AGENDA

KELLER AND HECKMAN LLP
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DAY 1: TSCA BASICS | MAY 7, 2019

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

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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.*

AGENDA

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DAY 2: FOOD-CONTACT SUBSTANCES | MAY 8, 2019

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** *Mitzi Ng Clark, Partner* ➢ Defining a Food Additive ➢ Clearance Options and Exemptions
9:45 a.m. – 10:45 a.m.	**Interpreting the Food Additive Regulations** *Cynthia B. Lieberman, Partner* ➢ Applying limits on clearances ➢ Evaluating cross-references
10:45 a.m. – 11:15 a.m.	**Break**
11:15 a.m. – 12:00 p.m.	**FDA's Food Contact Notification Program** *Cynthia B. Lieberman, Partner* *Mark A. Hepp, Ph.D.* ➢ FCN Submission Process and Pitfalls ➢ Data Requirements
12:00 p.m. – 12:30 p.m.	**Technical Considerations – Part I** *Mark A. Hepp, Ph.D.* ➢ Estimating Migration ➢ Modeling and Analytical Testing
12:30 p.m. – 2:00 p.m.	**Lunch,** *provided by Keller and Heckman*
2:00 p.m. – 2:30 p.m.	**Technical Considerations – Part II** *Mark A. Hepp, Ph.D.* ➢ Estimating Dietary Intake ➢ Safety Assessments
2:30 p.m. – 3:15 p.m.	**Customer Assurance** *Cynthia B. Lieberman, Partner* ➢ Forms of Customer Assurance ➢ Liability Issues
3:15 p.m. – 3:30 p.m.	**Break**
3:30 p.m. - 4:15 p.m.	**Proposition 65 and Food-Contact Materials** *Mitzi Ng Clark, Partner* ➢ Warning Requirements ➢ Impact on Supply Chain
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*

AGENDA

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DAY 3: FDA-REGULATED PRODUCTS | MAY 9, 2019

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

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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**