After Decades of Broad Enforcement Discretion, FDA Signals New Approach to Homeopathic Drugs

Two announcements made by FDA in late October 2019 signaled a marked change to FDA's regulatory approach to "homeopathic" drugs. On October 25, 2019, FDA withdrew the 1988 Compliance Policy Guide ("CPG") 400.400 *Conditions Under Which Homeopathic Drugs May Be Marketed*, and, concurrently, published revised draft guidance titled *Drug Products Labeled as Homeopathic* (the "Revised Homeopathic Draft Guidance"). Please read links above for more complete details and context about these FDA changes.

The FDA has been working on this policy review since 2015. The U.S. based homeopathic industry and the Homoeopathic Pharmacopoeia Convention of the United States has had more than 5 years to prepare for or challenge these regulatory changes. The FDA was accepting comments to the Revised Homeopathic Draft Guidance through January 23, 2020. Additional time and advanced messaging from stakeholders might have encouraged a stronger industry a patient response. The time for input from professional the consumers for homeopathic products concludes on July 2, 2020 and current signals from the FDA point toward restructuring the approval and regulatory processes for homeopathic drug products in the U.S.

> Makers of Homeopathic products are asking providers and patients to contact their local federal legislators to voice concerns over the FDA's decision to remove legal protections and exemptions for homeopathic products sold and used in the United States.

Although homeopathic products meet the statutory "drug" definition under the Food, Drug, and Cosmetic ("FD&C") Act, FDA historically has exercised enforcement discretion for homeopathic drugs, subject to labeling and formulation requirements specified in CPG 400.400, and has not prioritized enforcement for products failing to meet these requirements.

At the time the FD&C Act was enacted, homeopathic products were a cottage industry—made primarily in small batches on an individual patient basis. Today, however, there is a burgeoning commercial industry, valued at approximately $ 5.39 billion globally as of 2017, marketing drug products labeled as "homeopathic." According to FDA, the increase in product availability has coincided with an increase in adverse event reports involving such products. These include reports of toxicity from belladonna-containing products and loss of smell caused by intranasal zinc products. FDA states in the Revised Homeopathic Draft Guidance that these adverse reactions occurred despite the products' apparent compliance with CPG 400.400's labeling and ingredient formulation requirements.

FDA first announced its intention to withdraw CPG 400.400 in a December 2017 draft guidance. At that time, the agency did not plan to withdraw CPG 400.400 until a final guidance with an updated regulatory strategy was issued. However, in a change of plans, FDA decided to withdraw CPG 400.400 concurrently with the release of the Revised Homeopathic Draft Guidance, thereby eliminating the "safe harbor" for homeopathic drug products. According to

FDA, the agency changed its plans because CPG 400.400, in addition to being out of date, also is inconsistent with the agency's current risk-based enforcement approach.

The Revised Homeopathic Draft Guidance explains that, in the absence of a safe harbor, all unapproved homeopathic drugs are "being marketed illegally [and] subject to FDA enforcement at any time." However, FDA is prioritizing for enforcement those homeopathic products that the agency determines pose the highest risks to consumers. Specifically, FDA is prioritizing *for enforcement* the following types of homeopathic drug products, starting with injectables:

- Products with reports of injury that, after evaluation, raise potential safety concerns;
- Products that contain or purport to contain ingredients associated with potentially significant safety concerns;
- Products for routes of administration other than oral and topical;
- Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions;
- Products for vulnerable populations; and
- Products with significant quality issues.

The Revised Homeopathic Draft Guidance does not offer any additional insight on where enforcement against homeopathic drug products falls within the FDA's overall enforcement priorities going forward or when FDA will start to step up enforcement activities. According to the agency's public database, FDA has issued a total of eight Warning Letters against manufacturers of homeopathic drug products, with the first being in 2015 and the most recent being in June 2020.

Manufacturers should consider assessing their products against the categories described in the Revised Homeopathic Draft Guidance in order to evaluate compliance options, otherwise they risk greater oversight and regulation that will likely disrupt or end the marketing and availability of new homeopathic drug products in the United States.

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