**NEW YORK STATE BAR ASSOCIATION**

**ANNUAL MEETING 2018**

**Food Drug and Cosmetic Law Section**

Hot Topics in Food, Drug & Cosmetic Law

**January 25, 2018 | New York Hilton Midtown | NYC**

7.0 Total Credits: 1.0 Ethics | 6.0 Professional Practice (Non-Transitional)

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**Program:**
8:30 a.m. - 5:00 p.m. | Nassau West, 2nd Floor

8:30 a.m. – 8:35 a.m.
Introduction – Brian J. Malkin, Section Chair

8:35 a.m. – 9:00 a.m.
Tobacco Law

- The feasibility and impacts of FDA's decision to delay regulatory deadlines for newly deemed products while undertaking rulemaking and eliminating the sunset provision
- The complications and potential public health benefits and harms related to FDA's proposed product standards for nicotine levels, tobacco flavors, and re-evaluation of premium cigars
- Analysis of FDA's request for input on most efficient use of its resources and review of provisional substantial equivalence reports

Moderator: Brian J. Malkin, Esq., Arent Fox LLP, Washington, DC

Speakers:
- Anne Pierson Allen, Esq., King & Spalding (former FDA Office of Chief Counsel (OCC) representative to the Center for Tobacco Products (CTP)), New York, NY
- Christina Young, Ph.D., King & Spalding (former Chemist to the FDA's CTP), New York, NY

9:05 a.m. – 9:55 a.m.
Animal Health Law
Are All Human Drugs Actually Animal Drugs Waiting to Be Developed? What it Takes to Develop a New Animal Drug and Other Animal Health Product Considerations

Moderator: Janet Linn, Esq., Eaton & Van Winkle, New York, NY

Speaker:
- Manya Deehr, Esq., Cooley LLP, Princeton, NJ

10:00 a.m. – 10:25 a.m.
Food Law
From Farm to Table – The Future of GMO Plants and Animals

- An update on the rulemaking the US Department of Agriculture (USDA) is undertaking to implement the Bioengineered Food Disclosure Law
- The status of regulatory proposals relating to the regulation of plant and animal products of biotechnology proposed by USDA and FDA, respectively
- Other emerging issues related to the regulation of plant and animal products of biotechnology

Moderator: Suchira Ghosh, Esq., Axinn Veltrop Harkrider LLP, New York, NY

Speakers:
- Karen Carr, Esq., Arent Fox LLP, Washington, DC
- Kristin Landis, Esq., Deputy General Counsel, Agriculture & Environmental, Biotechnology Innovation Organization (BIO), Washington, DC

10:25 a.m. – 10:40 a.m. Coffee Break

10:40 a.m. – 12:00 p.m.
Biologics Law
Gene Therapies Now FDA-Approved for Use: What You Need to Know to Address Safety and IP Considerations – Plus an Update on Biosimilars

- FDA Discusses New Gene Therapy Approval and Safety Considerations for REMS for Gene Therapy
- IP Considerations for Patenting Gene Therapies – When and How Do You Do It?
- Update on Biosimilar Approvals: The Legal Pathway After the Supreme Court Ruling in Sandoz v. Amgen and Marketing Challenges