

U.S. FOOD LAW SEMINAR (BRUSSELS)

3 – 4 OCTOBER 2018

DAY ONE: Wednesday, 3 October 2018

INSTRUCTORS: Melvin S. Drozen, Katia Merten-Lentz, Evangelia C. Pelonis, and Frederick A. Stearns

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| 8:00 – 8:30 | Registration/Continental Breakfast |
| 8:30 – 8:45 | Welcome and Introductory Activities <i>Katia Merten-Lentz, Partner</i> |
| 8:45 – 10:30 | Statutory Framework, Jurisdiction, and Adulteration I - II <i>Frederick A. Stearns, Partner</i> <ul style="list-style-type: none">• Federal Food, Drug, and Cosmetic Act and Related Statutes• Interstate Commerce• Classification as Food, Drug, Dietary Supplement, Cosmetic• “Poisonous”; Added/Deleterious; “May Render Injurious”; “Ordinarily Injurious”• Intentional Additives (Food and Color Additives, Pesticide Chemicals, Food Contact Materials)• GRAS Status• Contrast with E.U. |
| 10:30 – 10:45 | Break |
| 10:45 – 12:00 | Adulteration III and IV <i>Melvin S. Drozen, Partner</i> <ul style="list-style-type: none">• Delaney Clause• Unintentional Additives (e.g., Food Contact Substances, Pesticide Residues, Environmental Contaminants)• Dietary Ingredients• Filth• Unfit for Food, Emergency Permit Exemptions, and Good Manufacturing Practice/HACCP/HARPC• Contrast with E.U. |
| 12:00 – 13:15 | Lunch (<i>provided by Keller and Heckman LLP</i>) |
| 13:15 – 15:15 | Food Safety Modernization Act (FSMA) Requirements <i>Evangelia C. Pelonis, Partner</i> <ul style="list-style-type: none">• Hazard Analysis and Risk-Based Preventive Controls (HARPC)• Foreign Supplier Verification Program (FSVP)• Contrast with E.U. |
| 15:15 – 15:30 | Break |
| 15:30 – 16:45 | FDA Inspections and Import/Export Issues <i>Frederick A. Stearns, Partner</i> <ul style="list-style-type: none">• Managing Inspections, Record Review and Photographs• Recordkeeping and Retention• Import/Export Procedures and Requirements• Contrast with E.U. |
| 17:00 – 18:30 | Networking Cocktail Reception |

DAY TWO: Thursday, 4 October 2018

INSTRUCTORS: Melvin S. Drozen, Richard F. Mann, Katia Merten-Lentz, Evangelia C. Pelonis, and Frederick A. Stearns

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| 8:00 – 8:30 | Continental Breakfast |
| 8:30 – 10:15 | Mandatory Label Requirements and Nutrition Labeling <i>Melvin S. Drozen, Partner</i> <ul style="list-style-type: none">• Contrast with E.U. |
| 10:15 – 10:30 | Break |
| 10:30 – 12:00 | Nutrient Content Claims, Fresh, Natural, Organic, Health Claims, GM Labeling <i>Evangelia C. Pelonis, Partner</i> <ul style="list-style-type: none">• Contrast with E.U. |
| 12:00 – 12:45 | Working Lunch (<i>provided by Keller and Heckman LLP</i>) |
| 12:45 – 14:00 | Approving, Defending and Challenging Food Advertising Claims <i>Richard F. Mann, Partner</i> <p>When Is a Claim -</p> <ul style="list-style-type: none">• Constitutionally Protected?• Non-Actionable Puffery?• Material?• Substantiated Adequately?• Deceptive/Misleading?• False?• Unfair?• Banned?• Contrast with E.U. |
| 14:00 – 14:15 | Break |
| 14:15 – 14:45 | Related Issues - California Proposition 65 and Class Action Lawsuits <i>Richard F. Mann, Partner</i> |
| 14:45 – 15:45 | FDA Enforcement Tools <i>Frederick A. Stearns, Partner</i> <ul style="list-style-type: none">• Recalls: Overview and Tips for Handling• Enforcement Discretion, Warning Letters, Administrative Detention, Suspension of Food Facility Registration, Seizures, Injunctions, Criminal Prosecutions, Publicity• Contrast with E.U. |
| 15:45 | Wrap Up Discussion and Seminar Adjourns <i>Keller and Heckman LLP attorneys</i> |