

# 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 21<sup>st</sup> 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rule for the voluntary notification procedure for substances that are generally recognized as safe (GRAS) vs. FDA's new draft guidance for New Dietary Ingredient Notifications.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

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**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](mailto:lbataille@nysba.org).



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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](http://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.**