

### DAY ONE: October 10, 2018

- 8:15 a.m. – 8:45 a.m.     **Registration**, Continental Breakfast
- 8:45 a.m. – 9:00 a.m.     **Welcome and Introduction**
- 9:00 a.m. – 10:00 a.m.     **The Basics of FDA Food-Contact Regulation – an Overview**  
*George G. Misko, Partner*
  - Defining a Food Additive
  - Clearance Options and Exemptions
  - FDA's Food Contact Notification Program
- 10:00 a.m. – 10:45 a.m.     **Understanding Food Additive Regulatory Clearances**  
*Joan Sylvain Baughan, Partner*
  - Interpreting Scope and Limitations
  - Cross-References
- 10:45 a.m. – 11:15 a.m.     **Break**
- 11:15 a.m. – 12:00 p.m.     **An Update from the U.S. Food and Drug Administration**  
*Invited Guest Speaker: Michael Adams, Ph.D., Deputy Director, Office of Food Additive Safety, FDA*
- 12:00 p.m. – 1:30 p.m.     **Lunch**, provided by Keller and Heckman
- 1:30 p.m. – 2:30 p.m.     **The Basics of European Food-Contact Regulation – an Overview**  
*Hazel O'Keeffe, Counsel*
  - Framework Regulation
  - GMP Regulation
  - Plastics Regulation
  - Non-Harmonized Materials
- 2:30 p.m. – 3:30 p.m.     **Technical Considerations – USA and EU: Similarities and Differences**  
*Cheryl B. Bast Ph.D., D.A.B.T., Scientist, and Peter N. Coneski, Ph.D., Scientist*
  - Migration Calculations and Testing
  - Toxicity Considerations
- 3:30 p.m. – 4:00 p.m.     **Break**
- 4:00 p.m. – 4:45 p.m.     **Impurities and Non-Intentionally Added Substances**  
*Pamela L. Langhorn, Partner, and Holly H. Foley, Scientist*
  - Suitable Purity Assessments under FDA GMP Regulation
  - Regulation of NIAS under EU Plastics Regulation
  - Case Studies

# AGENDA

FOOD PACKAGING LAW SEMINAR

OCTOBER 10-11, 2018

4:45 p.m. – 5:00 p.m.    **Q&A**

5:30 p.m. – 9:00 p.m.    **Cocktail Reception and Networking Dinner**

Join the presenters and your colleagues for cocktails at the hotel followed by dinner at Ruth's Chris Steak House in Crystal City.

(both events are complimentary; RSVP is required for dinner at Ruth's Chris Steak House)

### DAY TWO: October 11, 2018

8:00 a.m. – 8:30 a.m. **Continental Breakfast**

8:30 a.m. – 9:15 a.m. **Customer Assurance Considerations**

*Jeffrey A. Keithline, Partner*

- U.S. and EU Approaches to Customer Assurance
- Types of Assurances/Warranties/Contracts
- Providing Suitable Assurance Statements

9:15 a.m. – 10:00 a.m. **Good Manufacturing Practices: How to Follow Them and What to Do When Something Goes Wrong**

*Catherine R. Nielsen, Partner*

- GMP Requirements
- GMP Failure - Assessing the Situation/Scope
- Customer Communications
- Recalls

10:00 a.m. – 10:30 a.m. **Break**

10:30 a.m. – 11:15 a.m. **Regulation of Food Packaging under MERCOSUR**

*Cynthia B. Lieberman, Partner*

- Regulatory Framework
- Sector-specific Legislation
- Update to Revision of Positive List of Additives

11:15 a.m. – 12:00 p.m. **Food Packaging Regulations in Japan**

*Guest Speaker, Mitsuhiro Shigekura Executive Director, JHOSPA*

12:00 p.m. – 1:30 p.m. **Lunch**, provided by Keller and Heckman

1:30 p.m. – 2:15 p.m. **Regulation of Food Packaging in China**

*Mark Thompson, Counsel, and Eric Gu, Associate*

- Updates on China's Food Safety Law and Hygienic Standards
- Petitioning for New Substances in China

2:15 p.m. – 3:00 p.m. **California's Proposition 65**

*Mitzi Ng Clark, Partner*

- Overview of Requirements
- Impact of New Warning Requirements

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## FOOD PACKAGING LAW SEMINAR

OCTOBER 10-11, 2018

3:00 p.m. – 3:30 p.m.

### **Recent Developments in the U.S. and EU**

*Devon Wm. Hill, Partner*

- U.S. State Law Activities
- Phthalates Petitions to FDA
- BPA Regulation in the EU
- Impact of Brexit on EU Food-Contact Regulation

3:30 p.m. – 3:45 p.m.

### **Q&A**

3:45 p.m.

### **Seminar Adjourns**