more robust regulatory framework. Six years later, the FDA and the Homeopathic Pharmacists Association issued [Compliance Policy Guide 400.400, Conditions Under Which Homeopathic Drugs May be Marketed](#) (“CPG 400.400”), which outlined how homeopathic medicines should be marketed in the United States.

Requirements to Market an OTC Homeopathic Drug

The Draft Guidance does not change preexisting requirements for homeopathic drug labeling or accepted Current Good Manufacturing Practices (CGMPs). A homeopathic drug must be listed in the HPUS and accepted by the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), a nongovernmental organization made up of scientists and clinicians trained in homeopathic medicine that maintains the HPUS. In addition, the Federal Trade Commission holds efficacy and safety claims made in the marketing of over-the-counter homeopathic drugs to the same substantiation standards as similar claims for non-homeopathic drugs.

The FDA's Enforcement Priorities and New Draft Guidance Document

The validity of homeopathic principles has been subjected to significant scientific skepticism, but the homeopathic drug market has nonetheless grown into a nearly \$3 billion industry. This growth includes an increasing number of untested, unapproved products that may make unsubstantiated health claims, which, in turn, may endanger patients.

The FDA's recently issued Draft Guidance recognizes that the agency lacks the resources to bring enforcement actions against all violators in the expanding homeopathy industry and therefore describes a risk-based approach to enforcement. Specifically, the FDA proposes prioritizing enforcement and regulatory action by evaluating risks associated with products:

- With reported safety concerns
- That contain or purport to contain ingredients associated with potentially significant safety concerns
- Administered other than orally or topically
- Intended to be used for prevention or treatment of serious and/or life-threatening diseases and conditions
- Directed at vulnerable populations
- Deemed adulterated under Section 501 of the FDCA

More simply, the FDA will prioritize targeting products that it believes pose the highest risk. For example, in 2017, the FDA issued warning letters to six manufacturers of homeopathic drug products, including [a warning letter to HomeoCare Laboratories, Inc.](#) for serious violations related to CGMPs, misbranding, and manufacturing processes that could expose patients to unnecessary risks. In particular, some of HomeoCare's products contained strychnine (rat poison), a highly toxic ingredient associated with potentially significant safety concerns. Further, the company offered drugs for conditions that require diagnosis or treatment by a licensed practitioner but did not comply with corresponding labeling requirements. The warning letter concluded by reiterating the FDA's position regarding homeopathic drugs: They "are subject to the same regulatory requirements as other drugs; nothing in the [FDCA] exempts homeopathic drugs from any of the requirements related to adulteration, labeling, misbranding, or approval."