Summit on Challenges and Solutions in Quality & Safety of Homeopathic Drug Products

June 27-28, 2019 | Hilton Baltimore Inner Harbor

Regulatory Track: Workshop 2
1:00–2:30 p.m.

Topics in Labels and Labeling

Presented by Eric L. Foxman, RPh, Regulatory Consultant, Secretary for American Association of Homeopathic Pharmacists, and Senior Scientist for Homeopathic Pharmacopeia Convention of the United States

FDA's draft guidance states the agency's enforcement actions will focus on various types of products, including those associated with potentially significant safety concerns; those intended for the prevention or treatment of serious and/or life-threatening diseases and conditions; and those intended for vulnerable populations. This workshop will examine how FDA's enforcement focus categories affect homeopathic product labeling and provide examples to help companies minimize risk.

What You Will Learn:

- OTC label format and content requirements.
- Self-medication vs. prescription indications disease claims:
  - Limits of self-medication;
  - Range of self-medication indications; and
  - Implications on non-self-limiting indications on a consumer product.
- What FDA has taken exception to in the past 18-24 months, both in terms of specific wording and promotional presentation; this awareness will help you create guideposts for your label indications.
- Review of standard regulatory labeling requirements.

About the Presenter

Eric L. Foxman, RPh, has been actively engaged in the homeopathic industry for over four decades, both on the manufacturing/laboratory side and on the regulatory/consulting side. He brings his years of experience working with both domestic and overseas manufacturers and clients to address labeling issues of critical importance.