Comparison of Homeopathic Medicines with Conventional Drugs

Approval Process

Contrary to law, the FDA's draft guidance entitled *Drug Products Labeled as Homeopathic: Guidance for FDA Staff and Industry* would require these medicines to be vetted through the New Drug Application (NDA) instead of the approval process authorized in the federal Food, Drug and Cosmetic Act.

> The federal Food, Drug and Cosmetic Act (the Act) **recognizes as official the drugs and standards in the Homeopathic Pharmacopoeia of the United States (HPUS)** and its supplements. *Sections 201 (g)(1) and 501 (b)*
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> Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia. *Section 501 (b)*

Key Decisions for FDA Reviewer under NDA (Source: U.S. Food and Drug Administration Website)	Key Decisions for Homeopathy (Source: HPUS Website)
The goals of the NDA are to provide enough information to permit an FDA reviewer to reach the following key decisions:	**These key decisions can be reached through the approval process specified in the Act, as well as the manufacturing and labeling requirements in the Code of Federal Regulations (CFR).**
Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.	To be eligible for inclusion in the HPUS, the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS) must have determined that the drug is safe and effective, has been prepared according to the specifications of the General Pharmacy and relevant sections of the HPUS, is submitted with documentation in an approved format, and has demonstrated efficacy in clinical provings, clinical trials or therapeutic experience.
Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.	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).
Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.	Homeopathic drugs generally must meet the standards for strength, quality, and purity set forth in the Homeopathic Pharmacopoeia.

Regulatory Framework

A comparison of conventional drugs and homeopathic medicines demonstrates the rationale for a separate regulatory framework.

Conventional Drugs	Homeopathic Medicines
ALLOPATHIC PRINCIPLES ▪ Uses drugs that produce effects **opposite** to those caused by the disease itself. ▪ These drugs work by **primary action** to chemically suppress symptoms and physiologic pathways. ▪ **Example:** In the case of a sprained ankle, using ice and NSAIDs along with immobilization opposes the innate homeostatic healing pathways by reducing symptoms such as heat and swelling (created by the body to repair the injury). This can delay recovery though it does relieve symptoms.	**HOMEOPATHIC PRINCIPLES** ▪ Uses medicines that produce effects **similar** to those caused by the disease itself. ▪ These medicines work by **secondary drug reaction**, a physiologic (nonchemical) healing response generated by the body. ▪ **Example:** In the case of a sprained ankle, swelling, heat, pain and redness indicate the body's natural inflammatory healing responses as extra blood rushes to the area to repair the damage. Adding warmth, along with the medicine Arnica and massage helps *increase* blood flow and repair processes that speed recovery.
INHERENTLY TOXIC ▪ Tend to be **toxic** and associated with **side-effects** which in some cases can be lethal. ▪ Drugs are synthesized **chemical compounds** that are inevitably toxic at high doses.	**INHERENTLY SAFE** ▪ Inherently safe, **nontoxic** and only rarely associated with **mild and self-limited** side-effects. ▪ These medicines are made from **highly diluted** (and succussed) ingredients originating from **animal, botanical and mineral** sources.
LEADING CAUSE OF DEATH ▪ In 2018 alone, the Federal Adverse Event Reporting System (FAERS) database received 1,109,481 reports of serious events and 197,060 death reports associated with the use of drug or biological products. By some estimates, Adverse Drug Reactions (ADR) are the 4th leading cause of death in the U.S. *FDA*	**NO DEATHS OR INJURIES** ▪ The FDA has not received a single Adverse Event Report for a homeopathic classical (single agent oral) medicine manufactured to the dilution level of 6c potency or greater.
NON-INDIVIDUALIZED ▪ Drugs used in both clinical trials and in practice **treat the body piecemeal** with different medicines for different pieces.	**INDIVIDUALIZED** ▪ Medicines used in both clinical trials and in regular practice use the **totality of symptoms** (mental & physical) as a guide to treat the whole person.

▪ Drugs are designed to address a specific symptom(s) or disease process and can therefore be labeled as such. ▪ Side-effects are common and often predictable.	▪ Where conventional medical practitioners might diagnose two people with the same condition and prescribe exactly the same medicine, a homeopathic practitioner would consider each individual's unique set of symptoms. This often results in a different medicine recommended for two people with the same underlying condition (as diagnosed by a conventional practitioner). ▪ This individualized approach is why labeling homeopathic medicines on the basis of a single clinical indication (for example, to treat a cough) is not consistent with the principles of homeopathy. ▪ Side-effects are exceedingly rare if the **totality of symptoms** approach is used.
SHORTER HISTORY ▪ Guidance for use is sometimes determined by Randomized Clinical Trials. According to *BMJ* Clinical Evidence*, 89% of clinical interventions are not supported by these studies, though they sometimes have other backing. ▪ Mechanisms of action are frequently "unknown." The theoretical framework is in accord with chemical pharmacodynamics and toxicology. *British Medical Journal	**LONG HISTORY** ▪ Guidance for use is determined by more than **two centuries** of compiled clinical experience and thousands of research studies, papers, and clinical trials. ▪ Mechanisms of action are consistent with observed pharmacokinetic and biochemical laws of: **Hormesis, Homeostasis, The Human Microbiome, Ecology, and Network Nanomedicine.**

Homeopathic Medicines Are In A Different Category

Homeopathic medicines are in a different category from conventional drugs, a fact recognized by the unique provisions in the federal Food, Drug, and Cosmetic Act. Americans for Homeopathy Choice is proposing legislation that will reaffirm this fact by enacting a comprehensive and sound regulatory framework designed to maintain the high quality and purity of homeopathic medicines and protect consumer access to the full range of inherently safe homeopathic products.