

2017 ANNUAL MEETING

Food Drug & Cosmetic Law Section

Hot Topics in Food Drug & Cosmetic Law

January 26, 2017 | New York Hilton Midtown | NYC

7.0 Total Credits, consisting of 6.0 credits in Professional Practice and 1.0 credit in Ethics.

Program

11:40 a.m. | Nassau West Room

SECTION CHAIRS

Brian J. Malkin, Esq. Section Chair
Arent Fox LLP
Washington, D.C.

11:40 a.m. – 11:45 a.m.

Welcome

Brian J. Malkin, Esq., Section Chair

11:45 a.m. – 12:35 p.m.

Ethics of Attorney Advertising

Including Blogging, Client Alerts, Social Media, and the potential for use of such advertising in other settings.

Daniel Lear, J.D.

Director of Industry Relations, AVVO
Seattle, WA.

12:35 p.m. – 1:25 p.m.

Developments in Drug Law

- Update on reverse payment litigation 3 years after *FTC v. Actavis*
- Drug pricing developments, including litigation, investigations, and proposed litigation (EpiPen and more)
- New Drug and New Chemical Entity Definitions
- Cannabis/Canabidiol (CBD) – Drug or dietary supplement?
- Old Compounds as New Chemical Entities

Larissa Bergin, Esq.

Jones Day
Washington, D.C.

Janet Linn, Esq.

Bleakley Platt & Schmidt, LLP
White Plains, N.Y.

Christopher Palermo, Esq.

Bleakley Platt & Schmidt, LLP
White Plains, N.Y.

Jeremy Unruh, Esq.

General Counsel and Chief Compliance Officer
PharmaCann LLC
Chicago, IL.

PROGRAM CHAIR

Brian J. Malkin, Esq., Section Chair
Arent Fox LLP
Washington, D.C.

1:25 p.m. – 2:15 p.m.

Medical Device Hot Topics for 2017

- Expected guidance documents
- Impact of 21st Century Cures Act
- Update on FDA public hearings on off-label and third-party servicing
- Vulnerable policies/guidance under the Trump Administration

Bethany Hills, Esq.

Mintz Levin P.C.
New York, N.Y.

Suzanne O'Shea, J.D.

Director (Former Regulatory Counsel at FDA)
Navigant Consulting, Inc.
Indianapolis, IN.

2:15 p.m. – 2:30 p.m.

Coffee Break

2:30 p.m. – 3:20 p.m.

Hot Topics in Food/Dietary Supplements

How can a new ingredient intended for use in dietary supplements be brought to market?

This panel will compare and contrast FDA's new final rule for the voluntary notification procedure for substances that are generally recognized as safe (GRAS) vs. FDA's new draft guidance for New Dietary Ingredient Notifications.

Dr. Daniel Fabricant, Ph.D.,

EC/CEO
Natural Products Association
Washington, D.C.

Marc Ullman, Esq.

Of Counsel
Rivkin Radler LLP
New York, N.Y.

Moderator:

Steven Shapiro, Esq.

Rivkin Radler, LLP
New York, N.Y.

3:20 p.m. – 4:10 p.m.

Animal Health

Regulation and Application of Animal Biologics
Speakers will address the regulation of animal biologics by both the FDA and USDA and how this interrelates to the regulation of human biologics and other product development considerations.

Hans Draayer

Chairman of the Board
Edge Veterinary Vaccines Consulting Group, LLC
Kalamazoo, MI.

Dr. Kent McClure

General Counsel
Animal Health Institute
Washington, D.C.

Clint Vranian, Esq.

Vice President & General Counsel
Vitalpet
Indianapolis, IN.

Moderator:

Brian J. Malkin, Esq.

4:10 p.m. – 5:00 p.m.

Recent Enforcement Developments in Organic and Natural Claims for Cosmetics

- Regulatory and self-regulatory officials and plaintiff/defense counsel will address recent enforcement activity concerning organic and natural claims for cosmetics
- FTC actions regarding cosmetics, all-natural claims and FTC-USDA study and workshop on organic claims for non-NOP products
- NAD decisions regarding challenges over organic and natural claims
- FDA requests for comments on use of “natural” in food labeling
- Guidance concerning impactful yet compliant organic and natural claims.

Rebecca L. Griffith, Esq.

ASRC National Advertising Division Program
Council of Better Business Bureaus
New York, N.Y.

Deborah A. Marrone

Assistant Regional Director
Federal Trade Commission
Washington, D.C.

Sheila A. Millar, Esq.

Keller & Heckman LLP
Washington, D.C.

Moderators:

Thomas A. Cohn, Esq.,

Director & Senior Counsel
New Avon LLC
New York, N.Y.

Jennifer L. Orendi, Esq.

Managing Attorney
Dalimonte Rueb Litigation Group LLP
Washington, D.C.

5:00 p.m. – 5:50 p.m.

Updates in Tobacco Product Law Legal Status Tobacco Products: Deeming Rule Comes of Age

Speakers:

Dean Cirotta, MBA
President and COO
EAS Consulting Group
Alexandria, VA

Mitch Zeller

Director
Center for Tobacco Products
US Food and Drug Administration
Washington, D.C.

Moderator:

Brian J. Malkin, Esq., Section Chair

5:50 p.m. – 6:00 p.m.

Concluding Remarks and Annual Business Meeting. Biosimilars Substitution Rule-Update

Brian J. Malkin, Esq.

6:00 p.m. – 7:30 p.m.

Offsite Reception

Arent Fox LLP
1675 Broadway
New York, NY 10019

Register Online www.nysba.org/AM2017 | **Get Social: #nysba17**

IMPORTANT INFORMATION

Under New York’s MCLE rule, this program has been approved for a total of 7.0 credit hours (6.0 Areas of Professional Practice and 1.0 credit in Ethics). This program 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 for their hardship, if approved, can receive a discount or scholarship, depending on the circumstances. Request for discounts or scholarships must be received prior to January 13th, 2017. For more details, please contact Lisa Bataille in writing at New York State Bar Association, One Elk Street, Albany, New York 12207 or lbataille@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 Lisa Bataille at 518-487-5680.



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. Reservations must be made by Wednesday, January 4, 2017. You also can reserve your overnight room on the web at www.nysba.org/am17accomm.



For questions about this specific program, please contact Lisa Bataille at 518-487-5680. **For registration questions only, please call the Member Resource Center at 800-582-2452. Fax registration form to 518-463-5993.**