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HOMEOPATHIC PRODUCTS MANUFACTURERS BEWARE – FDA STEPS UP PLANS FOR NEW ENFORCEMENT REGIME

The centuries-old practice of homeopathic medicine, which has been the subject of much controversy and debate for nearly the entire length of its existence, may finally be going to the mat with the Food & Drug Administration ("FDA"). Amidst growth in the homeopathic products industry and associated concerns with their safety, efficacy and quality, the FDA has announced how the agency plans to prioritize enforcement actions associated with unapproved homeopathic drug products.[i] As a part of this two-pronged plan, Acting FDA Commissioner Sharpless announced the issuance of revised draft guidance, incorporating updated considerations and comments received to date, and that the agency is withdrawing its previous compliance policy guide as it no longer reflects the agency's current thinking.[ii]

While the FDA's statutory mission is to approve only those products that have been determined to be safe and effective, a number of homeopathic practitioners historically believed that their product's effectiveness should be determined exclusively by individual patient satisfaction, obviating the need for clinical trials.[iii] Though patient satisfaction is important, equally so is actual research into the effects these products have on the human body. Today, homeopathic product researchers claim that study practices have improved, citing certain instances of effectiveness determinations, though even those results remain clouded in controversy.[iv] With allopathic and homeopathic medicinal practices at odds as to safety and efficacy measures, manufacturers of homeopathic products need to acknowledge this new development and prepare accordingly.

BACKGROUND

On October 24, 2019, the FDA issued a revised draft guidance[v] document outlining its rationale for shifting to a risk-based regulatory enforcement methodology for unapproved homeopathic drug products. Specifically, the guidance states that there exists no exemption in the federal Food, Drug, and Cosmetic Act ("FDCA") from the requirements of drug approval, adulteration, misbranding or labeling, yet because of the agency's historical approach to these products, no FDA-approved homeopathic drug products currently exist.[vi] Citing as rationale for the shift in regulatory enforcement policy, FDA details in the guidance numerous instances of adverse event reports involving patient injury associated with homeopathic drug products as well as significant departures from federal Current Good Manufacturing Practices ("CGMP") by the manufacturers of those products.[vii],[viii]

In this recent draft guidance, FDA outlines specific categories of homeopathic drug products that can potentially pose greater risks to consumers relative to others and indicated enforcement action would be prioritized for enforcement action with respect to premarket approval requirements for drugs; though the agency specifically states that any homeopathic drug being marketed illegally is always subject to enforcement action.[ix] With respect to homeopathic drugs that will be prioritized for enforcement action, the FDA has developed the following risk assessment criteria:

- Products raising potential safety issues following evaluation of reports of injury;[x]
- Products that may contain ingredients with known or potentially significant safety profiles, including those ingredients that, when combined with one another, could have possible negative adverse effects on the user;[xi]
- Any product with a route of administration that is injectable, ophthalmic or any other route of administration other than oral and topical;[xii]
- Products that are intended to treat serious or life-threatening diseases as it may cause a user to forgo or delay use of FDA-approved drugs;[xiii]
- Products intended for populations known to be vulnerable such as infants, children, pregnant women, immunocompromised individuals

and the elderly;[xiv] and

- Products possessing significant quality issues such as contamination or with significant departures from CGMP requirements.[xv]

PRACTICAL TAKEAWAYS

Although FDA guidance documents are not binding on the industry or the agency, they do represent FDA's current thinking. Moreover, manufacturers of homeopathic products should not assume that because this guidance document is in draft form that it must be finalized before the agency can initiate enforcement activities. As is the case with any unapproved drug, FDA may take enforcement action at any time. If you are a manufacturer of homeopathic drug products, you should work with your legal counsel to carefully assess whether your products fall into any of the proposed enforcement prioritization criteria.

Hall Render regularly monitors regulatory and enforcement developments relating to FDA-regulated products, including homeopathic products. Interested parties should note that comments on the draft guidance are due to the FDA by January 23, 2020. If you have any questions about this guidance please contact:

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For more information about Hall Render's FDA & Life Science services, click here.

[references]

[i] U.S. Food & Drug Administration, Statement on the agency's efforts to protect patients from potentially harmful drugs sold as homeopathic drug products," 10/24/2019, https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-protect-patients-potentially-harmful-drugs-sold-homeopathic-products (last accessed 10/24/2019).

[ii] *Id.*

[iii] Loudon, Irvine. "A brief history of homeopathy." Journal of the Royal Society of Medicine vol. 99,12 (2006): 607-10. doi:10.1258/jrsm.99.12.607, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1676328/ (last accessed 10/24/2019)

[iv] Homeopathy Research Institute, "Suppressed NHMRC 2012 report found 'encouraging' evidence homeopathy is effective for some medical conditions," 10/9/2019, https://www.hri-research.org/wp-content/uploads/2019/10/20191009_HRI-Statement_NHMRC-First-Report-Findings-2.pdf (last accessed 10/24/2019).

[v] U.S. Food & Drug Administration, Drug Products Labeled as Homeopathic Guidance for FDA Staff and Industry, 10/2019, https://www.fda.gov/media/131978/download (last accessed 10/24/2019).

[vi] Refer to endnote (v), lines 62-66.

[vii] *Ibid*., lines 104-113, 115-118, and 120-125.

[viii] See also similar rationale cited in U.S. Food & Drug Administration's response to Americans for Homeopathy Choice denying the organization's citizens petition, Docket No. FDA-2018-P-2962, https://www.regulations.gov/document?D=FDA-2018-P-2962-16596, (last accessed 10/25/2019).

[ix] Refer to endnote (v), lines 152-156.

[x] *Ibid*., lines 158-200.

[xi] *Ibid.*

[xii] *Ibid.*

[xiii] *Ibid.*

[xiv] *Ibid.*

[xv] *Ibid.*

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