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insights

# FDA to step up enforcement of homeopathic medicine

Homeopathic medicine has long occupied a niche in American culture. Since 1988, with the issuance of the Compliance Policy Guide, § 400.400, "Conditions Under Which Homeopathic Drugs May be Marketed," the FDA has had a relatively hands-off relationship with homeopathic products. However, this is likely to change as the agency shifts to a risk-based enforcement approach under new FDA Draft Guidance issued in December 2017.

As a general matter, homeopathic medicine is based on two core concepts:

1. Substances that cause symptoms in a healthy person can be used in a diluted form to treat the same symptoms and illnesses in sick people. This is also known as the principle of "like cures like."

2. The more diluted a substance becomes, the more potent it becomes. This is also known as the "law of infinitesimals."

Practitioners of homeopathic medicine claim that taking a given compound and diluting it with water in increasing amounts results in a solution with a commensurate increase in therapeutic efficacy. That is, the lower the amount of symptom-causing compound in a homeopathic medicine, the greater the efficacy. Historically, practitioners have found therapeutic uses by dosing healthy people with symptom-inducing compounds, diluting the compound in water and giving the resulting compounds to unhealthy people presenting the same symptoms.

Homeopathy was recognized when the FDA was formed in 1938 with the passing of the Federal Food, Drugs and Cosmetics Act (FDCA). See 21 U.S.C. § 201(g)(1). When the FDCA was drafted, an article recognized in the Homeopathic Pharmacopoeia of the United States (HPUS) was considered a drug. However, the FDA's enforcement of the FDCA as to homeopathic companies has been inconsistent. Since 1988, the FDA has applied internal Compliance Policy Guide, CPG § 400.400 when regulating the homeopathic industry. Essentially, CPG §400.400 stated that the FDA will focus its enforcement efforts on those entities and products that did not comply with the relatively minimal requirements of the CPG.

Homeopathic medicine has in recent years expanded to include other niche industries that claim their products can cure diseases, decrease symptoms, or relieve discomfort. The homeopathic medicine industry has grown to a $3 billion per year industry in the U.S. and has seen an increase in products making claims of dubious accuracy.

With the FDA's new Draft Guidance entitled "Drug Products Labeled as Homeopathic: Guidance for FDA Staff and Industry," the FDA's enforcement policy is changing entirely and CPG § 400.400 from 1988 is being rescinded.

In releasing the new draft guidance, FDA Commissioner Scott Gottlieb stated:

"In recent years, we've seen a large uptick in products labeled as homeopathic that are being marketed for a wide array of diseases and conditions, from the common cold to cancer. In many cases, people may be placing their trust and money in therapies that may bring little to no benefit in combating serious ailments, or worse – that may cause significant and even irreparable harm because the products are poorly manufactured, or contain active ingredients that aren't adequately tested or disclosed to patients. Our approach to regulating homeopathic drugs must evolve to reflect the current complexity of the market, by taking a more risk-based approach to enforcement. We respect that some individuals want to use alternative treatments, but the FDA has a responsibility to protect the public from products that may not deliver any benefit and have the potential to cause harm."

## Homeopathic drugs are drugs once more

CPG § 400.400 stood for, among other things, an exception to the general rules surrounding drug products in the U.S. and applied relaxed requirements to homeopathic products. However, the FDA's new guidance re-establishes the FDCA's status quo wherein homeopathic products are once again drugs as defined in 21 U.S.C. § 321(g) and 21 U.S.C. § 262(a) and, as such, subject to the same pre-market application and review processes applicable to

drugs, biologics and over-the-counter products. This applies to product labeling and marketing requirements, as well as current good manufacturing practices and other regulatory requirements.

Now, instead of waiving many regulatory requirements applicable to drugs, the FDA is applying a risk-based enforcement approach, focusing the agency's efforts on products that pose the highest risk to patients:

- Products with reported safety concerns. These include products that are the subject of MedWatch reports or other reports received by the FDA related to safety or efficacy, adverse events, or other safety issues.
- Products containing high-risk ingredients. These products have ingredients the FDA recognizes as associated with safety concerns. These include:
  - Infectious agents
  - Controlled substances
  - Ingredients that can interact and cause safety issues
  - Ingredients that pose potential toxic effects in a given concentration found in the product
- Products that use dangerous or risky routes of administration. Products that use administration methods other than oral and topical applications, such as injections or ophthalmic application.
- Products that claim to treat serious and/or life threatening diseases of conditions or that target vulnerable populations. These products may put patients at risk by causing patients to delay or discontinue proven safe and effective treatment methods.
- Products found to be adulterated under FDA regulations.

## Implementation, enforcement and timelines are unknown

In the Draft Guidance and press release accompanying it, the FDA did not provide any kind of timeline for these enforcement activities. However, the agency explicitly stated that it will not be providing companies with advanced warning of enforcement actions. As such, it will be difficult to determine where a given product or company falls within the FDA's enforcement priorities. However, members of the homeopathic industry should immediately review current product offerings and related marketing to identify any relation to the five groups of high-risk products described by the FDA above.

If you or your company market homeopathic products and have any questions about this enforcement initiative or the Draft Guidance, or are interested in reviewing your current product offerings, please feel free to reach out to one of our team members for assistance. We have a team of attorneys experienced working with the FDA, FDA enforcement actions and product reviews that can help you understand where your risks may lie.

## authorsTest