

**LEGAL STATUS OF HOMEOPATHY
IN THE UNITED STATES OF AMERICA**

**A JOINT DOCUMENT PRODUCED BY THE
AMERICAN INSTITUTE OF HOMEOPATHY**

AND THE

**HOMEOPATHIC PHARMACOPOEIA CONVENTION
OF THE UNITED STATES**

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Historically in the United States of America, the manufacture and the sale of drugs are regulated at the federal level and the physician practice of medicine is regulated at the state level.

SECTION I HOMEOPATHIC DRUG PRODUCTS

Homeopathic medicine was introduced to the United States in New York in 1825 by American born, European educated Dr. Hans Burch Gram. Established physicians were drawn to homeopathy when they witnessed success in their unresolved cases, in their family members, or in themselves. The medical practice of homeopathy spread next into Pennsylvania and thence to Virginia, following German immigration, as, until 1835, texts were available only in the founder Dr. C.F. Samuel Hahnemann's native German. Thus, these medicines had been available and had been used safely and effectively in this country for over a century prior to the enactment of the Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. § 301. See attachment #1). The actions, at the time, of homeopathic physician and U.S. Senator Dr. Royal S. Copeland (1868-1938), ensured the inclusion of homeopathic medicines in that act as drugs, both prescription and non-prescription (SEC. 201. (g)(1) of the Act 21 U.S.C. §321. See attachment #2). The inclusion of homeopathic pharmaceuticals in that act means that the FDA is charged with regulating homeopathic, as well as allopathic medicines, and, therefore, recognizes uniformly the *Homeopathic Pharmacopoeia of the United States (HPUS)* and the *USP*.

The *HPUS* having been first published in 1897 by the American Institute of Homeopathy (1844), the oldest extant national medical association in the United States, the *HPUS* is now published under the separately incorporated auspices of the Homeopathic Pharmacopoeia Convention of the United States (1981(501(c)(3)). Among the purposes for which the HPCUS is organized are the following: "...to research and obtain a thorough knowledge of the pathogenicity of each drug offered for inclusion in the *Homeopathic Pharmacopoeia of the United States* as a homeopathic drug; to develop criteria for eligibility of drugs for inclusion in the *Homeopathic Pharmacopoeia of the United States*..." The *HPUS* is declared a legal source of information on drug products as an "official compendium" in the Federal Food, Drug, and Cosmetic Act (SEC. 201. (j) of the Act 21 U.S.C. §321. See attachment #2). The *HPUS* is also recognized in the Controlled Substances Act (21 U.S.C. § 802 See attachment #3).

Official homeopathic medications, which may carry a legend *HPUS* on their label (See atthmt #4), are manufactured under Good Manufacturing Practices according to methods set forth in the General Pharmacy section of the *HPUS*. Therefore, such medicines are uniform in their preparation, production, and labeling and by their inclusion therein, they come under the ultimate legal sanction of the FDA (Act, 21U.S.C. SEC. 501[351](b), SEC. 502[352](e)(3), SEC.502[352](g). See atthmt #5). Moreover, since in their preparation, homeopathic medical products are serially diluted and succussed, the active ingredient is present in minute amounts which would not prompt drug interactions with conventional medications, whether prescription or non-prescription. This is in contradistinction to phytopharmaceuticals, also termed herbal preparations, in which such drug interaction may present itself, e.g., ginkgobiloba and aspirin. While homeopathic medicine is an holistic, natural branch of complementary medicine whose medicinal sources may be botanical (including herbs), animal and mineral, homeopathy is not naturopathy or herbology and does not include the prescribing of phytopharmaceuticals.

Combination homeopathic products have been available to and used by the public from the earliest days of homeopathy in this country. Many westward migrating settlers carried such preparations in their medicine kits on their journey. (Statement Regarding Combinations of Homeopathic Drugs, *HPUS*, Introduction, p.3. See atthmt #6) There are and have been texts available to guide the interested individual in the use of homeopathic medications for appropriate self or family treatment.

Non-prescription and prescription (OTC/Rx) homeopathic drugs are regulated by the Food, Drug, and Cosmetic Act (FDCA) as promulgated in the regulatory document, the Compliance Policy Guide, 05/88. (FOOD AND DRUG ADMINISTRATION Compliance Policy Guides, Guide 7132.15, renamed 400.400 . See atthmt #7). Many combination homeopathic proprietaries and lower potency single remedy homeopathic medications are readily available to the public for use in minor self-limited conditions in health food stores, whole food supermarkets, and chain grocery stores and pharmacies. These products are analogous to allopathic OTC proprietaries and, as such, should be a viewed in a like manner by oversight committees (Compliance Policy Guides, Guide 7132.15, renamed 400.400. See atthmt #7). Homeopathic drugs offered for non-OTC conditions must by marketed as prescriptions (See atthmt #7). Further, the CPG exempts homeopathic drugs from expiration date labeling.

A petition to the FDA from the Homeopathic Pharmacopoeia Convention of the United States and from the American Association of Homeopathic Pharmacists was successful in reversing the CPG marketing condition that the homeopathic drug products be labeled with English names, permitting them to be marketed under their traditional Latin names. (Correspondence dated 06/27/1989. See atthmt #8)