

**Annual Meeting of the  
Food, Drug and Cosmetic Law Section**

<p><b>Thursday, January 28, 2016</b>  <b>New York Hilton Midtown</b>  <b>1335 Avenue of the Americas, New York City</b></p>
<p><b>NEW TIME THIS YEAR! - Afternoon Program</b>  <b>1:00 p.m. - 5:30 p.m.</b>                  Nassau West, 2nd Floor</p>

**IMPORTANT INFORMATION**

**Under New York's MCLE rule**, this program has been approved for a total of up to 4.5 credit hours in professional practice for experienced attorneys only. **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 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 this policy, any member of our Association or non-member who has a genuine basis of hardship, if approved, can receive a discount or scholarship, depending on the circumstances. Request for discounts or scholarships must be received **before January 13, 2016**. For more details, please contact Catheryn Teeter at the New York State Bar Association, One Elk Street, Albany, New York 12207 or cteeter@nysba.org.

**Brian J. Malkin, Esq.**  
**Section Chair and Program Chair**  
 McGuireWoods LLP, Washington, DC

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|-------------------------|--|--|
| <b>1:00 - 1:05 p.m.</b> | <p><b>Welcome</b><br/> <b>Brian J. Malkin, Esq.</b><br/>                 Section Chair and Program Chair</p>   |  |
| <b>1:05 - 1:55 p.m.</b> | <p><b><i>Legal Developments During 2015: Expanding Federal and State Antitrust Enforcement Against Drug Companies, Shrinking Patent Protection in the Life Science Area, and Amarin v. FDA: FDA Regulation of Off Label Marketing</i></b></p>                                  |  |
| <b>Moderator:</b>       | <p><b>Janet B. Linn, Esq.</b><br/>                 Bleakley Platt &amp; Schmidt, LLP<br/>                 White Plains</p>   |  |
| <b>Panelists:</b>       | <p><b>Elinor R. Hoffmann, Esq.</b><br/>                 Antitrust Bureau<br/>                 NYS Office of the Attorney General<br/>                 New York City</p>  | <p><b>Elena Rossano, Esq.</b><br/>                 Assistant General Counsel<br/>                 Purdue Pharma, LP<br/>                 Stamford, CT</p>  |
| <b>2:00 - 2:50 p.m.</b> | <p><b><i>Biosimilars: Biosimilars Substitution Proposal for New York's Pharmacy Laws and Nonproprietary Naming of Biological Products</i></b></p>  |  |
| <b>Panelists:</b>       | <p><b>Brian J. Malkin, Esq.</b><br/>                 McGuireWoods LLP<br/>                 Washington, DC</p> <p><b>Karl G. Williams, Esq.</b><br/>                 Wegmans School of Pharmacy<br/>                 St. John Fisher College<br/>                 Rochester</p> | <p><b>Alex C. Brownstein, Esq.</b><br/>                 BioScience Communications<br/>                 New York City</p> <p><b>Thomas Felix, MD, Director</b><br/>                 R &amp; D Policy, Global Regulatory Affairs &amp; Safety<br/>                 Amgen<br/>                 Washington, DC</p> |
| <b>2:50 - 3:05 p.m.</b> | <p><b>Coffee Break</b></p>   |  |
| <b>3:05 - 3:30 p.m.</b> | <p><b><i>Next Generation Sequencing: Followup to FDA's Guidance "Framework for Regulatory Oversight of Laboratory Tests"</i></b><br/> <i>(In association with the NYSBA Health Law Section's Committee on Medical Research and Biotechnology)</i></p>                          |  |
| <b>Moderator:</b>       | <p><b>Bethany Hills, Esq.</b><br/>                 Epstein Becker Green PC<br/>                 New York City</p>  |  |

Continued Over...



3:05 - 3:30 p.m.

**Next Generation Sequencing: Followup to FDA's Guidance "Framework for Regulatory Oversight of Laboratory Tests", Continued...**

Panelists:

**Ann M. Willey, Ph. D., J.D.**  
Former Director, Office of Laboratory Policy/Planning, NYS Health Dept. Wadsworth Center; Professor, Genetics & Public Health Law Albany Law School  
Albany

**David B. Solit, MD,**  
Geoffrey Beene Chair in Cancer Research, Director, Marie-Josée and Henry R. Kravis Center for Molecular Oncology, Memorial Sloan Kettering Cancer Center  
New York City

3:35 - 4:25 p.m.

**Animal Health: Followup to FDA's Guidance "Compounding Animal Drugs from Bulk Drug Substances"**

Panelists:

**Brian J. Malkin, Esq.**  
McGuireWoods LLP  
Washington, DC

**Magdalena H. Spencer, DVM, LLM, JD**  
Axinn, Veltrop & Harkrider LLP  
New York City

**Rachael G. Pontikes, Esq.**  
Partner  
Duane Morris LLP  
Chicago, IL

**Clint Vranian, Esq.**  
General Counsel  
Elanco Animal Health  
Indianapolis, IN

**Susan Wylegala, DVM**  
President  
New York Veterinary Medical Society  
Buffalo

4:30 - 5:20 p.m.

**Cosmetics Law Update Including Personal Care Products Safety Act & Food Law Update**

Developments and legislation proposed to amend FDA's regulation of cosmetics, including the Personal Care Products Safety Act and an update on dietary supplement cases.

Moderator:

**Suchira Ghosh, Esq.**  
Axinn, Veltrop & Harkrider LLP  
New York City

Panelists:

**Sharon A. Blinkoff, Esq.**  
Counsel  
Locke Lord LLP  
New York City

**Alan D. Kaplan, Esq.**  
Partner  
Herrick, Feinstein LLP  
New York City

**Steven Shapiro, Esq.**  
Of Counsel  
Rivkin Radler LLP  
New York City

**Farah Ahmed, Esq.**  
Associate General Counsel & VP - Chair, Cosmetic Entrepreneurs, Sunscreen/Skincare, and Marketing/Ad Committees  
Personal Care Products Council  
Washington, DC

5:20 - 5:30 p.m.

**Concluding Remarks and Annual Business Meeting**  
**Brian J. Malkin, Esq.,** Section Chair

5:30 - 7:00 p.m.

**Complimentary Offsite Reception,** McGuireWoods, 1345 Avenue of the Americas  
*All Meeting Attendees Welcome!* RSVP to [kplog@nysba.org](mailto:kplog@nysba.org)



**Accommodations for Persons with Disabilities:** NYSBA welcomes participation by individuals with disabilities. NYSBA is committed to complying with all applicable laws that prohibit discrimination against individuals on the basis of disability in the full and equal enjoyment of its goods, services, programs, activities, facilities, privileges, advantages, or accommodations. To request auxiliary aids or services or if you have any questions regarding accessibility, please contact Catheryn Teeter at 518-487-5573.



For overnight room accommodations, please call the New York Hilton Midtown at 1-800-445-8667 and identify yourself as a member of the New York State Bar Association. Room rates are \$260.00 for single/double occupancy plus taxes. Reservations must be made by Friday, January 8, 2016. You can also reserve your overnight room on the web at [www.nysba.org/am16accomm](http://www.nysba.org/am16accomm).



For questions about this specific program, please contact Catheryn Teeter at 518-487-5573. **For registration questions only, please call 800-582-2452. Fax registration form to 518-463-5993.**

## Food, Drug and Cosmetic Law Section

Thursday, January 28, 2016  
New York Hilton Midtown  
1335 Avenue of the Americas, NYC  
Program  
1:00 p.m.  
Nassau West, 2nd Floor

**Offsite Reception**  
**5:30 to 7:00 p.m.**

McGuireWoods LLP, 1345 Ave. of the Americas  
Photo ID Required. RSVP: [kplog@nysba.org](mailto:kplog@nysba.org)