



---

## FDA Warning Letters to Producers of Homeopathic Medicines Show that CPG 400.400 Works

*Americans for Homeopathy Choice continues to urge adoption of CPG 400.400 as a long-term framework for homeopathy regulation*

April 3, 2019

[Recent warning letters](#) to four manufacturers of homeopathic medicines from the U.S. Food and Drug Administration (FDA) show that the process outlined in [Compliance Policy Guide Section 400.400 \(CPG 400.400\)](#) – a process which ensures that manufacturers abide by Current Good Manufacturing Practices (CGMP) and meet standards of quality and purity – is alive and well.

While AFHC takes no position on these particular warning letters, we believe that the totality of FDA actions regarding homeopathic medicine producers demonstrates that CPG 400.400 is working as designed. In its inspections, the FDA is identifying problems it believes affect the quality and purity of homeopathic products, and it is then taking actions to correct those problems.

CPG 400.400 has served as the FDA’s framework for governing homeopathic medicines for more than 30 years. That framework has protected the public and made it possible for homeopathy to thrive. This is why AFHC is seeking a legislative approach that would secure protections found in CPG 400.400.

This is also why we oppose [the FDA’s proposed draft guidance on homeopathic medicines](#) which would repeal and replace CPG 400.400. CPG 400.400 explicitly states that producers of homeopathic medicines must follow CGMP and meet quality and purity standards outlined in the Homeopathic Pharmacopoeia of the United States (HPUS). Under the draft guidance the role of the FDA in policing quality and purity would become uncertain at best.

The draft guidance also violates the Food, Drug and Cosmetic Act by ignoring the review and approval process used for homeopathic medicines to determine inclusion in the HPUS. The HPUS is specifically referenced in the law. The draft guidance defines all homeopathic medicines as “unapproved” and subject to the New Drug Application process designed for conventional pharmaceuticals. This means that the more than 1,300 homeopathic medicines currently approved and listed in the HPUS would suddenly become “unapproved” and subject to a ban by the FDA.

Our legal counsel has advised us that such an outcome would be illegal. We at AFHC would oppose it vigorously in the courts and by all other means available.

It is unfortunate that the FDA continues to release misleading information about homeopathy when the correct information can be found in its own policy documents, namely CPG 400.400, and in the Food, Drug and Cosmetic Act. In the news release mentioned above, the FDA states the following:

Products labeled as homeopathic have not been approved by the FDA for any use and may not meet modern standards for safety, effectiveness and quality.

This statement by the FDA leaves the impression that homeopathic medicines do not go through an approval process. This is false. They go through a review and approval process administered by the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) which determines which medicines are eligible for inclusion in the HPUS. Again, the HPUS is specifically referenced in the Food, Drug and Cosmetic Act.

A second claim made in the statement is vague. What the agency means by “modern standards” isn’t spelled out. Manufacturers of homeopathic medicines are required like all other manufacturers regulated by the FDA to follow CGMP. When they don’t, the FDA can take action under CPG 400.400 as the agency has done against the four companies mentioned above. However, if the draft guidance were to become final, the agency’s ability to enforce CGMP or quality and purity standards mandated by the HPUS would become uncertain at best.

Regarding safety and effectiveness, homeopathic medicines do, in fact, meet current standards for safety and effectiveness which are determined by the HPCUS.

Homeopathic medicines are an important and growing component of American health care because they are inexpensive, widely available, easy to administer, inherently safe (nontoxic) and, most of all, because they work.

**Prepared by:**  
**Americans for Homeopathy Choice**  
**Info@HomeopathyChoice.org**  
**homeopathychoice.org**