

Homeopathic Drug Regulation

By Paul J. Wisniewski*

The following summarizes the manner in which the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) generally enforce the legal requirements covering Over-the-Counter (OTC) Homeopathic drugs. The legal authority for these Agencies includes the Federal Food, Drug and Cosmetic Act (FDCA) and the false advertising prohibitions of Sections 12 and 15 of the Federal Trade Commission Act (FTC Act)(15 U.S.C. §§ 52, 55).

I. HOMEOPATHIC PHARMOCOEPIA OF THE UNITED STATES (HPUS)

The HPUS constitutes the official compendium of homeopathic drug products recognized by the FDA. The HPUS is produced from the standpoint of safety, efficacy, and standardization of therapeutic ingredients. It establishes tables that identify available remedies and indicate potency levels at which those remedies may be sold. This compendium provides a clear set of standards for manufacturers of Homeopathic drug products which have not fostered any notable controversy with the FDA.

Homeopathy and the HPUS also receive special status under the FDCA as well as other federal legislation which classifies or defines drugs. For example, Section 201(g)(1) of the FDCA, 21 U.S.C. §321(g)(1), defines the term "drug" as "articles recognized in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, official National Formulary or any supplement to any of them . . ." (emphasis added).

Whenever a drug is recognized in both the United States Pharmacopoeia (USP) and the HPUS, Section 501 of the FDCA, 21 U.S.C. §351, states that drugs labeled and offered for sale as homeopathic drugs are governed only by HPUS standards. The quality or purity standards set forth in the HPUS apply exclusively to Homeopathic drugs. In addition, Section 502 of the FDCA, 21 U.S.C. §352, also recognizes the HPUS as one of only three "official" compendia under the

law. That section applies HPUS labeling standards to products labeled and offered for sale as Homeopathic drugs.

Homeopathy also is recognized in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (popularly known as the Federal Controlled Substances Act), 21 U.S.C., §801 et seq.

The HPUS has undergone continual revision for more than a Century. A candidate for inclusion as a drug ingredient recognized in the HPUS must generally undergo the "provings" which have always been the primary basis of homeopathic preparations or have demonstrated that it produces "cured symptoms". In turn, the evidence in support of a candidate is closely evaluated by a Monograph Review Committee, an expert panel which broadly represents homeopathy. It is only when a particular remedy is satisfactory to this Committee with reference to its safety and efficacy, as well as passes scrutiny by the Pharmacopoeia Review Committee and the Board of Directors, is it approved for inclusion in the HPUS. Thus, the inclusion of an ingredient in the homeopathic literature confirms that it has passed the applicable homeopathic approval process analogous in many ways to the new drug approval process to which allopathic medicals are subjected.

In sum, Homeopathic drugs that meet standards for strength, quality and purity set forth in the HPUS are completely lawful to sell. The safety and efficacy of homeopathic drugs are based upon a time-tested system that allows only those ingredients that have been "proven" by Homeopathic methods to appear in the official compendia of that medical discipline. Homeopathic drugs permitted for OTC sale are not plagued by questions of safety and efficacy when labeled for use by infants and young children.

II. FDA COMPLIANCE

The FDA, Congress and the courts have long recognized that certain signs, symptoms or indications are widely known to the general population and that these conditions can be treated by individuals who select their drugs without the need for intervention by a licensed medical practitioner. For example, ordinary stress, coughs, colds, minor aches and pains, and discomforts associated with the menstrual cycle are widely recognized by the FDA as appropriate for individual diagnosis and subsequent treatment with preparations without the need for intervention of a physician, whether allopathic or homeopathic.

Consistently, Homeopathic drugs are readily available to treat a vast array of symptoms and concerns represented by OTC pharmaceutical preparations and beyond, including safe, homeopathically proven remedies for infants and young children.

A. Compliance Policy Guide. In 1988, the FDA issued Compliance Policy Guide No. 7132.15 ("CPG") which discusses the conditions under which homeopathic drugs may be marketed in the United States (http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg400-400.html). One of the key provisions is how the FDA classifies prescription versus non-prescription drugs. The CPG states that the criteria specified in Section 503(b) of the Act, which dictates prescription status for drugs (habit-forming, toxicity/safety, issues of administration/uses or approved by FDA for prescription use only), apply to determine the prescription drug status of a homeopathic drug. The CPG also states that if the HPUS specifies the distinction between OTC and prescription status, based upon the strength of the active homeopathic ingredient, the more stringent criteria would apply.

In addition, the CPG states that homeopathic drugs intended solely for self-limiting disease conditions which are amenable to self-diagnosis and treatment by lay persons may be marketed over-the-counter. On the other hand, homeopathic drugs offered for conditions which may not be amenable to self-diagnosis or self-treatment by an untrained lay person must be marketed as prescription products. Thus, the FDA generally permits the OTC sale of a number of categories of drugs such as bronchodilators, laxatives, allergy relief products, decongestants, antacids, analgesics and others.

Although the FDA has never imposed strict limitations on homeopathic drug preparations, homeopathic drug products falling in or closely related to the foregoing categories are acceptable for OTC sale. The critical distinction is whether the illness can be adequately diagnosed and appropriate remedies selected by an untrained lay person. The FDA's Compliance Policy currently remains in effect.

When the active homeopathic ingredients, required labeling, indications, warnings, etc., of a product conform to the standards set forth in the homeopathic literature and the FDA's CPG and the product is intended solely for self-limiting conditions which symptoms are amenable to self-diagnosis and treatment, the product may be marketed over-the-counter pursuant to current FDA guidelines.

B. Drug Establishment Registration, GMP and Drug Listing Requirement Compliance. Pursuant to 21 U.S.C. §306(d), drug manufacturers, must "register" their establishments and be sure to "list" all drug products with the FDA. In addition, under regulations promulgated pursuant to the FDCA, the FDA has established current minimum good manufacturing requirements for drug products. See, 21 CFR §§ 210-211. Thus, a firm which prepares drug products is obligated to comply with detailed processing, packaging and labeling controls. Consumers should make sure that they are purchasing only those Homeopathic drugs that have been manufactured in an FDA-registered drug establishment in

accordance with all applicable good manufacturing and other practice standards that apply to this unique class of OTC drug products.

III. ADVERTISING PRACTICE COMPLIANCE

The FTC and state consumer protection agencies have authority to regulate advertising for OTC drugs pursuant to the FTC Act and parallel state consumer protection and deceptive trade practices laws.

Objective product claims, such as claims about a product's attributes, performance or efficacy, require adequate "substantiation". In turn, product representations that cannot be adequately demonstrated as being truthful and not misleading by advertisers at the time the claim is made can be considered "deceptive" by the FTC or a parallel state agency.

It is significant to note that, while FTC staff is aware of and acknowledges the FDA Compliance Policy Guide regarding homeopathic drugs, it is also aware of the fact that the FDA's document states the following: "A product's compliance with requirements of HPUS . . . does not establish that it is shown by appropriate means to be safe, effective and not misbranded for its intended use". (FDA CPG 7132.15, p.13). However, FTC personnel have also confirmed that "the Commission has not historically challenged advertising claims for homeopathic drugs that are listed in HPUS for uses for which there is a proving." It is also generally consistent with our experiences that the FTC does not ordinarily object to advertising for homeopathic drugs that make claims consistent with the standards established in the recognized homeopathic literature. Advertising for responsibly made and labeled OTC drug preparations have been accorded a very favorable regulatory environment.

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