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**Recent FDA Draft Guidance**
***Impact to the Compliance Policy Guide section 400.400***

In December 2017, the FDA issued the new Draft Guidance titled, *Drug Products Labeled as Homeopathic,* which informs that the Compliance Policy Guide 400.400 (CPG) will be withdrawn by the agency. The CPG 400.400 has fairly guided the FDA's enforcement principles for the manufacturing and marketing of homeopathic products for the last 30 years, during which time homeopathy has grown into a 3-billion-dollar industry while also experiencing virtually no safety concerns to consumers. Withdrawing the CPG returns the homeopathic industry to an environment of unclear and burdensome guidelines.

**What are the origins of the CPG 400.400?**
Before the FDA issued the Compliance Policy Guide 400.400 (CPG), *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 consult with the American Association of Homeopathic Pharmacists (AAHP) issued the CPG 400.400, providing clear expectations for the manufacturing and marketing of homeopathic products. As a result, the manufacturing standards of homeopathic medicines were fine-tuned and the goal of removing counterfeit homeopathic products from the market was better achieved, both of which contributed to the high standard of safety of homeopathy products.

**What actions have 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, and pointing to the growth in the market along with alleged but rare safety concerns. As a result, the FDA assembled a public hearing to determine if any areas of the CPG needed further clarification. During the 2015 hearing, the homeopathic industry provided sound recommendations for improvement to the CPG, which the FDA could review and propose for implementation.

**Were any improvements to the CPG proposed by the FDA?**
Unfortunately, despite having received the evidence from homeopathy and other health professionals at the 2015 hearing, the FDA issued the new Draft Guidance in December 2017, which states they will remove the CPG, clearly disregarding all recommendations provided in 2015. The FDA had the opportunity to further clarify and enhance the compliance and consistency of an already well demonstrated, successfully-regulated industry, but has chosen instead to rescind it.

**What does the current Draft Guidance actually propose?**
The Draft Guidance pulls homeopathy back to a pre-CPG era, a return to unclear regulation enforcement principles that is subject to the impulses and arbitrary interpretations of the Agency's individual deputies. The FDA proposes to introduce a risk-based safety approach to the kinds of homeopathic products it will act against, even though the safety of these products has been well-established. The FDA has removed a fair and enforceable guidance document that only needed basic adjustments and proposes to replace it with unclear guidelines for the manufacturing and marketing of homeopathic products.

Finally, the FDA notes that because of their low-risk safety record, the great majority of homeopathic products on the market would continue to be made available under their new prospective guidance. They are then obligated to provide the homeopathic market with clear, effective guidance for the manufacturing and marketing or these products.

The homeopathic industry would like to enlist the help of Congress so that the FDA maintains the use of the CPG 400.400, a document which has—for decades—allowed for the safe and reliable delivery of homeopathic products to the consumer.