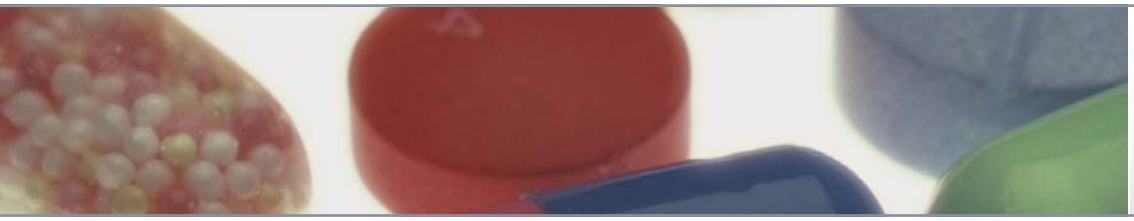
May 29-30, 2008 • Hotel Whitcomb • San Francisco

American Conference Institute's

FDA BOOT CAMP

Basic Training for Products Liability and Patent Lawyers



Distinguished Co-Chairs:

Paul T. Kim
Partner
Foley Hoag LLP

Peter O. Safir
Partner
Covington & Burling LLP

Featuring Special Drug Marketing Guidance Sessions on:

Advertising & Promotion
DTC Advertising
Off-Label

SPECIAL TRACKS:

Patent Track

Non-Patent Exclusivity
Bioequivalency
Follow-On Biologics

Medical Device Track

Classification and Premarket Review
Post-Market Requirements
Labeling and Advertising

The **FDA Amendments Act of 2007 (FDAAA)** is one of the most comprehensive revisions of the FFDCA in decades. Preeminent members of the nation's Food and Drug bar will **drill you in the basics of FDA law and regulation — and the nuances of FDAAA** — as they help you:

- MASTER the basics of the **application and approval processes** for drugs, biologics and devices
- COMPREHEND the structure of the **FDA** and the roles of the three major agency centers: **CDER**, **CBER**, and **CDHR**
- DEVELOP a practical working knowledge of **clinical trials** for drugs and biologics and the **clearance process** for devices
- LEARN how **devices** are classified, monitored, and regulated
- UNDERSTAND the complexities of pharmaceutical IP and the regulatory balance between **brand name** and **generic** products
- RECOGNIZE the pivotal role of **labeling** in the drug and biologics approval process
- NAVIGATE the protocols of **adverse events** monitoring, signal detection, product withdrawals, and **recalls**
- GAIN a clear understanding of the laws and regulations controlling the **advertising**, marketing and promotion of drugs, biologics and devices

Plus, featuring special addresses by:

James H. Smith
Associate Chief Counsel
U.S. Food and Drug Administration

Ioana Petrou
Criminal Health Care Fraud Coordinator
U.S. Attorney's Office, NDCA

EARN CLE CREDITS

Media Partners:

www.PharmCast.com – Pharmaceutical Internet –

PharmaVOICE

Orange Book Blog – At the Intersection of Patent Law and FDA Law

American Conference Institute

Register Now • 888-224-2480 • AmericanConference.com/FDABootCampSF

FDA BOOT CAMP

So much hinges on what happened during the pre-approval, approval, or post-approval periods.

Learn to navigate your way through the regulatory maze that plays such a crucial role to your cases and practice areas.

The approval process…pre-approval concerns…product labeling…clinical trials…adverse events reports…patent concerns…exclusivity… All are critical aspects in the commercialization process for drugs, biologics, and devices that are governed by FDA law and regulation. Plus, the **FDA Amendments Act of 2007 (FDAAA)** is one of the most comprehensive revisions of FDA law in decades. And recent court cases and high-profile trials concerning FDA-regulated products have made it clear that it is essential for attorneys who do not have regulatory practices — but who do deal with FDA-regulated products — to have a familiarity with these concepts. The same can be said of securities experts and business executives in the life sciences arena.

Products liability and patent litigation concerning these products often hinges on what happened during the pre-approval, approval, or post-approval periods.

However, many products liability lawyers, patent counsel, and business and investment experts — despite their tenure in working with FDA-regulated products — are not well-versed in the essentials of the approval process and the regulatory hurdles of the post-approval period.

Boost your FDA regulatory IQ.
Develop expertise in the FDA approval process and the ins and outs of post-approval challenges.

ACI's FDA Boot Camp has been designed to give products and patent litigators, as well as patent prosecutors and life sciences investment and securities experts, a strong working knowledge of core FDA competencies, including **the nuances of FDAAA**.

A distinguished faculty of top FDA regulatory experts — a *"Who's Who of the FDA Bar"* — will share their knowledge and give you critical insights on:

- The organization, jurisdiction, functions, and operations of the FDA
- The essentials of the approval process for drugs, biologics, and devices, including:
  - NDAs
  - INDs
  - BLAs
  - OTC Approval
  - 510(k) submissions
  - PMA process
- Clinical trials for drugs and biologics and the clearance process for devices
- The classification of devices and the concept of "risk-based" classification
- The role of the Hatch-Waxman Act in the patenting of drugs and biologics
- Labeling in the drug and biologics approval process
- cGMPs and other manufacturing concerns relative to products liability
- Proactive adverse events monitoring and signal detection
- Requirements for post-approval advertising and promotion
- Recalls, product withdrawals, and FDA oversight authority
- Current government enforcement priorities and key legislative initiatives

Other program highlights include special Patent and Medical Device tracks.

Seats at two previous ACI Boot Camps sold out. Don't delay — register now by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563**, or registering online at **www.AmericanConference.com/FDABootCampSF**.

DISTINGUISHED FACULTY

Co-Chairs:


Paul T. Kim
Foley Hoag LLP


Peter O. Safir
Covington & Burling LLP

Speakers:


Jennifer L. Bragg
King & Spalding LLP


Jayne P. Bultena
Foley Hoag LLP


John D. Carlin
Fitzpatrick, Cella, Harper & Scinto


Robert F. Church
Hogan & Hartson


Dickerson M. Downing
Crowell & Moring, LLP


Mark A. Heller
Goodwin Procter LLP


Bret Koplow
Patton Boggs LLP


Gregory H. Levine
Arnold & Porter LLP


William A. McGrath
Wiley Rein LLP

Joyce L. Morrison
Xencor, Inc.


Stephen C. Payne
Sidley Austin LLP


Donna M. Praiss
Hunton & Williams LLP

Ioana Petrou
US Attorney's Office, NDCA

Eric Rogers
Genentech


Deborah M. Shelton
Sheppard Mullin Richter & Hampton LLP


Robin M. Silva
Morgan, Lewis & Bockius LLP

James H. Smith
U.S. Food and Drug Administration


Frederick A. Stearns
Keller Heckman LLP


Gretchen R. Stroud
Cooley Godward Kronish LLP


Stephen D. Terman
Olsson Frank Weeda Terman Bode Matz PC


Elaine H. Tseng
King & Spalding LLP


Judith A. Waltz
Foley & Lardner LLP

Karen A. Weaver
Epstein Becker & Green, P.C.


Jessica R. Wolff
Heller Ehrman LLP

Day One • Thursday, May 29, 2008

7:30 Registration and Continental Breakfast

8:10 Co-Chairs' Opening Remarks

Paul T. Kim
Partner
Foley Hoag LLP
(Boston, MA and Washington, DC)

Peter O. Safir
Partner
Covington & Burling LLP
(Washington, DC)

8:30 The Basics: Understanding and Working with the FDA — Jurisdiction, Functions, Organization, and Operations

Jayne P. Bultena
Partner
Foley Hoag LLP
(Washington, DC)

- FDA Overview
- How the FDA is organized
  - Department of Health and Human Services and the Commissioner
  - The 5 FDA Centers and the Office of Regulatory Affairs and their functions
- The 3 major centers and their roles
  - CDER (Drug)
  - CBER (Biologic)
  - CDRH (Device)
- Understanding how CDER and CBER intersect
  - intersection with CDRH
- Defining the scope of the FDA's jurisdiction
- Examining how the FDA exercises its jurisdiction:
  - rule making
  - product decisions
  - enforcement
  - informal mechanisms
- Reviewing the laws that the FDA enforces
  - Food Drug & Cosmetic Act
  - Prescription Drug Marketing Act
  - Public Health Services Act
  - Hatch-Waxman Act
  - other applicable laws
- Defining drugs, biologics, and medical devices
- Labeling: when is a drug a drug and not a medical device or cosmetic, and the consequences
- Defining combination products
- Working with the FDA
  - Administrative Procedures Act
  - formal and informal dispute resolution mechanisms
- FDA's policies and procedures

Preapproval and Approval

9:15 The Nature of the Approval Process

Gregory H. Levine
Partner
Arnold & Porter LLP
(Washington, DC)

Rx Drugs

- Understanding the difference between "new drugs" and other drugs
- Overview of the research, development, and approval process for new drugs
- The investigational new drug application (IND)
  - when you need to file one
  - what it needs to contain
  - what it entitles you to do
- The new drug application (NDA)
  - when you need to file one
  - what it needs to contain
  - FDA review process and timing
  - advisory committees
- Accelerated approval (fast track)
- FDA/CMS Coordination

Biological Products

- What are biological products?
- What does it mean to say that they are also "drugs"?
  - which "new drugs" require BLAs instead of NDAs?
- How does the research, development, and approval process for biological products differ from the process for new drugs?
- The biologics license application (BLA)
  - when you need to file one
  - what it needs to contain
  - FDA review process and timing
  - advisory committees
- Key similarities and differences between the drug and biological product schemes

OTC Products

- The concept of "OTC" (OTC-ness)
- The OTC Review
  - which drugs are covered?
  - what is a "monograph"?
  - what does a monograph contain?
  - what if you want to deviate from the monograph (innovate)?
- When is a new drug suitable for OTC?
  - when must a drug be Rx only?
  - how do you switch a new drug from Rx to OTC?
  - can a new drug be Rx in some forms/dosages/etc., and OTC in others?
- Overview of how an OTC drug comes to market
  - if it's a new drug
  - if it's not a new drug

10:10 Morning Coffee Break

10:25 Understanding the Clinical Trial Process for Drugs and Biologics

Robert F. Church
Partner
Hogan & Hartson
(Los Angeles, CA)

- Overview of the clinical trial process
  - phases of testing (I-IV)
  - what happens in each phase?
  - who conducts the testing?
  - special considerations for Phase IV testing
- Regulatory requirements
  - informed consent

- IRBs
- sponsor obligations
- investigator obligations
- FDA authority
- Other issues
  - CROs
  - how do clinical trials for drugs differ from clinical trials for biologics?
- Disclosure of clinical trial information
  - FDA Amendments Act of 2007
  - FDAMA § 113
  - clinicaltrials.gov
  - PhRMA policies
- CMS coverage for clinical trials and research

11:20 Patent and IP Overview: Hatch-Waxman, Trademark Protection, and More

Dickerson M. Downing
Partner
Crowell & Moring, LLP
(New York, NY)

Joyce L. Morrison
Vice President, Intellectual Property
Xencor, Inc.
(Monrovia, CA)

Robin M. Silva
Partner
Morgan, Lewis & Bockius LLP
(San Francisco, CA)

Gretchen R. Stroud
Special Counsel
Cooley Godward Kronish LLP
(Palo Alto, CA)

IP Protection

- Analyzing the patenting process
- Seeking patent protection during the pre-approval process
- Making up for time lost in the patent life cycle during the pre-approval process
  - IP and regulatory redress for lost time
- Distinguishing the patenting process for drugs from that of biologics
  - which biologics are treated as drugs and why?
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products

Drugs

- NDA v. ANDA (Abbreviated New Drug Application)
  - how do they differ?
- ANDA
  - what does an ANDA require?
  - potential actions by NDA and patent owners
- Paragraph IV Certifications and Notice Letters
- Bioequivalence defined
- The Orange Book: what is it and why is it Orange?
  - listings
  - de-listings
- The patent end game (Hatch-Waxman Overview)
  - overview of Hatch-Waxman and reforms under MMA
  - the Orange Book
  - exclusivity (180 day)
  - 30-month stay
  - patent extensions
  - the safe harbor
- FD&C 505b2 (an alternate pathway to an ANDA)

Trademark Issues

- Identifying the PTO and FDA clearances necessary for trade name/trademark approval on your product

12:50 Networking Luncheon for Speakers and Delegates

2:00 Drugs and Biological Products: Labeling

Karen A. Weaver
Member
Epstein Becker & Green, P.C.
(Los Angeles, CA)

The labeling of the drug/biological product is the final stage of the approval process. The labeling affects what you can do post-approval. It is the point of transition between the approval process and post-approval world.

- Labeling overview: key regulatory requirements, information, and contents
- Review process for labeling
- How does the final labeling control the scope of post-market activities?
- When should the labeling be amended post-market?
  - what is the process for doing so?
- How is the labeling a defense in products litigation?

2:55 Afternoon Refreshment Break

3:10 From Theory to Practice: FDAAA, Future FDA and Legislative Priorities, Other Enforcement Initiatives, and Beyond

James H. Smith
Associate Chief Counsel
U.S. Food and Drug Administration
(Rockville, MD)

Ioana Petrou
Criminal Health Care Fraud Coordinator
US Attorney's Office, NDCA
(San Francisco, CA)

Paul T. Kim
Partner
Foley Hoag LLP
(Boston, MA and Washington, DC)

Judith A. Waltz
Partner
Foley & Lardner LLP
(San Francisco, CA)

Moderator:

Bret Koplow
Partner
Patton Boggs LLP
(Washington, DC)

- FDAAA – how companies must now adapt
  - implementation considerations

FROM THEORY TO PRACTICE

- avoiding civil penalties and fines for noncompliance
- Overriding philosophy, goals, and priorities of the FDA at this juncture and what to expect to be high on the agency's agenda
- What now sparks an FDA investigation?
- Steps to take after receiving warning letters
- Consent decrees: what you now must know
- Other significant recently enacted and proposed legislation and their food and drug implications
  - Sunshine Acts and other bills requiring additional disclosures and greater transparency
  - proposed amendments to the Federal False Claims Act
  - analysis of increased legislative activity at the state level
  - developing methods for tracking and complying with diverse requirements
- When will DOJ prosecute?
- Understanding government enforcement tools and procedures
- Current enforcement priorities as evidenced by recent investigations
- Identifying conduct that can trigger government scrutiny
- How recent large settlements should be reflected in risk mitigation strategies

POST-APPROVAL

4:45 cGMPs: Drugs and Biologics (current Good Manufacturing Practices)

Stephen C. Payne
Partner
Sidley Austin LLP
(Washington, DC)

- Examining cGMPs and the scope of their importance in pharmaceutical/biological product commercialization
- Looking at how cGMPs factor into the scope of the FDA's authority and history
- Exploring the scope of the FDA's cGMP Initiative and how the concept of "risk-based" cGMPs is defined
- Defining the concept of validation
- How are laboratory investigations in relation to cGMPs conducted?
- Defining the term "quality systems"
- How are cGMPs factoring into products litigation?

5:35 Conference Adjourns

DAY TWO • FRIDAY, MAY 30, 2008

7:30 Continental Breakfast

8:00 Co-Chairs' Remarks

POST-APPROVAL (Continued)

8:10 Advertising and Promotion

William A. McGrath
Partner
Wiley Rein LLP
(Washington, DC)

- Overview of laws and regulations controlling the advertising, marketing, and promotion of prescription drugs and biologics
  - 21 CFR Sections 202.1, 352(n), 314.81(b)(3); Section 352(n) of FD&CA
  - guidance documents
- DDMAC (Division of Drug Marketing, Advertising and Communications)
  - what duties and responsibilities is DDMAC charged with?
  - what are its enforcement capabilities and jurisdiction?
  - analysis of sample warning letters
- Identifying the role of the FTC in the advertising and promotion of drugs
  - SEC?
- Advertising requirements for prescription v. nonprescription products
- Reviewing the steps which DDMAC takes for the review of launch campaigns and promotional materials
  - overview of the promotional materials submission and review process
- What constitutes a launch?
- What defines an advertisement?
  - what information must a drug advertisement include?
- Exploring the role of the label in advertising

9:05 Special Concerns for DTC Advertising

Peter O. Safir
Partner
Covington & Burling LLP
(Washington, DC)

- How is direct-to-consumer advertising regulated and monitored?
  - how is it different from other pharmaceutical advertising?
- What information must every DTC ad contain?
- How do the PhRMA DTC guidelines interplay with current FDA regulation?
- FDA's DTC Television User Fee Program
- Advertising and new media
  - how is Internet and e-mail advertising regulated?

9:55 Morning Coffee Break

10:10 Regulation and Dissemination of Off-Label Information

Jennifer L. Bragg
Partner
King & Spalding LLP
(Washington, DC)

- Overview of the FDA's regulation of off-label promotion
- How can information on off-label or unapproved uses of drugs and biologics be disseminated?
  - peer review articles v. ghost-writing
  - MSLs v. sales reps
- What are the consequences of inappropriate off-label promotion?
  - the role of the OIG, U.S. Attorney's Office, and states in monitoring off-label promotion

11:00 Adverse Events Monitoring, Pharmacovigilance and Risk Management

Bret Koplow
Partner
Patton Boggs LLP
(Washington, DC)

- What is pharmacovigilance?
- How pharmacovigilance uses adverse event reports
  - how ADE reports come to a company

    - solicited direct reports
    - unsolicited direct reports
    - indirect reports
  - how companies investigate, analyze and use ADE reports
    - causality assessments
    - labeling changes
  - requirements for reporting ADEs to regulatory agencies
    - premarket stage
    - post-market stage
  - how regulatory agencies use ADE reports
- Examining other tools for pharmacovigilance
- What is risk management?
  - the new Risk Evaluation and Minimization Strategies (REMS) law
  - Risk evaluation in the approval process
  - Risk minimization tools
  - REMS assessments
- Enforcement of ADE reporting and REMS requirements
- Examining the relevance to product liability risks

11:55 **Networking Luncheon for Speakers and Delegates**

Bifurcated Tracks Choose One

Patent Track (Advanced Life Cycle Considerations)

1:05 **Non-Patent Exclusivity**

Eric Rogers
Corporate Counsel
Genentech
(South San Francisco, CA)

Deborah M. Shelton
Special Counsel
Sheppard Mullin Richter & Hampton LLP
(Washington, DC)

- The different modes and methods of exclusivity (non-patent)
  - data
  - orphan drug
  - pediatric
  - new product
- FD&C 505b2 (alternate pathway to ANDA)
- What role does the FDA play in regulating these modes of exclusivity?
- When are each of these methods sought?
- Exploring the relation and intersection of each of these methods to 180-day exclusivity

2:05 **Bioequivalence: What Lawyers Need to Know**

John D. Carlin
Partner
Fitzpatrick, Cella, Harper & Scinto
(New York, NY)

- Defining bioequivalence in drugs and biologics
  - drugs v. biologics
- What an ANDA-filer must demonstrate for bioequivalence
  - bioequivalence and dosage form – oral tablet/capsule, injection, nasal sprays, topical
- How does bioequivalence relate to patents?
  - patenting of bioequivalence characteristics – extended-release drug products
  - bioequivalence v. Doctrine of Equivalents – what is the difference?
  - arguments about bioequivalence raised in Paragraph IV patent litigation
    - infringement, copying (non-obviousness)

2:50 **Afternoon Refreshment Break**

3:05 **Follow-On (Comparable or Biosimilar) Biologics**

Donna M. Praiss
Partner
Hunton & Williams LLP
(New York, NY)

Jessica R. Wolff
Shareholder
Heller Ehrman LLP
(San Diego, CA)

- What are biologic drugs and why are they different for purposes of generic competition?
- When can FDA approve a follow-on biologic under current law?
- Review of the Omnitrope approval – what does it say about FDA's views on follow-ons?
- What kind of abbreviated approval route for biologics is being considered in Congress?
- Will follow-on biologics ever be interchangeable with the innovators they copy?

Medical Device Track

1:05 **Medical Devices: Classification and the Essentials of the Device Premarket Review Process**

Mark A. Heller
Partner
Goodwin Procter LLP
(Washington, DC)

FDA's Risk-Based Classification Scheme for Medical Devices

- Understanding the concept of risk-based classification
- Three main classes of medical devices
  - Class I: "low risk" devices, e.g., orthopedic blade, tongue depressor
  - Class II: "moderate risk" devices, e.g., powered wheelchair, endoscope
  - Class III: "high risk" devices, e.g., cardiac ablation catheters, drug eluting stents
- Device reclassification

The Premarket Review Process for Medical Devices

- 510(k) exemptions for low risk devices
- Premarket notification (510(k)) process
  - understanding the selection of "predicate" devices when 510(k) submissions are made and the consequences of choosing the wrong predicate
- Premarket approval (PMA) process
- The role of the Investigational Device Exemption (IDE)

2:05 Post-Market Requirements and Concerns for Medical Devices

Elaine H. Tseng
Counsel
King & Spalding
(Washington, DC)

- What types of facilities must comply with FDA's establishment registration and device listing requirements?
- What is the scope of the Quality System Regulation (QSR)?
- What types of adverse events must be reported under the Medical Device Reporting (MDR) regulation?
- What kinds of field actions must be reported under the Reports of Corrections and Removals regulation?
- What other types of postmarket requirements can FDA impose on medical devices, e.g., tracking?

2:50 Afternoon Refreshment Break

3:05 Medical Device Labeling and Advertising

Stephen D. Terman
Principal
Olsson Frank Weeda Terman Bode Matz PC
(Washington, DC)

- What are the differences between labeling and advertising and do they include websites?
- What claims can device manufacturers make regarding cleared/approved devices, devices with pending 510(k) notices, and investigational devices?
- How can device manufacturers convey information about new uses to health care professionals and/or consumers?
- What are the consequences of illegal promotion of a device?

Recalls and Withdrawals

4:05 Recall Guidance for Drugs, Biologics, and Medical Devices: What You Need To Know

Frederick A. Stearns
Partner
Keller Heckman LLP
(Washington, DC)

- What is the FDA's recall and oversight authority?
  - from where does this authority derive?
  - overview of 21 CFR Part 7
  - guidance versus regulation
  - voluntary recalls versus mandatory recalls
  - market withdrawals and stock recoveries
- What product recalls need to be reported to FDA?
- When should a company institute a recall?
  - can new labeling or a new product warning constitute a recall?
- When should the decision be made to work with the FDA?
  - working with the FDA versus working alone?
    - what are the risks and benefits in each course of action?
- Interaction between recalls and corrective and preventive action
- What are the consequences of not instituting a recall?
- FDA seizure and injunction power
- When can product be reintroduced to the market?

5:00 Conference Ends

Who You Will Meet

Attorneys for the pharmaceutical, biotech, and medical device industries whose practices focus on:

- Products liability litigation
- Patent litigation
- Patent prosecution

In-house counsel for the pharmaceutical, biotech, and medical device industries with responsibility for:

- Litigation
- Patents and IP

Securities Attorneys with practices in pharmaceuticals, biotech and device

Investment Bankers and Venture Capitalists with practices in pharmaceuticals, biotech and device

Continuing Legal Education Credits

CLE CREDITS

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This ***transitional*** course is appropriate for both experienced and newly admitted attorneys.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board in the amount of 16.5 hours.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California in the amount of 13.75 hours.

ACI has a dedicated team who process requests for state approval. Please note that event accreditation varies by state and **ACI** will make every effort to process your request.

Global Sponsorship Opportunities

ACI, along with our sister organization based in London, **C5** Conferences, works closely with sponsors in order to create the perfect business development solution catered exclusively to the needs of any practice group, business line or corporation. With over 350 conferences in the United States, Europe, the Commonwealth of Independent States (CIS) and China, **ACI/C5** Conferences provides a diverse portfolio of first-class events tailored to the senior level executive spanning multiple industries and geographies.

For more information about this program or our global portfolio of events, please contact:

Wendy Tyler
Group Leader & Business Development Executive
American Conference Institute

Tel: 212-352-3220 Ext. 242
Fax: 212-220-4281
w.tyler@AmericanConference.com

The **FDA Amendments Act of 2007 (FDAAA)** is one of the most comprehensive revisions of the FFDCA in decades. Preeminent members of the nation's Food and Drug bar will **drill you in the basics of FDA law and regulation — and the nuances of FDAAA at:**

American Conference Institute's

FDA BOOT CAMP

Basic Training for Products Liability and Patent Lawyers

May 29-30, 2008 • Hotel Whitcomb • San Francisco

Featuring Special Drug Marketing Guidance Sessions on:

Advertising & Promotion
DTC Advertising
Off-Label

SPECIAL TRACKS:

PATENT TRACK

Non-Patent Exclusivity
Bioequivalency
Follow-On Biologics

MEDICAL DEVICE TRACK

Classification and Premarket Review
Post-Market Requirements
Labeling and Advertising

REGISTRATION FORM

PRIORITY SERVICE CODE:
892L08.WEB

ATTENTION MAILROOM: If undeliverable to addressee, please forward to:
LITIGATION, PRODUCTS LIABILITY ATTORNEY, PATENT ATTORNEY, COUNSEL

CONFERENCE CODE: 892L08-SNF
❑ YES! Please register the following delegate for
FDA BOOT CAMP

NAME _____ POSITION _____

APPROVING MANAGER _____ POSITION _____

ORGANIZATION _____

ADDRESS _____

CITY _____ STATE _____ ZIP CODE _____

TELEPHONE _____ FAX _____

EMAIL _____ TYPE OF BUSINESS _____

FEE PER DELEGATE	Register & Pay by Mar 21, 2008	Register & Pay by May 2, 2008	Register after May 2, 2008
❑ Conference	$1895	$1995	$2195
❑ I would like to add __ copies of the conference materials on CD–ROM to my order – $299 each			
❑ I cannot attend but would like information regarding conference publications			
❑ Please send me information about related conferences			

PAYMENT

Please charge my ❑ VISA ❑ MasterCard ❑ AMEX ❑ Please invoice me

Number _____ Exp. Date _____

Signature _____
(for credit card authorization and opt-in marketing)

❑ I have enclosed my check for $_____ made payable to **American Conference Institute** (T.I.N.—98-0116207)

Can be recycled

5 Easy Ways to Register

MAIL **American Conference Institute**
41 West 25th Street
New York, NY 10010

PHONE 888–224–2480

FAX 877–927–1563

ONLINE AmericanConference.com/FDABootCampSF

EMAIL CustomerService@AmericanConference.com

Hotel Information

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "ACI FDA Boot Camp" conference to receive this rate:

VENUE: Hotel Whitcomb
ADDRESS: 1231 Market Street, San Francisco, CA 94103
RESERVATIONS: 415-626-8000

Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add–ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

Cancellation and Refund Policy

Substitution of participants is permissible without prior notification. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other **ACI** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **ACI** reserves the right to cancel any conference it deems necessary and will, in such event, make a full refund of any registration fee, but will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by **ACI** for changes in program date, content, speakers or venue.

Incorrect Mailing Information

If you would like us to change any of your details please fax the label on this brochure to our Database Administrator at 1–877–927–1563, or email data@AmericanConference.com.

CONFERENCE PUBLICATIONS

To reserve your copy or to receive a catalog of **ACI** titles go to **www.aciresources.com** or call **1-888-224-2480**.

SPECIAL DISCOUNT

We offer special pricing for groups and government employees. Please email or call for details.
Promotional Discounts May Not Be Combined. **ACI** offers financial scholarships for government employees, judges, law students, non–profit entities and others. For more information, please email or call customer care.