

DAY ONE: October 10, 2017

- 8:00 a.m. – 8:30 a.m. **Registration, Continental Breakfast**
- 8:30 a.m. – 8:45 a.m. **Welcome and Introduction**
- 8:45 a.m. – 9:30 a.m. **The Basics of FDA Food-Contact Regulation – an Overview**
- Defining a Food Additive
 - Clearance Options
 - FDA’s Food Contact Notification Program
 - Exemptions
 - Suitable Purity
- 9:30 a.m. – 10:15 a.m. **Understanding Food Additive Regulatory Clearances**
- Limitations
 - Cross-References
 - Case Studies
- 10:15 a.m. – 10:45 a.m. **Break**
- 10:45 a.m. – 11:30 a.m. **Using Scientific Tools to Establish Clearances under the Exemptions**
- No Migration (Calculations, Migration Testing)
 - Traditional GRAS Analysis Based on Published Safety Data
 - GRAS Based on *De Minimis* Exposure
- 11:30 a.m. – 12:00 p.m. **Obtaining Clearances through the Food-Contact Notification Program**
- Administrative Requirements of the FCN Program
 - FCN Chemistry Data Requirements
 - FCN Toxicity Data Requirements
- 12:00 p.m. – 1:30 p.m. **Lunch**, provided by Keller and Heckman
Updates on Food Packaging Regulations in Canada
Guest Speaker – Elena Emelianova, Ph.D., Scientific Evaluator, Food Packaging Materials and Incidental Additives Section, Health Canada
- 1:30 p.m. – 2:30 p.m. **The Basics of European Food-Contact Regulation – an Overview**
- Framework Regulation
 - GMP Regulation
 - Plastics Regulation
 - Non-Harmonized Materials
 - Mutual Recognition

AGENDA

FOOD PACKAGING LAW SEMINAR

OCTOBER 10-11, 2017

2:30 p.m. – 3:30 p.m.

EU Technical Considerations

- Overview of EU Testing Requirements and Assumptions
- Compare and Contrast with FDA Requirements

3:30 p.m. – 4:00 p.m.

Break

4:00 p.m. – 4:45 p.m.

Customer Assurance Considerations

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

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.
(complimentary; *RSVP required)

DAY TWO: October 11, 2017

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

8:30 a.m. – 9:15 a.m. **Break Out Session 1**

Focus on Impurities and Non-Intentionally Added Substances

- Suitable Purity Assessments under FDA GMP Regulation
- NIAS Assessment under EU Plastics Regulation
- Assessment for NIAS under EU Member State legislation

Focus on California Proposition 65

- Proposition 65 Assessments
- Updated Warning Notice and Requirements

9:30 a.m. – 10:15 a.m. **Break Out Session 2**

Focus on GMP: When Something Goes Wrong

- GMP Requirements
- GMP Failure – Assessing the Situation/Scope
- Exposure Assessments and Safety Considerations
- Customer Communications
- Recalls

Focus on Printing Inks

- FDA Regulation of Printing Inks
- Swiss Ordinance
- Future EU Regulation of Printed Food-Contact Materials

10:15 a.m. – 10:45 a.m. **Break**

10:45 a.m. – 12:30 p.m. **Regulation of Food-Packaging Around the World**

China

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

Japan

- Overview of Food Sanitation Law Requirements
- New Positive List Proposal

Mercosur and Latin America

- Status of Mercosur Resolutions for Food-Contact Materials
- Petitioning for New Substances

The Rest of the World

- Korea
- India
- Australia/New Zealand
- Middle East (Gulf Cooperation Council)

12:30 p.m. – 2:00 p.m. **Lunch**, provided by Keller and Heckman

2:00 p.m. – 3:00 p.m.

View from the FDA:

Challenges at FDA's Division of Food-Contact Notifications / Post Market Compliance Considerations

Guest Speaker: Dennis Keefe, Ph.D., Director, Office of Food Additive Safety, FDA

3:00 p.m. – 3:30 p.m.

Hot Topics in the U.S. and EU

- Food Safety Modernization Act Update
- NGO/Citizen and Abandonment Petitions
- BPA Regulation in the EU
- Fate of EU Food Contact Legislation
- Upcoming Changes to Regulation of Drug Packaging

3:30 p.m. – 3:45 p.m.

Q&A

3:45 p.m.

Seminar Adjourns