

Registration Form

Offering # **0805-301**

Generic Drug Approvals

May 14–16, 2008 • New Brunswick, NJ

Priority Code: **520**
(Please use this code when registering)

Dr. Mr. Ms. _____
First Name Last Name

Job Title _____

Company/Institution _____

Company Address _____

City _____ State _____ Zip _____

Tel: _____ Fax: _____

E-mail Address _____
(CFPA does not rent or sell e-mail addresses)

How did you learn about this course?

- Direct Mail Colleague Website Other

Tuition and Payment Methods

Early Registration (Save \$200) U.S. \$ **1740** / \$ **1660***
(Must register and pay by March 19, 2008) (Group Rate)

Regular Registration U.S. \$ **1940** / \$ **1860***
(Group Rate)

Tuition payable in US funds net of all charges includes continental breakfast, luncheon, breaks and course notes.

Payment is due prior to course start date. If payment has not been received two weeks before the course, a credit card will be required to guarantee admittance.

*Group Rate is for two or more enrollments registering at the same time, from the same company, for the same course.

Send Invoice (POs must be received in advance of course)

Purchase Order # _____

Check (payable in U.S. funds to The Center for Professional Advancement)

Credit Card

Visa MasterCard American Express Discover

Card # _____ Exp. Date _____

Cardholder Name _____

Signature _____

4 Ways To Register

- Log on to www.cfpa.com
- Call: 732.613.4500
- Fax to: 732.238.9113
- Mail: **The Center for Professional Advancement (CFPA)**
P.O. Box 7077
East Brunswick, NJ 08816-7077

General Information

Discounts/Rates: Early registration discount requires payment at time of registration and before expiration or regular tuition will apply. Group Rate is for two or more enrollments registering at the same time, from the same company, for the same course. Multiple discounts not applicable.

Cancellations/Substitutions: All cancellations are subject to a \$150.00 processing fee. Applicants may cancel up to two weeks prior to the course start date for a refund. If less than two weeks, a credit will be issued that can be used towards a future course up to one year from the date of issuance. No refunds or credit will be issued for those who do not attend the scheduled course and/or cancel less than two working days before the start date. Substitutions are permitted at any time. If for any reason, CFPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice.

Confirmation Letters: Before each course begins, all registrants will receive written confirmation including detailed information regarding course location. If confirmation is not received two weeks prior to the course please contact us.

For our full terms and conditions, visit www.cfpa.com.

Accreditations



The Center for Professional Advancement has been reviewed and approved as an Authorized Provider (#640) of continuing education and training programs by the **International Association for Continuing Education and Training (IACET)**. **Continuing Education Units (CEU)** will be awarded for participation in this course at a rate of 0.1 CEU per contact hour. *CEU will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation.*



The Center for Professional Advancement (CFPA) is accredited by the **Accreditation Council for Pharmacy Education** as a provider of continuing pharmacy education. **Continuing Education Units (CEU)** will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The **CEU** rate is 0.1 CEU per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a **Learning Assessment**. *This offering is Program# 716-000-06-147-L04*

Who We Are

The **Center for Professional Advancement (CFPA)** is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty short courses in 18 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CFPA courses are offered in a variety of formats – Public offering, Client Site and Online- to fit you or your company's training needs.

Courses of Interest

- **Active Pharmaceutical Ingredients**
course id# 840
- **Applied cGMPs for Pharmaceutical and Allied Industries**
course id# 610
- **CMC Submissions in CTD Format**
course id# 1989
- **Excipient GMPs**
course id# 2050
- **ICH-Q7A**
course id# 2091
- **INDs, NDAs vs CTDs Global Regulations**
course id# 448
- **Patent Law for Managers, Engineers and Scientists**
course id# 520
- **Scale-Up and Post Approval Changes Guidelines (SUPAC & API Changes)**
course id# 1948

The Center for Professional Advancement

P.O. Box 7077, East Brunswick, NJ 08816-7077

Phone: 732.238.1600 • Fax: 732.238.9113

E-mail: info@cfpa.com

www.cfpa.com

Register by Mar 19 and SAVE \$200

May 14–16, 2008
New Brunswick, NJ

Generic Drug Approvals

A Comprehensive Review of the Legal and Regulatory Requirements for Preparing and Processing Abbreviated New Drug Applications (ANDA's)

Course Topics Include:

- Waxman-Hatch Act
- Market Exclusivity
- Bioequivalence/Bioavailability
- Format & Content for an ANDA

Co-Directed by:

Robert J. Anderson, Esq.
Vice President, Scientific Affairs
Nycomed

Michael A. Swit, Esq.
Vice President Life Sciences
The Weinberg Group Inc.
and

Gary L. Yingling, Esq.
Partner
Kirkpatrick & Lockhart Preston Gates Ellis, LLP



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Who Should Attend

This overview course is intended for personnel from generic and brand name drug manufacturers and bulk drug substance suppliers who seek a broad and thorough understanding of the legal, regulatory, and practical aspects of developing and compiling Abbreviated New Drug Applications (ANDAs) and obtaining FDA approval of generic drugs, including:

- Regulatory Affairs
- QA/QC
- Legal/Compliance
- Technical/Scientific/Research
- Management
- Manufacturing

Learning Objectives

Upon completion of this course, you will be able to:

- Describe the basic requirements for preparing an ANDA and the legal foundation for those requirements
- Organize and coordinate corporate activities related to ANDAs
- File a paper or electronic ANDA with FDA
- Manage the process of obtaining approval from FDA
- Respond to problems in the ANDA identified by FDA
- Address changes or other concerns that arise after approval

Course Description

When Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Waxman-Hatch Act"), it enabled the pharmaceutical industry to seek approval via an ANDA of generic versions of the vast majority of drugs approved by FDA since 1962. New, complex requirements were imposed on persons seeking FDA approval of these generic drugs. Congress also created incentives to encourage development of new branded products, including extended patent protection and periods of non-patent market exclusivity. This course will review the basic provisions of the Waxman-Hatch Act; the information and data required for an ANDA; which drugs are eligible for submission under an ANDA and why; the role of patent protection and market exclusivity; pitfalls and pointers in dealing with the FDA review process; bioequivalence testing; and changing pending ANDAs and Drug Master Files (DMFs). Particular attention will be given in the course to the impact of FDA's regulations and guidances on both paper and electronic ANDAs.

Generic Drug Approvals

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COURSE OUTLINE

first day

8:00 a.m.: Registration/Continental Breakfast

8:30–10:00 a.m.: Introduction to the Legal Basis for Abbreviated New Drug Applications:

- Federal Food, Drug, and Cosmetic Act of 1938
- Drug Amendments of 1962
- FDA Modernization Act of 1997
- Medicare Modernization Act of 2003
- DESI Review and Generic Drugs
- Paper [505(b)(2)] NDA Policy
- Office of Generic Drugs Organizational Structure

10:30–12:00 noon: Overview of the Waxman-Hatch Act:

- A Response to the Unavailability of Generic Versions of Post-1962 Drugs
- Requirements of ANDAs under Section 505(j) of the Act
- The Concept of "Listed" Drugs
- ANDA Suitability Petitions for Variations of an Approved Drug

1:00–2:30 p.m.: Bioequivalence/Bioavailability:

- Solid Oral Dosage Studies
- Non-Systemically Absorbed Products—Inhalers and Topicals
- Waivers of Bioequivalence Studies
- Guidances; Cross-Over Design; New Study Designs

3:00–5:15 p.m.: Patent Terms, and Certifications under the Waxman-Hatch Act:

- Intersection of Patents and Generic Drug Approvals

- Pioneer Companies' Duty to File Patent Information with FDA
- The ANDA Applicant's Duty to File Patent Certifications
- The Importance of Patent Certification
- Patent Challenges and Paragraph IV Certifications
- Effect on Approval Time Frames
- Patent Extension Eligibility

second day

8:30–10:00 a.m.: Patent Terms and 180-Day Exclusivity:

- NDA Exclusivity
- 180-day Exclusivity for ANDAs with Patent Challenge
- Related Case Law, Regulations and Policies

10:30–12:00 noon: The Format and Content of an ANDA:

- How to Make Sure Your ANDA is Both Intelligible and Organized—Tips and Caveats
- The Waxman-Hatch Act Provisions and Related Regulations
- The Chemistry, Manufacturing and Controls (CMC) Section
- Other Submission Obligations
- Verifying the Accuracy of Data for the ANDA

1:00–3:00 p.m.: The Format and Content of an ANDA (continued)

3:30–5:00 p.m.: The Format and Content of an ANDA (continued)

third day

8:30–10:15 a.m.: How to Format and File an Electronic ANDA

10:30–12:30 p.m.: How to Format and File an Electronic Bioequivalence Submission

1:30–3:00 p.m.: Drug Master Files (DMFs), Bulk Pharmaceutical Chemicals (BPCs) and Activities Triggered by an ANDA Filing:

- Filing of DMF
- DMF as Part of ANDA
- Dealing with Your Bulk Drug Supplier
- Auditing Your Supplier
- Pitfalls in Sourcing
- Post-Submission Amendments to ANDAs;
- Post Approval Changes (SUPAC) to ANDAs;
- Other Post-Marketing Requirements

Course Co-Directors

Robert J. Anderson, Esq., is Vice President, Scientific Affairs at Nycomed, a leading manufacturer of multi-source topical products. He has over 15 years of experience in regulatory and legal affairs, patent law, pharmaceutical research and development, clinical research and quality assurance. Mr. Anderson received his B.S. from Northwestern University (Neurobiology & Physiology) and a J.D. from the John Marshall Law School.

Michael A. Swit, Esq., is Vice President, Life Sciences at The Weinberg Group Inc., a premier scientific and regulatory consulting firm in the Life Sciences. Since 1984 he has been both in private practice with McKenna & Cuneo and Heller Ehrman, and as Vice President, General Counsel and Secretary of Par Pharmaceutical. He also served from 1994 to 1998 as CEO of FDANews.com.

Gary L. Yingling, Esq. is a Partner with the law firm of Kirkpatrick & Lockhart Preston Gates Ellis LLP. Mr. Yingling served in FDA's Office of General Counsel as a trial attorney, as Associate Chief Counsel for Veterinary Medicine, Deputy Chief Counsel for Administration and as Director of FDA's Over-the-Counter Drug Review. He is counsel to the International Society for Regulatory Toxicology and Pharmacology, is Editor of the *Guide to Good Clinical Practices*, and serves on the Editorial Board of both the *Clinical Research Practices* and *Drug Regulatory Affairs and Regulatory Toxicology and Pharmacology* journals.

Additional Faculty

Candis B. Edwards is currently Sr. Vice President, Regulatory Affairs & Compliance for Interpharm, Inc., a New York-based manufacturer of generic pharmaceuticals. Ms. Edwards has over 25 years of experience in Regulatory Affairs, Research and Development, Project Management, Quality Assurance, cGMP Compliance and Quality Control.

She is currently an Associate Professor in the graduate degree program at St. John's University College of Pharmacy and Allied Health Professions.

Course Location

This course will be held in the **Hyatt Regency** located in New Brunswick, New Jersey. A limited block of rooms in the hotel will be held for our registrants until four weeks before the course. Participants must, however, make their own reservations; the cost of hotel accommodation is not included in the course fee. Hotel information will be included with your acceptance. To receive **CfPA's** rate and room block, be sure to mention that you will be attending one of our courses. For reservations call 800.233.1234; outside U.S. call 732.873.1234.

Client Site

Training at your site and at your convenience. For further information, please contact **Client Site** Programs: Direct Dial (USA) +1/732.238.1600, ext. 4549; or fax +1/732.238.9113; or **E-mail** clientsite@cfpa.com.

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