




2-day In-person Seminar:

FDA Scrutiny of Promotion and Advertising Practices

-  Baltimore, MD
-  June 27th & 28th, 2019
-  9:00 AM to 6:00 PM



Casper Uldriks

ex-FDA Expert and former Associate Center Director of CDRH

Casper (Cap) Uldriks owns Encore Insight LLC, which provides consulting services on FDA Law. He brings over 32 years of experience from the FDA. He specialized in the FDA's medical device program as a field investigator, served as a senior manager in the Office of Compliance and as an Associate Center Director for the Center for Devices and Radiological Health. He developed enforcement actions and participated in the implementation of new statutory requirements. He is recognized as an exceptional and energetic speaker. His comments are candid, straightforward and of practical value. He understands how FDA thinks, operates and where it is headed.

Overview :

If you go "off label" with advertising and promotion, FDA's hammer can hit hard and seemingly out of the blue. Advertising and promotion for devices is weak and lacks legal clarity. For drugs, the regulations are prescriptive and guidance documents clamp down on nuances. Marketing and regulatory affairs departments must collaborate to avoid the hammer and penalties of FDA. The roadblock, however is that marketing managers and regulatory affairs managers rarely reach common ground and are loathe to even consult with each other.

Price

Price: **\$2,000.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **\$10,000.00**

Register for 10 attendees

Price: **\$20,000.00**

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*



Agenda:

Day One

8:30 AM - 9:00 AM: **Registration**

9:00 AM - 10:30 AM

Lecture 1: **FDA legal authority**

- FDA application of the FD&C Act and implementing regulations
- FTC / mass media
- SEC/False statements
- DOJ / False Claims
- Enforcement authority and options

Cognitive psychology vs. psychoanalytic motivation

10:30 AM - 12:00 PM

Lecture 2: **Promotion and Advertising: scope of labeling**

- Definitions for "label" and "labeling"
- Hard copy and electronic
- Testimonials
- Blogs
- Sales force
- What is "off-label?"
- Practice of Medicine exemption
- Drugs authority
- Devices
- Dietary supplements

12:00 PM - 1:00 PM Lunch

1:00 PM - 2:30 PM

Lecture 3: **Supreme Court / commercial free speech**

- Constitutional protection and case law
- Amarin Case: off-label, but true
- Safe harbor

Policy

- FDA organizational responsibility
- FDA Guidance

2:30 PM - 2:45 PM **Break**

2:45 PM - 4:30 PM

- Fair and balanced disclosure
- Social media
- Direct to Consumer Advertising

Hypothetical Workshop

Day Two

9:00 AM - 10:30 AM

Lecture 1:

Direct to consumer advertising vectors

Federal Trade Commission interest (economic vs. safety)

Context and format of messaging

Script versus message

- Target population
- Aspirations
- Emotional factors

10:30 AM - 12:00 PM

Lecture 2: **False and misleading information**

- Statutory basis (21 U.S.C. 352(a))
- New use
- Comparative claims
- Claims for safety and effectiveness
- Sales for solicitation

12:00 PM - 1:00 PM **Lunch**

1:00 PM - 2:30 PM

Lecture 3:

Off label use - practices and policy

FDA Warning Letters

2:30 PM - 2:45 PM **Break**

2:45 PM - 4:30 PM

Lecture 4:

Practice of medicine exemption

Custom Device promotion

(Group Hypothetical)

Corporate management responsibility



Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

- 1 Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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