Recent FDA Draft Guidance Concerning Homeopathy

Impact on the Compliance Policy Guide section 400.400

Prepared by Americans for Homeopathy Choice
www.homeopathychoice.org

In December 2017 the U.S. Food and Drug Administration issued the new Draft Guidance titled "Drug Products Labeled as Homeopathic" which states that the Compliance Policy Guide 400.400 (CPG) previously governing homeopathic remedies would be withdrawn by the agency if the draft guidance became final. The CPG 400.400 has successfully guided the FDA's enforcement activities regarding the manufacturing and marketing of homeopathic products for the last 30 years. During this time very few safety concerns have surfaced, especially when compared to those surrounding pharmaceuticals. Withdrawing the CPG returns the homeopathic industry to an environment of without clear guidelines for the manufacture and labeling of homeopathic remedies.

What are the origins of the CPG 400.400?

Before the FDA issued the Compliance Policy Guide 400.400 (CPG) called "Conditions Under Which Homeopathic Drugs May Be Marketed" in 1988, there was inconsistent enforcement of regulations for homeopathic products by the FDA and regulations were not clearly understood within the industry. The FDA in consulted with the American Association of Homeopathic Pharmacists (AAHP) while formulating what became CPG 400.400. This guidance provided clear expectations for the manufacturing and marketing of homeopathic products. This resulted in the elimination of substandard or mislabeled products and contributed to the enviable safety record of homeopathic products over the last 30 years.

What actions has the FDA taken in recent years to assess the CPG 400.400?

In 2015 the FDA initiated a review of the regulatory structure of homeopathic products noting the CPG had not been materially updated since 1988. The agency also pointed to the growth of the market for homeopathic products and alleged that there were safety concerns. The FDA held a public hearing to determine if any areas of the CPG needed further clarification. During the 2015 hearing the homeopathic community provided sound recommendations for improvement to the CPG.

Were any improvements to the CPG proposed by the FDA?

Unfortunately, the FDA largely ignored the recommendations made to it at the 2015 hearing and instead issued new Draft Guidance in December 2017 stating that, if adopted, the proposed guidance would remove the CPG. The FDA had the opportunity to further clarify and enhance an already successful regulation regime for the homeopathic industry. But instead the agency has chosen to rescind it.

What does the new Draft Guidance actually propose?

The Draft Guidance pulls homeopathy back into a pre-CPG era which means a return to unclear regulation and enforcement principles subject to arbitrary interpretations of the agency's staff. The FDA proposes to introduce a risk-based safety approach to certain categories of homeopathic products, even though the safety of these products has been long established.

The FDA wishes to remove a fair and enforceable guidance document that only needed some updating and proposes to replace it with unclear guidelines for the manufacturing and marketing of homeopathic products. Finally, the FDA has stated in face-to-face meetings that because of their admirable safety record, the great majority of homeopathic products on the market would continue to be available under their new guidance. But the proposed guidance does NOT state this and would NOT prevent the FDA from banning a substantial portion of homeopathic remedies now available.

In order to avoid this, the agency should provide the homeopathic industry with clear, effective guidance for the manufacturing and marketing of these products. That guidance is already available in the current CPG 400.400 guidance. The homeopathic industry seeks to enlist the help of Congress so that the FDA retains CPG 400.400, a guidance document which has for decades allowed for the safe and reliable delivery of homeopathic products to the consumer.