

7:30 a.m. – 8:00 a.m.

**Registration, Continental Breakfast**

8:00 a.m. – 8:30 a.m.

**Overview – LCSA's Continued Implementation**

*Thomas C. Berger, Partner*

- Progression of Section 5 Review Process
- Existing Chemical Regulation Marches On
- Inventory "Reset," Confidential Business Information (CBI)
- Increased Fees, Penalties, Enforcement

8:30 a.m. – 9:45 a.m.

**New Chemical Notification and Exemptions**

*James G. Votaw, Partner*

- Scope and Definition of "Chemical Substance"
- Exclusions and Exemptions from PMN Reporting
- Overview of Evolving PMN Process
- Written Approvals and Early Decisions
- Failure to Complete Review, Extensions

9:45 a.m. – 10:45 a.m.

**PMN Preparation Under New TSCA**

*Matthew B. Harney, Ph.D., Scientist*

- Completing PMN Forms, Chemical Names
- How Volume, Number of Sites, Cleaning Frequency, Transport and Wastewater Disposal Information Influences Review Outcomes
- EPA Models and How to Use Them in Predicting Review Outcomes

10:45 a.m. – 11:00 a.m.

**Break**

11:00 a.m. – 12:00 p.m.

**Regulation of New and Existing Chemicals**

*James G. Votaw, Partner*

- Insufficient Information, Exposure, and Risk-Based Findings
- How to Evaluate and Challenge EPA Decision to Regulate a New Chemical
- Significant New Use Rules (SNURs), Consent Orders
- Regulation of Existing Chemicals: New Section 4, New Section 6

12:00 p.m. – 1:15 p.m.

**Lunch, provided by Keller and Heckman**

1:15 p.m. – 2:00 p.m.

**TSCA Nomenclature Basics**

*Matthew B. Harney, Ph.D., Scientist*

- How to Interpret Chemical Names on TSCA Inventory
- Common Mistakes and How to Avoid Them

2:00 p.m. – 3:15 p.m.

### **Recordkeeping and Reporting**

*Thomas C. Berger, Partner*

- §8(a) PAIR, Chemical Data Reporting (CDR)
- §8(b) Inventory Active/Inactive “Reset” Rule, CBI
- §8(c) Allegations
- §8(d) Reporting
- §8(e) Substantial Risk Reporting

3:15 p.m. – 3:30 p.m.

### **Break**

3:30 p.m. – 4:00 p.m.

### **Imports and Exports**

*James G. Votaw, Partner*

- Basics of §13 Import Certification
- Basics of §12(b) Export Notification
- How to Effectively Track Inventory Status and Emerging Regulations

4:00 p.m. – 5:00 p.m.

### **Inspections, Enforcement, Audits, and Self-Disclosures**

*Thomas C. Berger, Partner*

- EPA Inspection and Enforcement Authority
- New Penalties and New Areas for Potential Non-Compliance
- Preparing for Compliance Inspections, Self-Auditing
- EPA “Audit Policy” and “New Owners Policy”
- Economic Benefit Considerations

5:00 p.m. – 5:15 p.m.

### **Question and Answer Session**

5:30 p.m. – 7:00 p.m.

**Cocktail Reception**, *hosted by Keller and Heckman*

*\*Please note, this is a draft agenda and is subject to change between now and the start of the program.*

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| 8:00 a.m. – 8:30 a.m.   | <b>Registration</b> , <i>Continental Breakfast</i>   |
| 8:30 a.m. – 8:45 a.m.   | <b>Introduction</b>  |
| 8:45 a.m. – 9:45 a.m.   | <b>Establishing FDA Compliance of Food-Contact Substances</b><br><i>Mitzi Ng Clark, Partner</i> <ul style="list-style-type: none"><li>➤ Defining a Food Additive</li><li>➤ Clearance Options and Exemptions</li></ul>                  |
| 9:45 a.m. – 10:45 a.m.  | <b>Interpreting the Food Additive Regulations</b><br><i>Cynthia B. Lieberman, Partner</i> <ul style="list-style-type: none"><li>➤ Applying limits on clearances</li><li>➤ Evaluating cross-references</li></ul>                        |
| 10:45 a.m. – 11:15 a.m. | <b>Break</b>   |
| 11:15 a.m. – 12:00 p.m. | <b>FDA’s Food Contact Notification Program</b><br><i>Cynthia B. Lieberman, Partner</i><br><i>Mark A. Hepp, Ph.D.</i> <ul style="list-style-type: none"><li>➤ FCN Submission Process and Pitfalls</li><li>➤ Data Requirements</li></ul> |
| 12:00 p.m. – 12:30 p.m. | <b>Technical Considerations – Part I</b><br><i>Mark A. Hepp, Ph.D.</i> <ul style="list-style-type: none"><li>➤ Estimating Migration</li><li>➤ Modeling and Analytical Testing</li></ul>  |
| 12:30 p.m. – 2:00 p.m.  | <b>Lunch</b> , <i>provided by Keller and Heckman</i>   |
| 2:00 p.m. – 2:30 p.m.   | <b>Technical Considerations – Part II</b><br><i>Mark A. Hepp, Ph.D.</i> <ul style="list-style-type: none"><li>➤ Estimating Dietary Intake</li><li>➤ Safety Assessments</li></ul>   |
| 2:30 p.m. – 3:15 p.m.   | <b>Customer Assurance</b><br><i>Cynthia B. Lieberman, Partner</i> <ul style="list-style-type: none"><li>➤ Forms of Customer Assurance</li><li>➤ Liability Issues</li></ul>   |
| 3:15 p.m. – 3:30 p.m.   | <b>Break</b>   |
| 3:30 p.m. – 4:15 p.m.   | <b>Proposition 65 and Food-Contact Materials</b><br><i>Mitzi Ng Clark, Partner</i> <ul style="list-style-type: none"><li>➤ Warning Requirements</li><li>➤ Impact on Supply Chain</li></ul>   |
| 4:15 p.m. – 4:30 p.m.   | <b>Questions and Answers</b>   |
| 5:00 p.m. – 6:00 p.m.   | <b>Cocktail Reception</b> , <i>hosted by Keller and Heckman</i>  |

- 8:00 a.m. – 8:30 a.m. **Registration, Continental Breakfast**
- 8:30 a.m. – 8:45 a.m. **Introduction**
- 8:45 a.m. – 9:45 a.m. **FDA Regulation of Food**  
*Natalie E. Rainer, Associate*
- Scope and Definitions
  - Self-Determination of FDA Compliance
  - Seeking Premarket Clearance from FDA
  - Claims for Food/Marketing Issues
- 9:45 a.m. – 10:30 a.m. **FDA Regulation of Dietary Supplements**  
*Frederick A. Stearns, Partner*
- Scope and Definitions
  - “Old” vs. “New” Dietary Ingredients
  - Claims/Marketing Issues
  - Additional Regulatory Obligations
- 10:30 a.m. – 10:45 a.m. **Break**
- 10:45 a.m. – 11:30 a.m. **Overview of the FDA Food Safety Modernization Act**  
*Natalie E. Rainer, Associate*
- FSMA Essentials
  - Status of Implementation
  - Implications for the Food Industry
- 11:30 a.m. – 12:15 p.m. **FDA Regulation of Drugs**  
*Frederick A. Stearns, Partner*
- Scope and Definitions
  - Prescription vs. Over-the-Counter (OTC)
  - Current Good Manufacturing Practices (cGMPs)
  - Additional Regulatory Requirements
- 12:15 p.m. – 1:30 p.m. **Lunch, provided by Keller and Heckman**
- 1:30 p.m. – 2:15 p.m. **FDA Regulation of Medical Devices and Biomaterials**  
*Frederick A. Stearns, Partner*
- Scope and Definitions
  - Premarket Clearance Procedures
  - Quality System Regulation (QSR) Obligations
  - Additional Regulatory Requirements
  - Legislative Protection Available to Suppliers of Biomaterials
  - Mitigating Liability Risks Associated with Supplying Raw Materials to Medical Device Customers
- 2:15 p.m. – 2:45 p.m. **FDA Regulation of Cosmetics**  
*Natalie E. Rainer, Associate*
- Scope and Definitions
  - Ingredient/Product Safety
  - Claims/Marketing Issues

# AGENDA

DAY 3: FDA-REGULATED PRODUCTS

MAY 9, 2019

2:45 p.m. – 3:30 p.m.

**Overview of FDA's Enforcement Powers**

*Frederick A. Stearns, Partner*

- Tools Available to FDA
- Agency Enforcement Priorities
- Examples and Takeaway Lessons

3:30 p.m.

**Seminar Adjourns**