REGULATION OF FOOD AND DRUGS

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Syllabus


January 14: FDA Enforcement Processes I: Inspectional Authority; Administrative Detention; Civil and Criminal Enforcement Litigation.

January 28: FDA Enforcement Processes II: Import Notification and Exclusion Authority; Administrative Rulemaking; Guidance Documents, Warning Letters, and Publicity.

February 4: Food Sanitation and Safety: Filth and Defect Action Levels; Unsafe Components; “Insanitary” Conditions; Emergency Permit Control, cGMP, HACCP, and HARPC; Environmental Contaminants, Tolerances, and Action Levels.


February 25: Dietary Supplements: Distinguishing Dietary Supplements from Foods and from Drugs; Market Entry Requirements; Safety; Structure-Function Claims. Health Claims in Dietary Supplement and Conventional Food Labeling. FTC Regulation of Food and Dietary Supplement Advertising.


April 8: Drug Distribution: The Prescription Requirement; Marketing Authorization for Nonprescription Drugs; Switching from Rx to OTC Status; Controlled Substance Regulation by DEA. Assuring Drug Product Quality; Regulation of Pharmacy Compounding of Rx Drugs

April 15: Prescription Drug Labeling, Promotion, and Advertising: Rx and Other “New Drug” Labeling Requirements; Rx Drug Advertisements; Direct-to-Consumer Advertisements for Rx Drugs; Promotion of Unapproved Uses; Emerging Constitutional Issues. OTC Drug Labeling and Advertisements: Adequate Directions for Use; FTC Regulation of OTC Drug Advertisements.

April 22: Medical Devices: Definition; Classifications; Marketing Clearance and Approval; Special and General Controls; Device Reclassification; Prescription Devices; Restricted Devices; Reprocessed Devices. Combination Products; Tissue, Cellular, and Gene Therapy Products