



## U.S. FDA Finalizes Homeopathic Drug Products Guidance

The United States Food and Drug Administration (FDA) finalized the Homeopathic Drug Products guidance, with few changes from the draft guidance issued in October 2019. The final guidance outlines a risk-based enforcement approach for unapproved homeopathic drug products.

The FDA generally intends to prioritize enforcement against homeopathic products that are marketed without FDA approval and potentially have higher risks to public health that fall within the following categories:

- 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
  - Such as injectable and ophthalmic drug products
- Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions
- Products for vulnerable populations
  - Including immunocompromised individuals, infants and children, the elderly, and pregnant women
- Products with significant quality issues
  - Such as those contaminated with foreign materials or objectionable microorganisms, and/or made in facilities with significant Current Good Manufacturing Practice (CGMP) deviations

While the FDA “anticipates that many homeopathic drug products will fall outside the categories of drug products that FDA intends to prioritize for enforcement and regulatory action,” they also state that “there are no FDA-approved products labeled as homeopathic, and the agency cannot ensure these drugs meet standards for safety, effectiveness, and quality.” Noting that, “this guidance is intended to provide notice that any homeopathic drug product that is being marketed illegally is subject to FDA enforcement action at any time.”

Link to guidance document: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-labeled-homeopathic-guidance-fda-staff-and-industry>

### How Does this Impact You? Contact Us to Discuss

If you have any questions, please contact your customer service representative or email: [info@us.bureauveritas.com](mailto:info@us.bureauveritas.com)

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