

2-Day Virtual Seminar

Ensuring Compliance with Advertising and Promotional Requirements for Drugs and Medical Devices

By: **Michael Swit**, Principal, Law Offices of Michael A. Swit

Dates: March 18-19, 2021 (10:00 AM to 5:00 PM EST)

Location: Virtual Training Through WebEx

Various parts of the country are still battling the Coronavirus (COVID-19), we will conduct the class 100% online.



SPEAKER

Michael Swit, Principal, Law Offices of Michael A. Swit

Michael A. Swit focuses on solving the legal challenges confronted by the pharmaceutical, medical device, and other life sciences industries in tackling the myriad of legal mandates enforced by the U.S. Food & Drug Administration. Mr. Swit has extensive experience counseling life sciences firms on the demands of compliance with FDA's statutory and regulatory requirements to develop and market safe and effective drugs, biologics, medical devices, IVDs and other products. He also has advised regulated firms on a wide range of FDA regulatory matters, including drug and device approvals and marketing/promotional claims, dietary supplement health claims and regulatory issues in corporate acquisitions. His experience includes FDA development strategies, compliance and enforcement initiatives, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts.

Mr. Swit has been addressing critical FDA legal and regulatory issues since 1984. Before joining Duane Morris LLP, Mr. Swit served for seven years as vice president at a preeminent scientific and FDA regulatory consulting firm, where he developed and ensured execution of a broad array of regulatory and other services to clients, both directly and through outside counsel.

LEARNING OBJECTIVES

Key goals of the conference will include learning:

- ✓ The basics of FDA law and regulations governing advertising and promotion, as well as sister agencies such as the Federal Trade Commission, which shares jurisdiction with FDA on certain regulated products (e.g., OTC drugs).
- ✓ The distinctions between labels, labeling and advertising and how that impacts FDA's powers, and
- ✓ How to properly position Direct-to-Consumer (DTC) promotions
- ✓ The Dos and Don'ts of promoting products on the internet, including social media sites such as Facebook and Twitter
- ✓ The perils of off-label promotion, including criminal and civil actions that have led to multi-billion dollar settlements by regulated drug companies
- ✓ Whether the First Amendment provides any insulation for truthful statements regarding regulated products;
- ✓ When disseminating medical educational materials crosses the line into improper promotion; and
- ✓ Key considerations on how to implement appropriate procedures and controls in your company to minimize the potential for regulatory action by the FDA or the FTC relative to promotion and advertising.

COURSE DESCRIPTION

Federal regulation of the advertising and promotion of pharmaceuticals and medical devices reflects an aggressive attitude on the part of the regulators that demands, in turn, that industry be keenly aware of the legal and regulatory duties, as well as key recent trends in enforcement activities by the Federal Government. This course will explore in detail what FDA requires of drug and device firms as well as recent current hot buttons in FDA enforcement activity for the advertising arena.

What's at stake if your advertising and promotional efforts violate the law? Colossal fines – the latest was \$3 Billion; criminal liability, including even prison time; and huge disruption in operations while dealing with federal probes into illegal marketing.

AGENDA

DAY ONE (10:00 AM – 5:00 PM EST)	DAY TWO (10:00 AM – 5:00 PM EST)
<p>I. Understanding the Basics</p> <ul style="list-style-type: none"> A. Who Has Jurisdiction <ul style="list-style-type: none"> 1. Drugs & Biologics <ul style="list-style-type: none"> a. Rx Drug Advertising b. Nutrient Content Claims 2. Devices <ul style="list-style-type: none"> a. Restricted b. all other B. Labeling vs. Advertising C. Basic drug rules <ul style="list-style-type: none"> 1. Fair balance D. Device rules <ul style="list-style-type: none"> 1. Intended use deviations E. DTC advertising <ul style="list-style-type: none"> 1. Print 2. TV F. Comparative Claims <ul style="list-style-type: none"> 1. Standard to support 2. Push to pursue CER G. Detailing and Sampling <ul style="list-style-type: none"> 1. is there still a future? 2. what can be said? 3. danger of "custom" pieces G. How FDA learns of violations <ul style="list-style-type: none"> 1. Keep your house clean or your competitors will rat you out <p>II. Scientific Exchange</p> <ul style="list-style-type: none"> A. Guidances on Dissemination of Scientific Information B. Risks involved in Off-Label Statements C. Procedural Requirements and Unsolicited Requests for Information <p>III. First Amendment</p> <ul style="list-style-type: none"> A. Understanding "Commercial Speech" Doctrine B. FDA and the Regulation of Advertising <p>IV. Websites & Social Media</p> <ul style="list-style-type: none"> A. FDA Policies on the Internet B. Recent FDA Enforcement Activities B. How to Handle at the Company Levels 	<p>V. Enforcement Trends</p> <ul style="list-style-type: none"> A. FDA Hot Buttons <ul style="list-style-type: none"> 1. Understating risk 2. Overstating effectiveness B. FTC <ul style="list-style-type: none"> 1. POM Wonderful and substantiation C. Private Litigation – Understanding <ul style="list-style-type: none"> 1. Lanham Act 2. State Unfair Competition <p>VI. False Claims Act and Criminal Liability</p> <ul style="list-style-type: none"> A. Review of Key Settlements B. "Responsible Corporate Official" Liability <p>VII. Handling at the Company Level</p> <ul style="list-style-type: none"> A. Compliance Programs B. Internal processes

WHO WILL BENEFIT

Senior executives, directors, managers and those who have responsibility for implementing advertising and promotional activities, as well as those that have key collateral roles in reviewing advertising for drug and device firms, including officials from these areas within regulated companies:

- ✓ Sales
- ✓ Marketing
- ✓ Medical Affairs
- ✓ Legal
- ✓ Regulatory
- ✓ Compliance



..... **Registration Form**

Registration Information:

REGISTER WITH NO WORRIES

- ✓ **Register Online.** Use your American Express, Visa or MasterCard.
- ✓ Get your group to attend the seminar at a discounted price call +1-201-871-0474.
- ✓ Call Toll Free: +1-201-871-0474 (USA) or Fax your PO: 253-663-7224
- ✓ Send your check to PMA Conference Management, 405 Highview Rd, Englewood NJ 07631

- ✓ Please fill this form with attendee details and payment details and fax it to +1-253-663-7224



Note: In view of Coronavirus situation and travel advisory issued, ComplianceOnline will waive off all cancellation charges for the registrations till December 31, 2020

Cancellations and Substitutions - In-person Seminars:

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 \$300 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 (\$300) 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.

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Seminar Topic: Ensuring Compliance with Advertising and Promotional Requirements for Drugs and Medical Devices

Date & Location: March 18-19, 2021 (10:00 AM to 5:00 PM EST)

Registration: \$1699. Call for Group Rates

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

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

Company Information

Organization

.....

Address

.....

City

State Zip.....

Country

Phone Fax

Payment Options

Check enclosed, payable in U.S. funds

Charge to: Visa MasterCard American Express

Credit card no.

Expiration date

Total amount \$

Signature

(Signature required on credit card and bill-me orders.)

Print name.....

Bill me/my company \$

Purchase order #