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One and a Half Day In-Person Seminar

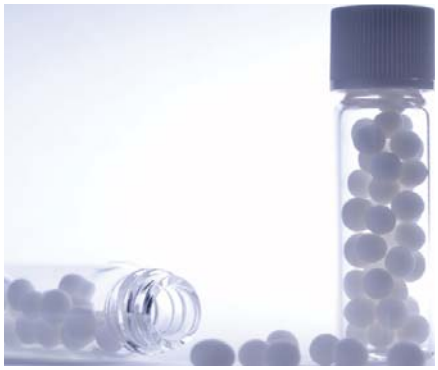
Manufacturing and Marketing OTC Drugs in Compliance with FDA Regulations (Emphasis on Topical Products)

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

Location 1: June 4-5, 2015 | Chicago, IL

Location 2: August 6-7, 2015 | San Francisco, CA






SPEAKER

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

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 regulations and policies regarding manufacturing and labeling of OTC drugs covered by OTC drug monographs (minimal information is provided to contrast the new drug approval process)
- Learn the definitions of drug, cosmetic, and dietary supplements
- Obtain tips on how to research FDA's OTC drug monograph rulemakings
- What labeling other than labels can define a product and cause it to be misbranded as a new drug
- Learn that certain ingredients are safe and suitable for use in both drugs and cosmetics
- Learn the basic requirements for marketing homeopathic OTC drugs
- Differentiate cosmetic 'puffery' claims from claims that FDA would likely consider drug claims
- Learn how to formulate and label cosmeceuticals (cosmetics which are also drugs)
- Understand the differences in how allopathic (conventional) drugs and homeopathic drugs are regulated
- 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

COURSE DESCRIPTION

This interactive one and a half day seminar is intended to help companies understand the legal definitions of cosmetics, drugs, dietary supplements and why certain labeling statements for non-drug products may cause the agency to consider them new drugs without FDA approval.

The instructor, a leading industry expert and former FDA official, will explain differences in the way homeopathic and conventional drugs are regulated and how the risks presented by different types of drug products affect the rigor of FDA enforcement of Good Manufacturing Practices Regulations. A workshop will be held at the finale of the course to emphasize certain issues by having participants review labels of misbranded products and examples of recent FDA Warning Letters.

The seminar will address issues such as:

- How both labeling and advertising establishes 'intended use' which defines a product?
- When cosmetics, dietary supplements and foods might become drugs requiring FDA approval?
- How OTC drug monographs can help one to formulate products and design labels?
- Why are OTC drug/cosmetic combinations (cosmeceuticals) allowed, but not OTC drug/dietary supplement combinations?
- What are common personal care product ingredients that have both cosmetic and drug uses?
- The restriction on combining allopathic and homeopathic ingredients in a drug formula.
- Things that one needs to know when designing labels:
  - Creative product names can cause a product to be misbranded.
  - Proper formatting of Drug Facts boxed panels.
  - Type size requirements and placement of information on principal display panels.
- Changes FDA now believes may be needed in monograph content and in changing monographs

Seminar instructor **Bill Schwemer** is an ex-FDA official with more than 50 years of experience in dealing with FDA compliance matters that include 30 years he spent working with the FDA as a field Investigator, director of field investigations, assistant associate commissioner for regulatory affairs, and special assistant to deputy commissioner for policy.

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 Monographs - Focus on Topical Products
  - 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
  - Finding your way to useful information in rulemakings
  - FDA seeking changes in monograph process
- 2:30 - 3:00 PM: OTC Drug Facts Labeling
  - The boxed labeling format
  - Relationship to monographs
- 3:00 - 3:30 PM: Break
- 3:30 - 4:15 PM: FDA Policy Regarding Marketing Homeopathic Drugs
  - Understanding CPG 400.400
  - FDA concern about health fraud
  - What is a homeopathic product
  - Labeling requirements
- 4:15 - 4:45 PM: Reporting Serious Adverse Events to FDA
  - Define reporter, adverse event and responsible person
  - When and how to report
- 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
  - Review and discuss FDA Warning Letters
- 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 also applicable to OTCs taken internally. It will especially benefit own 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

Registration Form

GROUP REGISTRATIONS

Send Your Team for Maximum Benefit Get your team up to speed!

2 Attendees	-	Get 10% off
3 to 6 Attendees	-	Get 20% off
7 to 10 Attendees	-	Get 25% off
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Call Toll Free +1-888-717-2436 if you have any queries.

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
- Call +1-888-717-2436 or Fax your PO: 650-963-2556.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-963-2556

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ +1-888-717-2436 or email us @ editor@complianceonline.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $150 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($150) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Manufacturing and Marketing OTC Drugs in Compliance with FDA Regulations (Emphasis on Topical Products)

Date & Location: .....

Attendee Details:

Register for 3 and 4th person gets a free pass.

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

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ComplianceOnline
The Largest GRC Advisory Network
www.complianceonline.com
2600 E. Bayshore Road Palo Alto, CA 94303
Ph: +1-888-717-2436 | Fax: 650-963-2556