FDA proposes new, risk-based enforcement priorities to protect consumers from potentially harmful, unproven homeopathic drugs

FDA continues to find that some homeopathic drugs are manufactured with active ingredients that can create health risks while delivering no proven medical benefits

For Immediate Release

December 18, 2017

Summary

FDA is proposing a new, risk-based enforcement approach to homeopathic drug products that have the greatest potential to cause risk to patients.

Release

Today, the U.S. Food and Drug Administration proposed a new, risk-based enforcement approach to drug products labeled as homeopathic. To protect consumers who choose to use homeopathic products, this proposed new approach would update the FDA's existing policy to better address situations where homeopathic treatments are being marketed for serious diseases and/or conditions but where the products have not been shown to offer clinical benefits. It also covers situations where products labeled as homeopathic contain potentially harmful ingredients or do not meet current good manufacturing practices.

Under the law, homeopathic drug products are subject to the same requirements related to approval, adulteration and misbranding as any other drug product. However, prescription and nonprescription drug products labeled as homeopathic have been manufactured and distributed without FDA approval under the agency's enforcement policies since 1988.

"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," said FDA Commissioner Scott Gottlieb, M.D. "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."

The FDA's proposed approach prioritizes enforcement and regulatory actions involving unapproved drug products labeled as homeopathic that have the greatest potential to cause risk to patients. Under this approach, many homeopathic products will likely fall outside the risk-based categories described in the new draft guidance and will remain available to consumers. The FDA intends to focus its enforcement authorities on the following kinds of products:

- products with reported safety concerns;
- products that contain or claim 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 and conditions;
- products for vulnerable populations; and
- products that do not meet standards of quality, strength or purity as required under the law.

Examples of products that may be subject to the enforcement priorities in the draft guidance are infant and children's products labeled to contain ingredients associated with potentially significant safety concerns, such as belladonna and nux vomica; and products marketed for serious conditions, such as cancer and heart disease.

While the FDA considers comments to the draft guidance, the FDA intends to examine how the agency is implementing its current compliance policy. Given the concerns about the proliferation of potentially ineffective and harmful products labeled as homeopathic, the FDA will consider taking additional enforcement and/or regulatory actions, consistent with the current enforcement policies, which also align with the risk-based categories described in the draft guidance, in the interest of protecting the public.

Homeopathy is an alternative medical practice developed in the late 1700s, based on two main principles: that a substance that causes symptoms in a healthy person can be used in diluted form to treat illness (known as "like-cures-like"); and the more diluted the substance, the more potent it is (known as the "law of infinitesimals"). Homeopathic drug products are prepared from a variety of sources, including plants, minerals, chemicals and human and animal excretions or secretions. These products are typically sold in pharmacies, retail stores and online.

Until relatively recently, homeopathy was a small market for specialized products. Over the last decade, the homeopathic drug market has grown exponentially, resulting in a nearly $3 billion industry that exposes more patients to potential risks associated with the proliferation of unproven, untested products and unsubstantiated health claims. During this time, the FDA has seen a corresponding increase in safety concerns, including serious adverse events, associated with drug products labeled as homeopathic. In addition, the agency has also found an increasing number of poorly manufactured products that contain potentially dangerous amounts of active ingredients that can create additional risks.

In September 2016, the FDA warned against the use of homeopathic teething tablets and gels containing belladonna, a toxic substance that has an unpredictable response in children under two years of age, after the products were associated with serious adverse events, including seizures and deaths, in infants and children. An FDA lab analysis later confirmed that certain homeopathic teething tablets contained elevated and inconsistent levels of belladonna. A similar issue occurred in 2010 when Hyland's Teething Tablets were found to contain varying amounts of belladonna. An FDA inspection of that product's manufacturing facility indicated substandard control of the product's manufacturing.

The FDA has issued warnings related to a number of other homeopathic drug products over the past several years. These include certain homeopathic zinc-containing intranasal products that may cause a loss of sense of smell, homeopathic asthma products that have not been shown to be effective in treating asthma and various homeopathic drug products labeled to contain potentially toxic ingredients, like nux vomica, which contains strychnine (a highly toxic, well-studied poison often used to kill rodents).

"Homeopathic products have not been approved by the FDA for any use and may not meet modern standards for safety, effectiveness and quality," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "The draft guidance is an important step forward in the agency's work to protect patients from unproven and potentially dangerous products."

In April 2015, the FDA held a public hearing to obtain input from stakeholders about the current use of drug products labeled as homeopathic, as well as the agency's regulatory framework for these products. The FDA sought broad public feedback on its enforcement policies related to drug products labeled as homeopathic. As a result of the agency's evaluation, which included consideration of the information obtained from the public hearing and the more than 9,000 comments received to the agency's public docket, the FDA has determined that it is in the best interest of the public health to issue a new draft guidance that proposes a comprehensive, risk-based enforcement approach to drug products labeled as homeopathic and marketed without FDA approval.

The FDA is not alone in reexamining its approach to homeopathy. In November 2016, the Federal Trade Commission (FTC) announced a new enforcement policy explaining that they will hold efficacy and safety claims for over-the-counter homeopathic drugs to the same standard as other products making similar health claims. Notably, the FTC said that companies must have competent and reliable scientific evidence for health-related claims, including claims that a product can treat specific conditions.

The FDA encourages public comments on the draft guidance during the 90-day comment period.

The agency also encourages health care professionals and patients to report adverse events or quality problems experienced with homeopathic or any drug products to the FDA's MedWatch program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or

- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###