

NEW YORK STATE BAR ASSOCIATION

Annual Meeting of the
Food, Drug and Cosmetic Law Section

Thursday, January 28, 2010 Hilton New York 1335 Avenue of the Americas, New York City	
Program 8:20 a.m. Bryant Suite, 2nd Floor	Lunch 1:00 p.m. Trianon Ballroom, 3rd Floor

IMPORTANT INFORMATION

Under New York’s MCLE rule, this program has been approved for a total of up to 5.5 credit hours, consisting of 5.5 credit hours in areas of professional practice. **This course will not qualify for credit for newly admitted attorneys because it is not a basic practical skills program.** To receive the full 5.5 credit hours, you will need to attend the Section luncheon. If you attend the meeting only, you will receive up to 4.5 credit hours.

Discounts and Scholarships: New York State Bar Association members and non-members may apply for a discount or scholarship to attend this program, based on financial hardship. ***This discount applies to the educational portion of the program only.*** Under that policy, any member of our Association or non-member who has a genuine basis of his her hardship, if approved, can receive a discount or scholarship, depending on the circumstances. For more details, please contact Linda Castilla at New York State Bar Association, One Elk Street, Albany, New York 12207.

David S. Weinstock, Esq.
Section Chair/Program Chair
Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, Connecticut

8:20 - 8:25 a.m.	Welcome David S. Weinstock, Esq. Section Chair and Program Chair
8:25 - 9:15 a.m.	<i>Corporate Protests and Extremism in the Pre-Clinical Testing Arena: Management and Legal Strategies</i> Jared Freedburg, Esq. Vice President Associate General Counsel Covance Inc. Princeton, NJ Barry M. Rosenfeld, Esq. Assistant General Counsel Novartis Corporation New York City Gina Maisto Smith, Esq. Ballard Spahr LLP Philadelphia, PA
9:15 - 10:05 a.m.	<i>Managing Off-Label Issues and Risks in an Era of Increased Federal and State Enforcement</i> James G. Sheehan, Esq. Medicaid Inspector General New York Office of Medicaid Inspector General Albany Bethany J. Hills, Esq. Hodgson Russ LLP Buffalo Michael E. Little, Esq. Deputy Medicaid Inspector General New York Office of Medicaid Inspector General New York City
10:05 - 10:20 a.m.	Coffee Break
10:20 - 11:10 a.m.	<i>Risk Information Guidance and Social Media—Drugs versus Devices</i> Tracy Palmer Berns, Esq. Chief Regulatory Counsel Covidien Mansfield, MA Roger C. Thies, Esq. Hyman, Phelps & McNamara, P.C. Washington, D.C. David G. Adams, Esq. Venable LLP New York City Dara Katcher Levy, Esq. Hyman, Phelps & McNamara, P.C. Washington, D.C.



11:10 - 11:20 a.m. Annual Business Meeting
David S. Weinstock, Esq.
Section Chair

11:20 - 12:35 p.m. FDA Chief Counsels Panel

Moderator: James J. Kelly, Esq.
President (retired)
Food and Drug Law Institute
Washington, D.C.

Panelists:
(in FDA Service
Chronological Order)

Peter Barton Hutt, Esq.
(1971-1974)
Covington & Burling LLP
Washington, D.C.

Richard A. Merrill, Esq.
(1975-1977)
Daniel Caplin Professor of Law
Emeritus
University of Virginia School of Law
Charlottesville, VA

Nancy L. Buc, Esq.
(1980-1981)
Buc & Beardsley, LLP
Washington, D.C.

Gerald F. Masoudi, Esq.
(2007-2009)
Covington & Burling LLP
Washington, D.C.

Ralph S. Tyler, Esq.
(2010-Present)
Chief Counsel
U.S. Food and Drug Administration
Rockville, MD

1:00 - 1:30 p.m. Section Luncheon - Trianon Ballroom, 3rd Floor

1:30 - 2:20 p.m. New Initiatives and Challenges for the FDA in 2010 and Beyond

Keynote Speaker:
The Honorable David S. Cade
(Acting) General Counsel
U.S. Department of Health and Human Services
Washington, D.C.

The Program Chair would like to thank the following people
for their assistance in organizing today's program:

June Stephenson
Executive Assistant to the Chief Counsel
Food and Drug Administration

Caryn M. Silverman, Esq.
Sedgwick, Detert, Moran & Arnold LLP, New York City

Bethany J. Hills, Esq.
Hodgson Russ LLP, Buffalo