

- 7:30 a.m. – 8:00 a.m. **Registration**, *Continental Breakfast*
- 8:00 a.m. – 8:30 a.m. **Overview - What Has and Has Not Changed**
Thomas C. Berger, Partner
- New Twists and Hurdles of Section 5 Review Process
 - Expanded Mandate to Review and Test Existing Chemicals
 - Inventory Reset and Confidential Business Information (CBI)
 - Fees, Penalties, Enforcement
- 8:30 a.m. – 9:45 a.m. **New Chemical Notification**
Thomas C. Berger, Partner
- Scope and Definition of “Chemical Substance”
 - Exclusions and Exemptions from PMN Reporting
 - Overview of the New 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**
Thomas C. Berger, Partner
- Insufficient Information, Exposure, and Risk-Based Findings
 - How to Evaluate and Challenge an Agency Decision to Regulate a New Chemical
 - Significant New Use Rules (SNURs), Consent Orders
 - Proposed Changes to SNUR Process
 - 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 Listed on the 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) Inventory Reset, CDR, and CBI
 - §8(a) and 8(d) Reports
 - §8(c) Allegations
 - §8(e) Substantial Risk Reporting

AGENDA

DAY 1: TSCA BASICS

MAY 9, 2017

3:15 p.m. – 3:30 p.m.

Break

3:30 p.m. – 4:00 p.m.

Imports and Exports

Thomas C. Berger, Partner

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

4:00 p.m. – 5:00 p.m.

Inspections, Enforcement, Audits, and Self-Disclosures

Thomas C. Berger, Partner

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

5:00 p.m. – 5:15 p.m.

Question and Answer Session

Thomas C. Berger, Partner

Matthew B. Harney, Ph.D., Scientist

5:30 p.m. – 7:00 p.m.

Cocktail Reception, *hosted by Keller and Heckman*

- 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. **Establishing FDA Compliance of Food-Contact Substances**
Joan Sylvain Baughan, Partner
- Defining a Food Additive
 - Clearance Options and Exemptions
- 9:45 a.m. – 10:30 a.m. **Interpreting the Food Additive Regulations**
Cynthia B. Lieberman, Partner
- End-tests
 - Cross-references
- 10:30 a.m. – 11:00 a.m. **Break**
- 11:00 a.m. – 11:45 a.m. **Technical Considerations**
Jason P. Schmidt, Ph.D., Scientist
- Determining Migration and Dietary Intake
 - Conducting Risk Assessments
- 11:45 a.m. – 12:30 p.m. **FDA's Food Contact Notification Program**
Joan Sylvain Baughan
Jason P. Schmidt, Ph.D., Scientist
- FCN Submission Process and Pitfalls
 - Data Requirements
 - FDA Draft Guidance on Infant Formula Packaging FCNs
- 12:30 p.m. – 2:00 p.m. **Lunch, provided by Keller and Heckman**
- 2:00 p.m. – 2:30 p.m. **Customer Assurance**
Joan Sylvain Baughan, Partner
- Forms of Customer Assurance
 - Liability Issues
- 2:30 p.m. – 3:15 p.m. **Good Manufacturing Practice Considerations**
Cynthia B. Lieberman, Partner
Jason P. Schmidt, Ph.D., Scientist
- GMP Requirements
 - What to do When Something Goes Wrong
 - Recalls and Customer Communications
- 3:15 p.m. – 3:45 p.m. **Break**
- 3:45 p.m. – 4:15 p.m. **Hot Topics**
Cynthia B. Lieberman, Partner
- FSMA Update
 - Proposition 65
- 4:15 p.m. – 4:30 p.m. **Questions and Answers**
- 5:00 p.m. – 6:00 p.m. **Cocktail Reception, hosted by Keller and Heckman**

- 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**
Laura D. Venker, 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**
Laura D. Venker, 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**
Laura D. Venker, Associate
- Scope and Definitions
 - Ingredient/Product Safety
 - Claims/Marketing Issues

AGENDA

DAY 3: FDA-REGULATED PRODUCTS

MAY 11, 2017

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