Manufacturing and Marketing OTC Drugs in Compliance with FDA Regulations (Updated to address recent Homeopathic Drug announcements by FDA & FTC)

By: Bill Schwemer, Principal, Schwemer Consulting and Former Senior FDA & Industry Official

Location: November 7-8, 2017 | San Francisco, CA

Bill Schwemer is an ex-FDA official with more than 50 years’ experience in FDA compliance matters. He was an FDA field investigator and compliance officer in two districts. As director, division of field investigations, he managed the FDA foreign inspection program and his staff supported the district investigations branches. He was a senior official in FDA’s Office of the Commissioner in both the Offices of Regulatory Affairs and Policy. His industry experience includes V-P of RA/QA at a personal care products company and consulting for businesses nationwide and in Europe and Asia.

His consulting business in recent years has been primarily for pharmaceutical and personal care products companies. He has published more than 125 articles and since becoming a consultant has successfully served as a regulatory compliance expert witness in 22 lawsuits.

In his FDA Office of Regulatory Affairs positions, Mr. Schwemer had insights on all current OTC Drug Compliance Policy Guides (CPGs) and approved either original drafts or revisions on behalf of the office. Recently, he petitioned FDA to revise the CPG “Conditions Under Which Homeopathic Drugs May be Marketed.”

LEARNING OBJECTIVE

- Understand FDA rules and policies regarding manufacturing and labeling of low risk OTC drugs not covered by approved New Drug Applications
- Learn the importance of knowing the legal definitions of FDA regulated products
- Understand how labeling other than labels and advertising can define a product and cause it to be misbranded or considered a new drug
- Differentiate cosmetic “puffery” claims from those that FDA would likely consider drug claims
- Understand the differences between allopathic (conventional) drugs and homeopathic drugs
- Recognize ways to manufacture low health risk products at minimum cost, yet still meet the intent and basic requirements of GMP regulations
- Learn how to minimize the regulatory risk of a Warning Letter (or other FDA action) and what to do if you get one
This interactive one-and-a-half-day seminar is intended to educate regulatory and quality professionals regarding the rather complicated regulations that distinguish Non-prescription Drugs from other products such as foods, cosmetics, dietary supplements and prescription drugs that sometimes contain the same ingredients. Recent FDA actions such as the banning of antibacterial soaps and ongoing programs that may impact manufacturers and private label distributors will be discussed. It will explain differences in the way homeopathic and conventional drugs are regulated and update participants on FDA's application of GMP regulations to manufacturing low risk drugs that could be sold as cosmetics with the same ingredients, but different labeling.

The seminar will address issues such as:

- Registering facilities and listing products with FDA
- How the intended use of the product owner defines a product?
- Can a drug contain both homeopathic and conventional drug ingredients?
- Update on activities following FDA’s 2015 Public Hearing on Homeopathic drugs?
- Information that must appear on principal display panels
- Format and type size requirements for label text.
- Must you have a contract and/or separate quality agreement with a contract manufacturer?
- FDA’s OTC Drug Monograph rules and how they benefit small business

### AGENDA

**DAY ONE: 8:30 AM - 5:00 PM**

**Registration Process:** 8:30 AM – 9:00 AM

**Session Start Time:** 9:00 AM

- 9:00 AM - 9:15 AM: Introduction
- 9:15 - 10:15 AM: Overview of Law & Regulations for Drug Products
  - History of legislation
  - Prohibited acts
  - Basic labeling definitions/requirements
- 10:15 - 10:30 AM: Break
- 10:30 - 11:15 AM: Labeling Idiosyncrasies - Cosmetics, Drugs, Dietary Supplements
  - Defining personal care products
  - Identifying confusing regulatory issues
- 11:15 - 12:00 PM: OTC Drug Facts Labeling
  - How they are established
  - Product categories
  - Requirements
- 12:00 - 1:00 PM: Lunch
- 1:00 - 1:45 PM: Cosmeceuticals - Cosmetics that are also Drugs
  - Dominance of drug labeling rules
  - Monographs most applicable to cosmeceuticals
  - Placing cosmetic and drug claims on labels
- 1:45 - 2:30 PM: More on Monographs
  - Comparing rulemakings
- 2:30 - 3:15 PM: FDA’s OTC Drug Monograph rules and how they benefit small business
  - Finding your way to useful information in rulemakings
  - FDA seeking changes in monograph process
- 3:15 - 3:30 PM: Break
- 3:30 - 4:15 PM: OTC Drug Facts Labeling
  - The boxed labeling format
  - Relationship to monographs
- 4:15 - 4:45 PM: Reporting Serious Adverse Events to FDA
  - What is a homeopathic product
  - Labeling requirements
- 4:45 - 5:00 PM: Q & A

**DAY TWO: 8:30 AM - 12:30 PM**

- 8:30 - 10:00 AM: Complying with Finished Drug CGMPs (for Low Risk Products)
- 10:00 - 10:30 AM: Break
- 10:30 - 11:00 AM: FDA Guidance: Contract Manufacturing of Drugs
- 11:00 - 12:15 AM: Workshop
  - Review labels and comment
- 12:15 - 12:30 PM: Wrap-up, Hand Out Certificates

### WHO WILL BENEFIT

This course is intended for personal care product manufacturers and other businesses that wish to develop and/or market drugs that do not require FDA approval. It will also benefit cosmetic, nutritional, liquid soap and other companies that are considering health related claims for their products, but wish to avoid labeling that would make them new drugs lacking FDA approval. While the emphasis is on topical OTCs, well over half of the presentations are applicable to OTCs taken internally. It will especially benefit in-house label distributors and smaller firms that do not have a regulatory professional on their staff. This includes:

- Senior Managers / Business Owners
- Product Managers
- Labeling and Artwork Designers
- Regulatory and Quality Professionals
- Sales and Marketing Managers
- R&D Managers and Staff
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## Seminar Topic:
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### Date & Location:

### Attendee Details:

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**Email address** (so you can receive order acknowledgements, updated news, product information and special offers)

### Company Information

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**Expiration date**

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Please fill this form with attendee details and payment details and fax it to 650-565-8542.