CPG Sec. 400.400 Conditions Under Which Homeopathic Drugs May be Marketed

BACKGROUND:

The term "homeopathy" is derived from the Greek words homeo (similar) and pathos (suffering or disease). The first basic principles of homeopathy were formulated by Samuel Hahnemann in the late 1700's. The practice of homeopathy is based on the belief that disease symptoms can be cured by small doses of substances which produce similar symptoms in healthy people.

The Federal Food, Drug, and Cosmetic Act (the Act) recognizes as official the drugs and standards in the Homeopathic Pharmacopeia of the United States and its supplements (Sections 201 (g)(1) and 501 (b), respectively). Until recently, homeopathic drugs have been marketed on a limited scale by a few manufacturers who have been in business for many years and have predominantly served the needs of a limited number of licensed practitioners. In conjunction with this, homeopathic drug products historically have borne little or no labeling for the consumer.

Today the homeopathic drug market has grown to become a multimillion dollar industry in the United States, with a significant increase shown in the importation and domestic marketing of homeopathic drug products. Those products that are offered for treatment of serious disease conditions, must be dispensed under the care of a licensed practitioner. Other products, offered for use in self-limiting conditions recognizable by consumers, may be marketed OTC.

This document provides guidance on the regulation of OTC and prescription homeopathic drugs and delineates those conditions under which homeopathic drugs may ordinarily be marketed in the U.S. Agency compliance personnel should particularly consider whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy. If so, priorities and procedures concerning the agency's policy on health fraud would apply. (See CPG 7150.10 "Health Fraud-Factors in Considering Regulatory Action" 6/5/87).

DEFINITIONS:

The following terms are used in this document and are defined as follows:

1. Homeopathy: The practice of treating the syndromes and conditions which constitute disease with remedies that have produced similar syndromes and conditions in healthy subjects.
2. Homeopathic Drug: Any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, or its supplements. The potencies of homeopathic drugs are specified in terms of dilution, i.e., 1x (1/10 dilution), 2x (1/100 dilution), etc. Homeopathic drug products must contain diluents commonly used in homeopathic pharmaceutics. Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.
3. Homeotherapeutics: Involves therapy which utilizes drugs that are selected and administered in accordance with the tenets of homeopathy.

4. Homeopathic Pharmacopeia of the United States (HPUS): A compilation of standards for source, composition, and preparation of homeopathic drugs. HPUS contains monographs of drug ingredients used in homeopathic treatment. It is recognized as an official compendium under Section 201(j) of the Act.
5. Compendium of Homeotherapeutics: An addendum to the HPUS which contains basic premises and concepts of homeopathy and homeotherapeutics; specifications and standards of preparation, content, and dosage of homeopathic drugs; a description of the proving* process used to determine the eligibility of drugs for inclusion in HPUS; the technique of prescribing the therapeutic application of homeopathic drugs; and a partial list of drugs which meet the criteria of the proving process and are eligible for inclusion in HPUS and other homeopathic texts.
6. Extemporaneously Compounded OTC Products: Those homeopathic drug products which are often prepared by dilution to many variations of potency from stock preparations, and which: (1) have at least one OTC indication; (2) are prepared pursuant to consumers' oral or written requests; and (3) are not generally sold from retail shelves. Those products which are prescription drugs only cannot be provided to consumers as extemporaneously compounded OTC products but, may only be prepared pursuant to a prescription order.
7. * Health Fraud: The deceptive promotion, advertisement, distribution or sale of articles, intended for human or animal use, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes. Such practices may be deliberate, or done without adequate knowledge or understanding of the article.*

*A proving is synonymous with the homeopathic procedure (identified in HPUS as a "Research Procedure") which is employed in healthy individuals to determine the dose of a drug sufficient to produce symptoms.

DISCUSSION:

Section 201(g)(1) of the Act defines the term "drug" to mean articles recognized in the official United States Pharmacopeia (USP), the official Homeopathic Pharmacopeia of the United States (HPUS), or official National Formulary (NF) or any supplement to them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or the prevention of disease in man or other animals; articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any articles specified in the above. Whether or not they are official homeopathic remedies, those products offered for the cure, mitigation, prevention, or treatment of disease conditions are regarded as drugs within the meaning of Section 201(g)(l) of the Act.

Homeopathic drugs generally must meet the standards for strength, quality, and purity set forth in the Homeopathic Pharmacopeia. Section 501(b) of the Act (21 U.S.C. 351) provides in relevant part:

Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

A product's compliance with requirements of the HPUS, USP, or NF does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use.

A guide to the use of homeopathic drugs (including potencies, dosing, and other parameters) may be found by referring to the following texts: A Dictionary of Practical Materia Medica by John Henry Clarke, M.D., (3 volumes; Health Science Press) and A Clinical Repertory to the Dictionary of Materia Medica by John Henry Clarke, M.D. (Health Science Press). These references must be reviewed in conjunction with other available literature on these drug substances.

POLICY:

LABELING

Homeopathic drug product labeling must comply with the labeling provisions of Sections 502 and 503 of the Act and Part 201 Title 21 of the Code of Federal Regulations (CFR), as discussed below, with certain provisions applicable to extemporaneously compounded OTC products. Those drugs in bulk packages intended for manufacture or preparation of products, including those subsequently diluted to various potencies, must also comply with the provisions of Section 502 of the Act and Part 201 (21 CFR 201).

General Labeling Provisions

Name and Place of Business: Each product must bear the name and place of business of the manufacturer, packer, or distributor in conformance with Section 502(b) of the Act and 21 CFR 201.1.

Directions for Use: Each drug product offered for retail sale must bear adequate directions for use in conformance with Section 502(f) of the Act and 21 CFR 201.5. An exemption from adequate directions for use under Section 503 is applicable only to prescription drugs.

Statement of Ingredients: Ingredient information shall appear in accord with Section 502(e) of the Act and 21 CFR 201.10. Labeling must bear a statement of the quantity and amount of ingredient(s) in the product in conformance with Section 502(b) of the Act, as well as 21 CFR 201.10, expressed in homeopathic terms, e.g., lx, 2x.

Documentation must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients.

Established Name: The product must be in conformance with Section 502(e)(1) of the Act and must bear an established name in accord with Section 502(e)(3) of the Act and 21 CFR 201.10. Many homeopathic products bear Latin names which correspond to listings in the HPUS. Since Section 502(c) of the Act and 21 CFR 201.15(c)(1) require that all labeling be in English, the industry is required to translate these names from Latin to their common English names as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first. It is permissible for industry to include in the labeling both English and Latin names.

Container Size - Labeling Exemption: For those products packaged in containers too small to accommodate a label bearing the required information, the labeling requirements provided under Section 502 of the Act and 21 CFR 201 may be met by placing information on the carton or outer container, or in a leaflet with the package, as designated in 21 CFR 201.10(i) for OTC drugs and in 21 CFR 201.100(b)(7) for prescription drugs. However, as a minimum, each product must also bear a label containing a statement of identity and potency, and the name and place of business of the manufacturer, packer, or distributor.

Language: The label and labeling must be in the English language as described and provided for under 21 CFR 201.15(c)(1), although it is permissible for industry to include foreign language in the labeling, as well.

Prescription Drugs

The products must comply with the General Labeling Provisions above, as well as the provisions for prescription drugs below.

Prescription Drug Legend: All prescription homeopathic drug products must bear the prescription legend, "Caution: Federal law prohibits dispensing without prescription," in conformance with Section 503(b)(1) of the Act.

Statement of Identity: The label shall bear a statement of identity as provided for under 21 CFR 201.50.

Declaration of Net Quantity of Contents and Statement of Dosage: The label shall bear a declaration of net quantity of contents as provided in 21 CFR 201.51 and a statement of the recommended or usual dosage as described under 21 CFR 201.55.

General Labeling Requirements: The labeling shall contain the information described under 21 CFR 201.56 and 21 CFR 201.57. For all prescription homeopathic products, a package insert bearing complete labeling information for the homeopathic practitioner must accompany the product.

OTC Drugs

Product labeling must comply with the General Labeling Provisions above and the provisions for OTC drugs below, as current labeling stocks are depleted or by June 11, 1990, whichever occurs first.

Principal display Panel: The labeling must comply with the principal display panel provision under 21 CFR 201.62.

Statement of Identity: The label shall contain a statement of identity as described in 21 CFR 201.61.

Declaration of Net Quantity of Contents: The label shall conform to the provisions for declaring net quantity of contents under 21 CFR 201.62.

Indications for Use: The labeling for those products offered for OTC retail sale must bear at least one major OTC indication for use, stated in terms likely to be understood by lay persons. For extemporaneously compounded OTC products, the labeling must bear at least one major OTC indication for use, stated in terms likely to be understood by lay persons. For combination products, the labeling must bear appropriate indications(s) common to the respective ingredients. Industry must comply with the provisions concerning indications for use as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first.

Directions for Use: See the General Labeling Provisions above.

Warnings: OTC homeopathic drugs intended for systemic absorption, unless specifically exempted, must bear a warning statement in conformance with 21 CFR 201.63(a). Other warnings, such as those for indications conforming to those in OTC drug final regulations, are required as appropriate.

Prescription/OTC Status

The criteria specified in Section 503(b) of the Act apply to the determination of prescription status for all drug products, including homeopathic drug products. If the HPUS specifies a distinction between nonprescription (over-the-counter (OTC)) and prescription status of products which is based on strength (e.g., 30x) - and which is more restrictive than Section 503(b) of the Act - the more stringent criteria will apply. Homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. Homeopathic products offered for conditions not amenable to OTC use must be marketed as prescription products.

Home Remedy Kits Homeopathic home remedy kits may contain several products used for a wide range of conditions amenable to OTC use. When limited space does not allow for a list of those conditions on the labels of the products, the required labeling must appear in a pamphlet or similar informational piece which is enclosed in the kits. However, as a minimum, each product must also bear a label containing a statement of identity and potency.

Other Requirements

All firms which manufacture, prepare, propagate, compound, or otherwise process homeopathic drugs must register as drug establishments in conformance with Section 510 of the Act and 21 CFR 207. Further, homeopathic drug products must be listed in conformance with the sections above. (Note: For a given product, variations in package size and potency are not required to be listed on separate forms 2657 but instead, may be listed on the same form). Homeopathic drug products must be packaged in accordance with Section 502(g) of the Act. Homeopathic drug products must be manufactured in conformance with current good manufacturing practice, Section 501(a)(2)(B) of the Act and 21 CFR 211. However, due to the unique nature of these drug products, some requirements of 21 CFR 211 are not applicable, as follows:

1. Section 211.137 (Expiration dating) specifically exempts homeopathic drug products from expiration dating requirements.
2. Section 211.165 (Testing and release for distribution): In the Federal Register of April 1, 1983 (48 FR 14003), the Agency proposed to amend 21 CFR 211.165 to exempt homeopathic drug products from the requirement for laboratory determination of identity and strength of each active ingredient prior to release for distribution.

Pending a final rule on this exemption, this testing requirement will not be enforced for homeopathic drug products.

REGULATORY ACTION GUIDANCE:

Those firms marketing homeopathic drugs which are not in compliance with the conditions described above will be considered for regulatory follow-up. <> The Office of Compliance, HFD-304, Center for Drug Evaluation and Research, should be consulted before *warning* letters are issued.

Recommendations for the issuance of *warning* letters or other regulatory sanctions must be submitted in conformity with the Regulatory Procedures Manual and other Agency guidance concerning the review of regulatory actions.

Material between asterisks is new or revised
<> Indicates material has been deleted

Issued: 5/31/88
Revised: 3/95

More in Compliance Policy Guides (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

Foreword: Compliance Policy Guides (CPGs) (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm)

Chapter 1 - General (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116280.htm)

Chapter 2 - Biologics (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116336.htm)

Chapter 3 - Devices (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116801.htm)

Chapter 4 - Human Drugs (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119572.htm)

Chapter 5 - Food, Colors, and Cosmetics (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm)