

Protect Access to Homeopathic Medicines: Co-Sign Letter to FDA

Endorsed by: Americans for Homeopathy Choice, National Center for Homeopathy, American Institute of Homeopathy, Alliance for Natural Health USA, Citizens for Health

Commissioner Janet Woodcock
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Woodcock,

Thank you for your ongoing efforts to protect public health, particularly during this critical stage of the COVID-19 pandemic. We are writing about the draft guidance on drug products labeled as homeopathic as issued by the Food and Drug Administration (FDA or Agency) in 2017 and revised in 2019. We understand that the FDA is concerned about products labeled as homeopathic that push the envelope, prompting the Agency to reevaluate its regulatory approach to keep them within the appropriate guardrails of traditional homeopathic drugs. Unfortunately, the guidance has disproportionately impacted manufacturers who produce safe, genuine homeopathic products, which in turn has made a growing number of these medicines less accessible, if not entirely unavailable, to consumers who rely on them.

Since 1938 until 2017, the FDA consistently recognized the distinction between pharmaceutical and homeopathic drugs, and Congress has repeatedly reaffirmed this distinction as set forth in the Food, Drug, and Cosmetic Act. Most recently in 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which exempts homeopathic drugs from review under its provisions regarding pharmaceutical drugs. In 1938, the FDA supported the decision to recognize the Homeopathic Pharmacopoeia of the United States and its supplements as the official compendium of standards and monographs for homeopathic drug ingredients giving the Agency the tools to regulate homeopathic drugs as a unique and separate category of drugs. On several occasions the FDA has commented on this distinction as set forth by Congress, and the Agency's policies have been in adherence with the law which, as the FDA stated in 1988, "gives no premarket review of true homeopathic dilutions."¹

This distinction has previously allowed the FDA to enforce standards that separate and safeguard legitimate homeopathic products while permitting swift action against products that are adulterated, misbranded, or improperly labeled as homeopathic. It helps to protect consumers, provides manufacturers with a clear pathway to market their products, and ensures access to products which meet homeopathic standards for quality and purity.

However, the draft guidance outlines enforcement priorities that do not distinguish between products that meet homeopathic standards and those that are adulterated, misbranded, or

¹ Food and Drug Admin., Talk Paper No. T-88-68 (Sept. 15, 1988). The FDA Talk Paper states, "...the law gives FDA no pre-market review of true homeopathic dilutions," and the authors of the Food, Drug, and Cosmetic Act "wrote into the law a recognition of any product listed in the Homeopathic Pharmacopoeia of the United States. This exempted homeopathic products from safety review, but that was of little concern at the dilutions being used. The 1962 drug amendments left the homeopathic exemption intact..."

improperly labeled as homeopathic. Under this guidance, manufacturers who comply with standards for quality, purity, and proper dilution are subject to enforcement action for products which are nontoxic by their very nature when made according to those standards. Additionally, the draft guidance no longer references the framework by which homeopathic manufacturers can legally market their products without risk of enforcement action, raising concerns about the stability of the market and the availability of homeopathic drug products among our constituents.

In congruence with both the 2021 and 2022 Appropriations report in which Congress “urges FDA to consider the views of patients in finalizing its draft guidance,” we are writing to understand how the FDA intends to utilize and adhere to the framework established by Congress as well as the Agency in order to protect consumers and ensure access to the products that meet homeopathic standards for quality and purity. Thank you again for your ongoing work to improve access to safe and affordable healthcare and thank you for your full and fair consideration of this inquiry.

Sincerely,

Ro Khanna
Member of Congress

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