CDER
SBIA CHRONICLES

MARCH 22ND, 2018

A New Era of Homeopathic Drug Product Regulation

Listen to our Audio Podcast!

Resources:

1. Guidance for Industry: Drug Products Labeled as Homeopathic
2. FDA Homeopathic Products webpage
3. FDA News Release
4. CPG 400.400
5. 2015 Public Hearing
6. Homeopathic Product Regulation Docket 2015-N-0540
7. 12/20/2017 Federal Register Notice
8. 03/20/2018 Federal Register Notice: extension of comment period

Upcoming Events:

1. SBIA REdI Generic Drugs Forum – April 11-12 in Silver Spring, MD.
2. SBIA REdI Spring Conference – TBA – May 15-16 in San Francisco, CA.

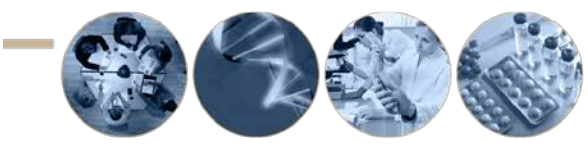
On December 18, 2017, the U.S. Food and Drug Administration (FDA) proposed a new, risk-based enforcement approach to drug products labeled as homeopathic. FDA re-examined its enforcement approach because the homeopathic drug industry has grown and we need to better address situations where homeopathic treatments are being marketed for serious diseases and/or conditions but where the products have not been shown to offer clinical benefits. The approach also covers situations where products labeled as homeopathic contain potentially harmful ingredients or do not meet current good manufacturing practices.

Homeopathy is an alternative medical practice developed in the late 1700s. It is based on the principle that a substance that causes symptoms in a healthy person can be used in diluted form to treat symptoms and illnesses, a concept known as "like-cures-like". The more diluted the substance, the more potent it is considered to be.

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. In FDA's news release on its new risk-based enforcement approach for homeopathic drug products, FDA Commissioner Scott Gottlieb M.D. states, "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."

Proposed Risk-based Enforcement Approach: FDA's proposed approach prioritizes enforcement and regulatory actions involving unapproved drug products labeled as homeopathic that pose the greatest risk to patients. As described in the draft guidance, "Drug Products Labeled as Homeopathic," FDA intends to focus its enforcement authorities on the following kinds of products:

- Products with reported 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 for vulnerable populations such as those with compromised immune systems, infants and children, the elderly, and pregnant women;



CDER Small Business and Industry Assistance (SBIA)
Division of Drug Information | Office of Communications
10001 New Hampshire Avenue | Hillandale Bldg, 4th Floor | Silver Spring, MD 20993
(866) 405-5367 or (301) 796-6707
CDERSBIA@fda.hhs.gov
www.fda.gov/cdersbia

- Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases and conditions;
- Products deemed adulterated under section 501 of the Federal Food, Drug and Cosmetic (FD&C) Act.

FDA recognizes that many homeopathic products will fall outside these categories, but as stated by CDER Director Janet Woodcock, M.D., "The draft guidance is an important step forward in the agency's work to protect patients from unproven and potentially dangerous products." Moreover, the risk-based enforcement approach is consistent with the agency's mission to protect public health.

Under the FD&C Act, homeopathic drug products are subject to new drug requirements related to approval, adulteration, and misbranding. However, prescription and nonprescription drug products labeled as homeopathic have been manufactured and distributed without FDA approval since 1988 under the enforcement policies in FDA's Compliance Policy Guide (CPG) 400.400.

In 2015, FDA held a public hearing to obtain information and comments from stakeholders about drug products labeled as homeopathic, as well as the agency's regulatory framework for such products. FDA sought broad public input on its enforcement policies and received more than 9,000 comments to the docket.

As a result of the agency's evaluation, which included consideration of public input, FDA determined that it is in the best interest of public health to issue a draft guidance. The guidance proposes a risk-based enforcement approach to drug products labeled as homeopathic, which is consistent with FDA's risk-based regulatory approaches generally.

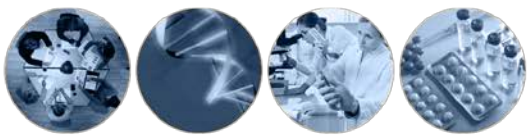
Safety and efficacy concerns: There are no homeopathic drug products marketed in the United States that are FDA-approved. This means that FDA has not evaluated them for safety or effectiveness. Thus, such products may not meet modern standards for safety, effectiveness, and quality. They may also cause harm to consumers who forgo treatment for serious conditions with medical products that have been scientifically proven to be safe and effective. People sometimes assume that homeopathic remedies are unlikely to cause harm because they are marketed as "natural." However, as with all drug products, the safety of homeopathic drugs depends upon many factors, including the manufacturing quality and the identity and amount of the "active" ingredient. Homeopathic products are often found next to over-the-counter products, and may not be labeled as homeopathic. So consumers may not realize that they have not been evaluated by FDA for safety or effectiveness.

Although homeopathic drug products are generally labeled as highly diluted, some of these products have been found to contain measurable amounts of active ingredients, and therefore could cause significant patient harm. Additionally, FDA has tested products that were improperly manufactured, which can cause incorrect dilutions and increase the potential for contamination. Further, some products labeled as homeopathic are marketed to treat serious diseases or conditions.

Please read the complete draft guidance and submit comments per the Federal Register Notice. Note that the comment period has been extended to May 21st, 2018.

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

Issues of this newsletter are archived at http://www.fda.gov/cdersbiachronicles



CDER Small Business and Industry Assistance (SBIA)
Division of Drug Information | Office of Communications
10001 New Hampshire Avenue | Hillandale Bldg, 4th Floor | Silver Spring, MD 20993
(866) 405-5367 or (301) 796-6707
CDERSBIA@fda.hhs.gov
www.fda.gov/cdersbia