

## REGULATION OF FOOD AND DRUGS

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### Syllabus

- January 7: Introduction; Core Regulatory Concepts; Constitutional Foundations
- January 12: Inspectional Authority; Enforcement Litigation Processes
- January 14: Import Exclusion Authority; Administrative Proceedings
- January 19: NO CLASSES
- January 21: Food Safety: Filth; Fitness for Food
- January 26: Food Safety: Insanitary Conditions; cGMPs; HACCP; Establishment Registration
- January 28: Food Safety: “Added” and “Non-Added” Substances
- February 2: Food Safety: Environmental Contaminants; Tolerances; Food Additives Defined
- February 4: Food Safety: Food Additive Safety Standard; Anti-Cancer Clauses
- February 9: Food Safety: GRAS and Prior-Sanctioned Substances; Food Contact Substances
- February 11: Food Safety: Risk Assessment; Pesticide Residues; Safety of Bioengineered Foods
- February 16: Food Composition: Economic Adulteration; Imitation Foods; Standards of Identity
- February 18: Food Labeling: Required Elements; Warnings; False and Misleading Labeling
- February 23: Food Labeling: Problems of Proof; Special Terms; Labeling Bioengineered Foods
- February 25: Dietary Supplements: Distinguishing from Drugs; Evolution of Regulation
- March 2: Dietary Supplements: Safety; Structure/Function Claims in Labeling
- March 4: Dietary Supplements: Health Claims in Labeling; FTC Regulation of Advertising
- March 9: NO CLASSES
- March 11: NO CLASSES
- March 16: Drugs: Definition of “Drug”; Core Regulatory Concepts
- March 18: Drugs: Effectiveness Standard; Grandfather Clauses; Generic Drug Effectiveness
- March 23: Drugs: Safety Standard; Scope of Premarket Approval Requirement
- March 25: Drugs: Regulation of Drug Development; Informed Consent; Investigational Drugs
- March 30: Drugs: Premarket Approval and Revocation Process; Imminent Hazards
- April 1: Drugs: Approval of Generics, Biologics, and OTC Drugs; Product Quality
- April 6: Drugs: Scope of Prescription Requirement; Controlled Substance Regulation
- April 8: Drugs: Labeling, Promotion; and Advertising
- April 13: Devices: Definition; Classifications; Marketing Clearance and Approval
- April 15: Devices: Special and General Controls; Reclassification
- April 20: Devices: Prescription Devices; Restricted Devices; Reprocessed Devices
- April 22: Combination Products; Tissue, Cellular, and Gene Therapy Products