COURSE FEE
$2150.00 PER PERSON

EARLY BIRD DISCOUNT
If you register at least thirty days in advance you will receive a $200 discount on the course.

ADDITIONAL DISCOUNTS
Contact us at 610-648-7550 or info@cfpie.com for additional discounts on multiple registrations.

CANCELLATION POLICY
All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CFPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses
Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CFPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

ABOUT CFPIE
Learn from the Leader
In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CFPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

HOW TO REGISTER

1. Go to http://www.cfpie.com

2. Go to “REGISTER” and select your course.

3. Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
7 Great Valley Parkway
Suite 295
Malvern, Pennsylvania 19355

http://www.CfPIE.com

MARKETING & ADVERTISING OF PHARMACEUTICAL & MEDICAL DEVICES
INSTRUCTOR: IRVING L. WIESEN
Please refer to our website for upcoming course dates and times

COURSE DESCRIPTION
This course provides a comprehensive description of the various regulatory and legal standards and their specific application to the advertising and promotion of drug and medical device products including detailed analysis of advertisements and promotion. These include regulations and policies of the FDA, FTC, DEA, PHS, Office of the Inspector General (OIG), state attorneys general and prosecutors, and professional guidelines of relevant organizations including ACCME, ACP, PhRMA and the AMA.

The course will cover marketing and promotional issues specific to brand-name (prescription and OTC), generic, and compounding pharmacy contexts, including such areas which are “in flux” as Continuing Medical Education, Advertising of Compounding Products, Off-Label Promotion, Gifts to Physicians, and Direct-to-Consumer Advertising. Advertisements and case studies, including notable enforcement actions by the FDA and FTC will be discussed.

Additionally, case law will be examined in detail, including strategies for staying under the “regulatory radar” and developing an effective in-house promotional review system.

Participants will receive resource materials including:
- Copies of laws, regulations, agency policies and court opinions, and guidance on the FDA’s, FTC and OIG websites
- Guidelines of professional and industry organizations

Attendees will have the opportunity to consult with the instructor during breaks and after hours on specific issues. The Course Director has over twenty-five years experience as a food and drug attorney with extensive involvement in drug marketing and advertising issues both in private practice, in-house for a multi-national pharmaceutical company, with direct interaction with the FDA and FTC.
INSTRUCTOR CREDENTIALS

Irving L. Wiesen is a food and drug attorney with over thirty years’ experience in the pharmaceutical, food supplement and medical device industry. His law practice – located in New York City – specializes in food and drug law and other regulations that affect the pharmaceutical, biotech and medical device industries. There, he counsels pharmaceutical companies in all areas of FDA compliance; including marketing, advertising/promotion, GMPs, drug applications and representation before the FDA – as well as licensing, R&D agreements, commercial transactions and litigation.

Formerly, Mr. Wiesen was a partner at Bass & Ullman – one of the pioneer food and drug firms in the country – and Division Counsel for Boehringer Ingelheim Pharmaceuticals. Mr. Wiesen received his JD from NYU and his MA in English Literature from Columbia University.

Mr. Wiesen counsels pharmaceutical companies in allied regulatory schemes administered by the FTC and DEA. He has lectured widely on food and drug law, including before the Food and Drug Law Institute and at the Weizmann Institute in Israel.

WHO SHOULD ATTEND

This two-day course was developed to assist personnel who have varying levels of experience in drug and device advertising, marketing and promotion. It is intended for those involved with:

- Regulatory affairs
- Marketing and promotional legal issues
- Marketing, sales and support functions

The course will provide attendees with a better understanding of responsibilities in the areas mentioned above. Additionally, participants will gain a greater knowledge of the issues faced which can affect common marketing and promotional activities.

FIRST DAY

Session 1
Introduction

Advertising and Promotion Regulation Overview
- What types of matter constitute advertising and promotion
- The jurisdiction of the various agencies, principally the FDA and FTC
- Professional Organizations guidelines: PhRMA, AMA, ACCME

Session 2
The Laws Governing Advertising and Promotion: FDA
- Food, Drug and Cosmetic Act
- Code of Federal Regulations
- Case law review and discussion

The Role of the Federal Trade Commission
- Memorandum of Understanding
- Jurisdiction of FTC and FDA over drug advertising
- Case law review and discussion

Other Agencies
- Office of the Inspector General
- Public Health Service

Session 3
In-Depth Analysis of Requirements for Advertising and Promotion
- Submission of materials to the Agency
- The Role of OPDP (formerly DDMAC) and pre-clearance of advertising
- Fair Balance
- Brief Summary and Full Prescribing Information
- Reminder advertisements
- Standards in the CFR; Agency policies and guidelines

Session 4
Anatomy of a Drug Ad
- What triggers the issue of advertising and promotional review
- Various types of advertising and promotion
- Third Party literature
- Case studies of ads and promotion
- When things go wrong: prevention; remedial measures

SECOND DAY

Session 1
Specific Issues in Drug Promotion and Advertising

Off-Label Promotion
- What is off-label promotion
- What does FDA consider off-label
- Comparative advertising and claims of superiority
- Examples of off-label promotion
- Examples of FDA enforcement efforts
- Whistleblower cases involving off-label promotion
- Quality of life claims

Medical Education
- Continuing Medical Education (CME)
- Responding to requests from physicians and health care professionals
- Single sponsor publications
- Seminars, exhibits, scientific symposia
- Honoraria, gifts, compensation and remuneration

Session 2
Other Communications and Promotion
- Financial disclosure and investor relations
- Communications with health professionals
- Product sampling
- Pharmacy compounding

FDA and FTC Enforcement
- Standards applied by each Agency
- Case studies of enforcement Actions
- Warning Letters
- Consent decrees
- Court adjudicated cases and sanctions imposed

Session 3
New FDA Initiatives and Special Situations
- Social Media and other recent FDA guidances
- Internet, web sites, blogging and how to comply
- Off-label issues—what is allowed and how should it be handled?
- Videos, emails, and other situations presenting particular compliance issue

Session 4
In-depth analysis of FDA Warning Letters
- Applying the lessons learned to company promotion via Warning Letters
- What are the most frequent FDA objections
- What are FDA hot button items
- How to construct advertising and promotion to avoid a Warning Letter

Current Hot Topics in Advertising and Promotion

Questions and Answers