

Annual Meeting of the
Food, Drug and Cosmetic Law Section

Thursday, January 31, 2008
New York Marriott Marquis
1535 Broadway, New York City

Program
8:45 a.m. - 12:20 p.m.
Marquis Ballroom A & B, 9th Floor

Luncheon
12:30 - 2:00 p.m.
Palace Suite, 6th Floor

IMPORTANT INFORMATION

Under New York's MCLE rule, this program has been approved for a total of 3 credit hours, consisting of 3 credit hours in professional practice. **This course will not qualify for credit for newly admitted attorneys because it is not a basic practical skills program.**

Discounts and Scholarships: New York State Bar Association members may apply for a discount or scholarship to attend this program based on financial hardship. Under that policy, any member of our Association who has a genuine financial hardship may apply in writing not later than two working days prior to the program, explaining the basis of his/her hardship, and 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 and Program Chair
Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, Connecticut

8:45 - 9:00 a.m.	Welcome and Annual Business Meeting David S. Weinstock, Esq. Section Chair and Program Chair
9:00 - 9:25 a.m.	The Advertising Industry's Self-Regulatory Forum's Challenges in the FDA-Regulated Products Arena
Speaker:	Jennifer Fried, Esq. Staff Attorney National Advertising Division of the Council of Better Business Bureaus, New York City
9:25 - 9:50 a.m.	Pharmacogenomics: Personalized Medicine-Risk and Potential Liability for Product Manufacturers
Speakers:	Eric M. Kraus, Esq. Sedgwick, Detert, Moran & Arnold LLP, New York City Joanne Williams, Esq. Counsel, Bristol-Myers Squibb Company, New York City
9:50 - 9:55 a.m.	Presentation by The New York Bar Foundation
9:55 - 10:10 a.m.	Coffee Break
10:10 - 11:15 a.m.	FDAAA/PDUFA IV • The Current Political Landscape: What Pharma Lawyers Can Worry About Next • Risk Evaluation and Mitigation Strategy (REMS) Program • Unique Device Identifiers • Biosimilars: What Happened?
Speakers:	Conan Grames, Esq. Hunton & Williams LLP, Washington, DC Robert A. Dorner, Esq. Hyman, Phelps & McNamara, P.C., Washington, DC Mr. Jay Crowley Senior Advisor for Patient Safety, Center for Devices and Radiological Health, U.S. Food and Drug Administration, Rockville, Maryland Sheldon Bradshaw, Esq. Immediate Past Chief Counsel, U.S. Food and Drug Administration Hunton & Williams LLP, Washington, DC



- 11:15 - 11:45 a.m.

Pre-Emption (Drug and Device)

 - 'Buckman Preemption' Revisited: *Warner-Lambert v. Kent*
 - The Case for Medical Device Preemption-*Riegel v. Medtronic*
 - Understanding Tort Preemption Claims

Speakers:

David Klingsberg, Esq.

Kaye Scholer LLP, New York City

Caryn M. Silverman, Esq.

Sedgwick, Detert, Moran & Arnold LLP, New York City

Brian Wolfman, Esq.

Director, Public Citizen Litigation Group, Washington, DC

11:45 - 12:20 p.m.

Major Drug and Device Regulatory Developments in China

Speakers:

I. Scott Bass, Esq.

Sidley Austin LLP, Washington, DC

Industry Speaker - TBA

12:20 p.m.

Meeting Adjournment

12:30 - 2:00 p.m.

Section Luncheon - Palace Suite, 6th Floor

FDAAA Implementation: Reflections of the Chief Counsel

Speaker:

Gerald F. Masoudi, Esq.

Chief Counsel

U. S. Food and Drug Administration

Rockville, Maryland

2:00 - 2:30 p.m.

Executive Committee Meeting - Members of the Executive Committee

The Program Chair would like to thank the following members of the Section's Executive Committee for their efforts in identifying and arranging for the speakers who participated in today's program:

Barry A. Berger
 Joseph J Conklin
 Michael DiBello
 Julian Hammond
 Scott A. Margolin
 Diane Crosson McEnroe
 Caryn M. Silverman
 Mohammad A. Syed
 David S. Weinstock



If you need assistance relating to a disability, please contact the NYSBA Meetings Department sufficiently in advance so that we can make every effort to provide reasonable accommodations.



For overnight room accommodations, please call the New York Marriott Marquis at 1-800-843-4898 and identify yourself as a member of the New York State Bar Association. Room reservations will honored on a space and rate availability basis.



For questions about this specific program, please contact Linda Castilla at 518-487-5562. For registration questions only, please call 518-487-5621. Please use 866-680-0946 to fax your registration form.

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