FDA Scrutiny of Promotion and Advertising Practices (ntz)

Date : May 17, 2018 - 09:00 AM - May 18, 06:00 PM

Event URL : http://www.nyeventslist.com/events/fda-scrutiny-of-promotion-and-advertising-practices-ntz-may-2018

Organizer : Netzealous LLC - NewYorkEventsList

Venue :

Location : DoubleTree by Hilton Hotel Philadelphia Airport4509 Island AvenuePhiladelphia, PA 19153United States,
Philadelphia, PA , US, ZIP: 19153

Description

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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.

FDA's Center for Devices and Radiological Health (CDRH) has never issued a comprehensive guidance on advertising and promotion. You are on your own. In contrast, FDA's Center for Drug Evaluation and Research (CDER) uses long-standing regulations and a growing number of guidance documents in its regulatory approach. Policing social media has become a new regulatory responsibility and FDA is still trying to figure out how to deal with it. Bottom line, do you know when you fail to meet FDA's requirements or are you guessing? Can you afford to guess? The cost to your business and the confusion left in your customers' mind becomes an unwelcomed nightmare.

In this seminar, you will learn how to navigate FDA's numerous legal options and how to interpret them based on basic legal principles. Applying new guidance documents becomes a new test of the FDA's legal boundaries and enforcement options. The agency is now conducting clinical studies and applies the principles of cognitive psychology to aid in its determination of what a message really conveys. This academic discipline may or may not get to the root of what consumers take away as the message.

Congress and the new FDA Commissioner seem more sympathetic to expanding access to medical treatment before all the conclusive evidence for safety and effectiveness is evaluated by the FDA. Valid off-label information may take the lead in that direction.

This conference will provide insight on how to manage your marketing activity and gauge what regulatory risks your business is willing to accept. You will learn how corporate management requires cooperation between marketing, regulatory affairs, legal counsel, manufacturing, engineering and finance departments. Operating in a stovepipe environment will not work. You need to understand that a weak link in any department leaves the entire corporation vulnerable to FDA enforcement. Most importantly, you will understand the boundaries that FDA uses and how easy it is to cross them. With information from this course, you can step back and rationally evaluate your firm's regulatory profile for advertising and promotion practices.

Learning Objective:

- Learn how FDA faces constitutional constraints on enforcement decisions
- Learn about intersecting federal requirements by the Department of Justice, the Federal Trade Commission, the Securities and Exchange Commission and the Consumer Product Safety Commission
- Learn how the FDA interprets advertising and promotion in principle and in fact
- Understand ways that a firm violates FDA requirements
- Evaluate advertising and promotional material based on interactive group hypotheticals
- See how sales and marketing departments play a central role, for better or worse

- Learn how the federal government holds executive management responsible for missteps in promotion and advertising practices.

Who Will Benefit:

- Sales and Marketing executives and managers
- Regulatory Managers
- In-house Legal Counsel and Contract Specialists
- 3rd party consultants
- Venture Capitalists
- Investors
- Business Acquisition Executives
- Owners of New or Developing Firms
- Own label distributors
- International Trade Managers
- Product specification developers

Background

FDA regulates advertising and promotion material as labeling. The legal definition of labeling covers just about anything that explicitly or implicitly conveys a message intended to affect a person's behavior and decision outcomes. The vehicle for communication has evolved dramatically over the past 100 years and continues to evolve at a rate faster than one can anticipate at times. How FDA applies its legal tenants of false and misleading information or variations on that theme requires continual updating by FDA and constant re-evaluation by industry. Now the legal field playing field involves other federal agencies and departments, and they work in concert with FDA. It has become very complicated and very costly if you knowingly or unknowing walk into a legal snare. This seminar is designed to bring you up to speed so you are clearer about what is a problem, what is not a problem and what becomes a risk laden judgment call.

Day 1 Schedule

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 2 Schedule

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

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.

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