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Alert | Health Care & FDA Practice

October 2019

FDA Toughens Enforcement of Homeopathic Products

FDA recently announced that it was taking two significant actions with respect to products marketed as homeopathic drugs, suggesting that increased enforcement related to these products is imminent. Homeopathy is a form of alternative medicine that is based on the idea that illnesses and their symptoms can be treated by small doses of ingredients that produce similar symptoms in healthy people.

First, the Agency has withdrawn Compliance Policy Guide (CPG) Sec. 400.400, entitled "Conditions Under Which Homeopathic Drugs May be Marketed." The CPG was issued in 1988 and described an enforcement policy that permitted unapproved homeopathic drugs to be marketed if certain conditions related to labeling, ingredients, manufacturing, and other considerations were met. In withdrawing the CPG, the Agency observed that products that seemed to meet the criteria described in the CPG nonetheless caused or could have caused serious harm.

Second, the Agency has revised its draft guidance entitled "Drug Products Labeled as Homeopathic." The revised draft guidance describes enforcement priorities for homeopathic drugs marketed without required approval. According to the revised draft guidance, these priorities include:

- ***Products with reports of injury that, after evaluation, raise potential safety concerns.*** For example, MedWatch reports on other information submitted to the Agency can indicate or signal a potential association between the product and an adverse event, medication errors, or other safety issues.

- ***Products that contain or purport to contain ingredients associated with potentially significant safety concerns.*** For example, potentially significant safety concerns are raised by products that contain or purport to contain:
  - An infectious agent with the potential to be pathogenic;
  - A controlled substance, as defined in the Controlled Substances Act, 21 U.S.C. 812;
  - Multiple ingredients that, when used in combination, could result in possible interactions, synergistic effects, or additive effects of the various ingredients; and,
  - Ingredients that pose a risk of toxic, or other adverse effects, particularly when the ingredients are concentrated or in low dilution presentations (e.g., 1X, 2X, or 1C), or are not adequately controlled in the manufacturing process.
- ***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. . . .***
- ***Products with significant quality issues. . . .***

The revised draft guidance stresses that "nothing in the FD&C Act exempts homeopathic drug products from any of the requirements related to approval, adulteration, or misbranding, including labeling requirements." It further emphasizes that "any homeopathic drug product that is being marketed illegally is subject to FDA enforcement at any time."

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