OVERVIEW
This program is designed both for people who are new to advertising and promotion issues, as well as those who have been involved in this area for some time. It is designed to provide practical, day-to-day guidance on what can be learned from the latest FDA enforcement actions, and how companies and their legal, regulatory, marketing, advertising and PR consultants can do their jobs better.

This year’s program focuses on the key issues facing advertising and promotion today, such as enforcement, off-label promotion, training, the new physician labeling rules, state regulations, and the increasingly important role of the Office of Inspector General.

TUTORIAL
Tuesday, February 20, 1:00-4:00 pm
DDMAC and Compliance 101: A Primer
LUCY ROSE, MBA, LUCY ROSE, MBA, Lucy Rose & Associates
PAUL SAVIDGE, JD, Paul Savidge, Bristol-Myers Squibb
KELLY FREEMAN, PhD, Kelly Freeman, Eli Lilly and Company

CONCURRENT BREAKOUT SESSIONS
Wednesday, February 21, 1:45-3:15 pm and 3:45-5:15 pm
Four breakout sessions will be offered in each time period enabling registrants to attend two of the following sessions.
- Sales and Marketing Compliance
- Working with FDA – Parts 1 and 2
- Just What Quality Data IS Required to Support a Claim?

LUNCHEON PRESENTATIONS
Wednesday, February 21, 12:15-1:30 pm
An Entrepreneur’s View of Pharma Innovation
DAVID SCHEER, Scheer and Company, Inc.

Thursday, February 22, 12:45-2:00 pm
FDA’s Budget Problem and What it Means
STEVE GROSSMAN, Executive Director, FDA Alliance

WILLIAM HUBBARD, Former FDA Associate Commissioner for Policy

KEYNOTE PRESENTATION
Thursday, February 22, 9:00-9:15 am
LINDA F. GOLODNER, National Consumer League

TARGET AUDIENCE
This program is designed for individuals involved in marketing, legal, regulatory, public affairs, and advertising executives in the pharmaceutical and biologics industries, plus their consultants and agencies.

CONTACT INFORMATION
Ellen Diegel, Program Manager
Phone +1-215-442-6158 / Fax +1-215-442-6199
email Ellen.Diegel@diahome.org

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!
TUESDAY • FEBRUARY 20

12:00-1:00 PM  TUTORIAL REGISTRATION

1:00-4:00 PM  TUTORIAL

DDMAC AND COMPLIANCE 101: A PRIMER
INSTRUCTORS
Lucy Rose, MBA  
President, Lucy Rose & Associates
Paul Savidge, JD  
Vice President, Labeling and Promotion, Bristol-Myers Squibb
Kelly Freeman, PhD  
Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company

If you are new, or relatively new, to DDMAC and/or advertising/promotional compliance, this tutorial is for you! The leaders will provide a strong introductory foundation for anyone working in our new regulatory environment. Whether you are a regulatory, legal, medical, or marketing professional, the information will be interesting, practical and vital!

Tutorial Learning Objectives
At the conclusion of this tutorial, participants should be able to:

• Discuss the latest regulations, enforcement actions, guidelines, and trends affecting the advertising and promotion of medical devices, drugs, and biologics
• Describe how companies can best navigate the FDA regulatory review process
• Provide an overview of the current direct-to-consumer advertising/promotion environment
• Outline the latest policies and actions being taken by the Office of Inspector General (OIG) and Department of Justice (DOJ)

5:00-7:00 PM  CONFERENCE REGISTRATION

WEDNESDAY • FEBRUARY 21

8:00-9:00 AM  REGISTRATION AND CONTINENTAL BREAKFAST

9:00-9:15 AM  WELCOME AND OPENING REMARKS  
Wayne L. Pines  
President, Regulatory Services and Healthcare APCO Worldwide Inc.
9:15-10:15 AM  SESSION 1

FDA UPDATE AND RECENT ENFORCEMENT ACTIONS

CHAIRPERSON
Wayne L. Pines
President, Regulatory Services and Healthcare, APCO Worldwide Inc.

This address provides an overview on current issues, laws and regulations to the promotion of prescription drugs. Learn the latest on policy development, enforcement and FDA’s future initiatives.

PRESENTERS
Thomas W. Abrams, MBA, RPh
Director, Division of Drug Advertising, Marketing and Communications (DDMAC), CDER, FDA
Elenita Ibarra Pratt, RN, MPH
Branch Chief, Advertising and Promotional Labeling Branch, Division of Case Management, Office of Compliance and Biologics Quality, CBER, FDA
Martine Hartogensis, DVM
Promotion and Advertising Liaison, Center for Veterinary Medicine, FDA

10:15-10:45 AM  QUESTION & ANSWER PERIOD

10:45-11:15 AM  REFRESHMENT BREAK

11:15AM-12:00 PM  SESSION 2

NEW TRENDS IN STATE AND FEDERAL ENFORCEMENT AND INDUSTRY RESPONSE

CHAIRPERSON
John F. Kamp, JD, PhD
Executive Director, Coalition of Healthcare Communication

This session will focus on trends in state and federal enforcement and the changes inside the industry in response to them. Several states have developed new laws regulating drug company marketing, including use of prescriber data, limits on interactions with doctors and formulary groups, and new reporting requirements. Meanwhile, both state and private actions have increased. Meanwhile, federal enforcement by the HHS-IG and Department of Justice has created a new focus on the need for internal controls and investigations.

PRESENTERS
Randolph Frankel
Vice President, Public Affairs and Government Relations
Marjorie Powell
Senior Assistant, General Counsel, PhRMA
I. Scott Bass, JD
Partner, Sidley Austin LLP

12:15-1:30 PM  LUNCHEON PRESENTATION

AN ENTREPRENEUR’S VIEW OF PHARMA INNOVATION
David Scheer
President, Scheer and Company, Inc.

1:45-3:15 PM  CONCURRENT BREAKOUT SESSIONS – PART A

1:45-3:15 PM  BREAKOUT SESSION 1-A

SALES AND MARKETING COMPLIANCE

The pharmaceutical industry is a highly regulated environment covered by laws, regulations, guidances, and codes from the FDA, OIG, PhRMA and state specific legislation. Many companies have negotiated Corporate Integrity Agreements (CIAs) or Consent Decrees with the government. The current environment requires development of an effective compliance program for sales and marketing practices covering all seven elements. However, there are considerations for monitoring and auditing of sales and marketing practices that are unique from traditional financial auditing. Effective monitoring and auditing programs are important for assuring there is compliant conduct in the organization. But they also serve as a feedback loop to the policy, training, and communication elements.

Kelly Freeman, PhD
Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company
Michael Dusseau
Senior Director, Global Compliance, Schering-Plough

1:45-3:15 PM  BREAKOUT SESSION 2-A

WORKING WITH FDA – PART 1

What do you need to know to effectively work with CDER-DDMAC and CBER-ABLB on a daily basis? Join us in an interactive exploration of a variety of topics and your questions covering the following and more.

- Launch
- Advisory comments
- DTC
- FDA Form 2253

Jean-Ah Kang, PharmD
Senior Regulatory Affairs Scientist, Science Applications International Corporation, BioPharma Regulatory Science and Technology
Glenn N. Byrd, MBA, RAC
Director, Regulatory Affairs, PDL BioPharma, Inc.

1:45-3:15 PM  BREAKOUT SESSION 3-A

JUST WHAT QUALITY DATA IS REQUIRED TO SUPPORT A CLAIM?

This workshop will probe the data quality required to support promotional claims. Following a regulatory-grounding presentation by DDMAC, panelists will discuss such challenges as post-hoc subgroup analyses, open label extension trials, secondary and tertiary endpoints, and patient-reported outcomes. Understanding the challenging promotional pressures in today’s world, this interactive session will provide important information to inform your responses to marketing claims requests.

Lucy Rose, MBA
President, Lucy Rose & Associates
Heidi Jolson, MD
Consultant
Elaine Hu, PharmD
Regulatory Review Officer, Division of Drug Advertising, Marketing and Communications (DDMAC), CDER, FDA

BREAKOUT SESSIONS

This will be an opportunity for the participants to discuss case studies, issues, challenges and their possible resolution. Attendees are encouraged to provide sanitized cases for discussion. There will be three breakout sessions. Each session will be repeated, giving participants the opportunity to attend two sessions of their choice.
SALES AND MARKETING COMPLIANCE

The pharmaceutical industry is a highly regulated environment covered by laws, regulations, guidelines, and codes from the FDA, OIG, PhRMA and state specific legislation. Many companies have negotiated Corporate Integrity Agreements (CIAs) or Consent Decrees with the government. The current environment requires development of an effective compliance program for sales and marketing practices covering all seven elements. However, there are considerations for monitoring and auditing of sales and marketing practices that are unique from traditional financial auditing. Effective monitoring and auditing programs are important for assuring there is compliant conduct in the organization. But they also serve as a feedback loop to the policy, training, and communication elements.

Kelly Freeman, PhD
Director, US Affiliate, Compliance and Ethics, Eli Lilly and Company

Michael Dusseau
Senior Director, Global Compliance, Schering-Plough

WORKING WITH FDA – PART 2

What do you need to know to effectively work with CDER-DDMAC and CBER-ABL on a daily basis? Join us in an interactive exploration of a variety of topics and your questions covering the following and more:

- Accelerated approval
- Enforcement responses
- Labeling updates

Jean-Ah Kang, PharmD
Senior Regulatory Affairs Scientist, Science Applications International Corporation, BioPharma Regulatory Science and Technology

Glenn N. Byrd, MBA, RAC
Director, Regulatory Affairs, PDL BioPharma, Inc.

JUST WHAT QUALITY DATA IS REQUIRED TO SUPPORT A CLAIM?

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Consultant

Elaine Hu, PharmD
Regulatory Review Officer, Division of Drug Advertising, Marketing and Communications (DDMAC), CDER, FDA

Mark S. Hirsch, MD
Acting Deputy Director, Division of Reproductive and Urologic Products, CDER, FDA
Register 3 individuals from the same company and receive complimentary registration for a 4th!

TRAVEL AND HOTEL  La Guardia, Kennedy, and Newark Airports are conveniently located and airline reservations should be made as early as possible to ensure availability. Amtrak’s Penn Station is located several blocks from the New York Marriott Marquis Times Square. For Amtrak reservations, call 1-800-USA-RAIL. The New York Marriott Marquis Times Square is holding a block of rooms at the reduced rate below until January 29, 2007, for DIA conference attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.

To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.
19th Annual Conference for MARKETING OF PHARMACEUTICALS IN A TIME OF CHANGE
New York Marriott Marquis Times Square
New York, NY, USA
February 20-22, 2007 | Event ID #07007

Register online or fax this page to +1-215-442-6199

CONTACT INFORMATION
Contact Ellen Diegel at the DIA office by telephone +1-215-442-6158, fax +1-215-442-6199 or email Ellen.Diegel@diahome.org.

GROUP DISCOUNTS (not available online or on already discounted fees)
Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and pay at the same time – no exceptions. See page 6 for complete details.

Registration Fees
If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY
Available on nondiscount member fee only
On or before After
JAN. 31, 2007 JAN. 31, 2007
Member Fee
US $1210 ❑ US $1390 ❑
Join DIA now to qualify for the early-bird
MEMBERSHIP
US $ 130 ❑
AboutMembership/AboutMembership

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to governmental/academic/nonprofit members.

Nonmember Fee
US $1520 ❑
A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discord Fees
Government (Full-time)
MEMBER US $ 300 ❑ US $ 430 ❑
NONMEMBER US $ 700 ❑ US $ 830 ❑
Charitable Nonprofit/Academia (Full-time)
MEMBER US $ 300 ❑ US $ 430 ❑
NONMEMBER US $ 700 ❑ US $ 830 ❑

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

TUTORIAL
Tuesday, February 20
1:00-4:00 pm
US $ 375 ❑

CANCELLATION POLICY: On or before FEBRUARY 14, 2007
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial = $50
Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.
DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.
I cannot attend but please keep me informed of DIA’s future events.
(required completion of name, postal address and email address on this form)

TUTORIAL DDMAC and Compliance 101: A Primer

CONCURRENT BREAKOUT SESSIONS
• Sales and Marketing Compliance
• Working with FDA
• Just What Quality Data IS Required to Support a Claim?

FDA PARTICIPANTS
Thomas W. Abrams
Kathryn Aikin
Kristin I. Davis
Maryann Gallagher
Martine Hartogensis
Marci Kiester
Elenita Ibarra Pratt
Christine Smith

PAYMENT OPTIONS
Register online at www.diahome.org or check payment method

CREDIT CARD number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

Card # ____________________________
Name (printed) ____________________________
Exp Date ____________________________
Signature ____________________________

CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of your event.

BANK TRANSFER
When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.