The Role of the Homoeopathic Pharmacopoeia Convention of the United States in the Regulation of Homeopathic Drug Products

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Publication by the independent Homoeopathic Pharmacopoeia Convention of the United States
HPCUS is incorporated as an independent body.

1980

Eighth edition, Supplement A (Baker)

Development of Compliance Policy Guide 7132.15

1982

HPUS Revision Service (HPRS)

1983

Compliance Policy Guide 7132.15 becomes effective

1988

HPRS is complete, semi-annual updates:
Supersedes Compendium and Supplement A as the official compendium.

1990

Monographs, General Pharmacy, Standards and Controls updated semi-annually

1992

HPUS online begins, immediate/real-time updates

2004

Publication by the independent Homoeopathic Pharmacopoeia Convention of the United States
HPCUS Mission

1. “To accumulate pertinent information and publish and to sell the *Homoeopathic Pharmacopoeia of the United States* and any additions or supplements thereto,

2. to promote the art of healing according to the natural laws of cure from a strictly homoeopathic standpoint;

3. to diffuse knowledge among the laity and professionals in the health care field concerning homoeopathic principles through means of publications;

4. to research and obtain a thorough knowledge of the pathogenicity of each drug offered for inclusion in the *Homoeopathic Pharmacopoeia of the United States* as a homoeopathic drug;

5. to develop criteria for eligibility of drugs for inclusion in the *Homoeopathic Pharmacopoeia of the United States* to serve as a repository for homoeopathic literature and drugs;

6. and generally to do, perform, undertake, direct, encourage and investigate all aspects and functions of any nature directed to the furtherance of homoeopathic healing.”
HPCUS Activities

Drug Monograph Evaluation

Pharmaceutics and Pharmaceutical Methods including GMPs

Generation and evaluation of Standards and Controls parameters

Continual Safety and Toxicology evaluation

Continuous improvement to methods of data
1906

Food and Drugs Act, Pub. L. No. 59-384, only listed the United States Pharmacopoeia ("USP") and the National Formulary.
1912

Senator Jacob Gallinger (R-NH), a homeopathic physician, sponsored a bill that would have added the Homeopathic Pharmacopoeia of the United States (HPUS) to the 1906 Act.
1934

Senator Royal Copeland (D-NY), also a homeopathic physician, became the sponsor of legislation for a New Food and Drug Act that included reference to HPUS.
Senator Copeland sought a bill that would recognize the diversity of medical practice in order to gain support for the legislation.
1938

The Federal Food, Drug and Cosmetic Act finally passed and it included reference to the HPUS.
Drug – 21 U.S.C. §321(g)(1)

The term “drug” means (A) articles recognized in the official USP, official HPUS or National Formulary, or any supplement.
In 1972, in a meeting concerning the OTC Review between a homeopathic representative and FDA, the agency decided to postpone the review of homeopathic drugs until after the OTC Review.

(37 Fed. Reg. 9464, Comment 25 (May 11, 1972))
1988
FDA issued Compliance Policy Guide (CPG) Section 400.400 Conditions Under Which Homeopathic Drugs May be Marketed.

1995
The CPG was revised.
Over the 77 years since the 1938 Federal Food, Drugs, and Cosmetic Act was passed, FDA has taken action against adulterated and misbranded drugs whether non-homeopathic or homeopathic.
Monographs by the Numbers

699  Monographed substances in HPUS Eighth edition
+ 428  Substances in Compendium of Therapeutics
+ 167  Substances in long term use (prior to 1972)
+ 9  Recently completed monographs (2007 -2015)
- 8  Substances found in the literature or submitted that were duplicates under other names

1295 present monographs
HPUS Guidance

• Guidelines for homeopathic manufacturing
  – GMPs
• Official Short Names
• Official Synonyms
• Labeling Guidelines
• Minimum Safe Potency Guidelines
  (Drug Tables)
Monograph Review History

- 18 monograph submissions
- 9 monograph approvals
- 3 monographs in review

In the past 10 years
Monograph Review Committee

Experts in homeopathic pharmacy, toxicology, and analytic methodology

Primary evaluation tasks:

• GMP
• Safety
Monograph Review Committee

1. Substance Identification
2. Quality standards
3. Manufacturing process
4. Analytic procedures
5. Storage and stability data
6. Toxicology
7. First safe OTC and Rx attenuations
Pharmacopeia Review Committee

Expert panel of physicians, methodologists, and epidemiologists with experience using and researching homeopathic medicines

Primary evaluation tasks:
• Safety
• Potential usefulness
Pharmacopeia Review Committee

1. Investigator qualifications
2. Historical information
3. Study design and methodology
4. Data collection and recordkeeping
5. Safety assurance
6. Ethical and legal compliance
7. Analysis of study results
Monograph Process Overview

Monograph Review Committee

Pharmacopeia Review Committee

HPUS Board of Directors

HPUS Editor