FDA Mission, Structure & Authority
FDA Jurisdiction

- FDA regulates over $\frac{1}{4}$ of the U.S. Economy
- FDA is responsible for ensuring the safety, efficacy and/or security of:
  - human and veterinary drugs;
  - biologics (vaccines, blood products);
  - human tissues;
  - medical devices;
  - food (now including tobacco products);
  - dietary supplements; and
  - cosmetics.
FDA Functions

- Pre-market product review and approval;
- Standard-setting;
- Rulemaking (formal vs. informal);
- Regulatory Guidance;
- Public education;
- Law Enforcement; and
- Litigation.
FDA Structure

- FDA is a sub-Agency to the U.S. Department of Health and Human Services (HHS)
- Commissioner’s Office and 4 Directorates
- Headquartered in White Oak, MD with District Offices covering CONUS with Offices in China, Chile, Costa Rica, India, Mexico, Belgium and the UK
FDA Structure

- Commissioner’s Office
  - Commissioner and Principle Deputies
  - Office of the Chief Scientist (includes OCET)
  - Offices of Policy and Planning (OPL), and Legislation (OL)
  - Office of the Chief Counsel (OCC) (HHS Office of the General Counsel, Food and Drug Division)
  - Office of Criminal Investigations (OCI)
FDA Structure

- Office of Medical Products and Tobacco
  - Center for Drug Evaluation and Research (CDER)
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Devices and Radiological Health (CDRH)
  - Center for Tobacco Products (CTP)
  - Center for Special Medical Programs

- Office of Global Regulatory Operations and Policy
  - Office of International Programs
  - Office of Regulatory Affairs (ORA)
FDA Structure

- Office of Foods and Veterinary Medicine
  - Center for Food Safety and Applied Nutrition (CFSAN)
  - Center for Veterinary Medicine (CVM)

- Office of Operations
  - Office of Finance, Budget & Acquisitions
  - Office of Informational Management and Technology
ORA Overview

- Chief FDA Field Entity
- Within Office of Global Regulatory Operations and Policy Directorate
- Responsible for inspection and enforcement for regulated products
  - Often initial actor in criminal investigations
  - Imports
- 227 Offices, 13 laboratories
- Closely coordinate with Center offices of compliance on FD&C Act violations
Example Center Structure

**CDER**
- Office of the Center Director
- Office of New Drugs
  - ODEs
- Office of Generic Drugs
- Office of Compliance
  - Drug and Labeling; Mfr./Qual.; Risk Mgmt.
- Office of Medical Policy
  - OPDP(formerly DDMAC)

**CBER**
- Office of the Center Director
- Office of Cellular, Tissue and Gene Therapies
- Office of Blood Research and Review
- Office of Vaccine Research and Review
- Office of Compliance and Biologics Quality
Other Federal Agencies Involved in Drug Regulation

- CMS – Medicare/Medicaid Reimbursement
- NIH – Federally Funded Research
- FTC – OTC drug advertising and antitrust
- DOJ – Criminal prosecutions
- DEA – Controlled substances
- SEC – Reporting of material information by publicly traded companies
- DHS, Bureau of Customs and Border Protection – Imports
- States
Hierarchy of Legal Authority

- U.S. Constitution
- Federal Statutes (United States Code)
  - Federal Food, Drug and Cosmetic Act (FD&C Act) as amended
  - Public Health Service Act (PHSA)
- Regulations (Code of Federal Regulation)
  - Title 21: Food and Drugs
  - Rulemaking consistent with the Administrative Procedures Act (*Chevron* Doctrine)
Sources of FDA Guidance

- Federal Register Notices
  - ANPRM, NPRM, PR, FR (note: Final Rules have force and effect of law)

- Guidance Documents

- Compliance Policy Guides

- Enforcement and Compliance Actions
  - 483s (Establishment Inspection Reports)
  - Warning, Untitled and Cyber Letters

- Judicial Pleadings
Legal Authority

- The Commerce Clause (Article 1, §8, Clause 3):
  - “The Congress shall have the power to...To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes”.

- The Necessary and Proper Clause (Art. 1, §8, Clause 18)
  - “To make all Laws which shall be necessary and proper for carrying into Execution the foregoing powers...”
Legal Authority

- The Supremacy Clause (Article VI, Clause 2):
  - “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof….shall be the supreme Law of the Land…”
Legal Authority

- The Biologics Control Act of 1902
- Pure Food and Drugs Act of 1906
- Federal Food Drug and Cosmetic Act of 1938
  - Kefauver-Harris “Efficacy” Amendments of 1962
  - The Medical Device Amendments of 1976
  - Orphan Drug Act of 1983
  - Prescription Drug Marketing Act of 1987 (“PDMA”)
  - Safe Medical Devices Act of 1990 (SMDA)
Legal Authority

- FD&C Act of 1938 (cont.)
  - Prescription Drug Use Fee Act of 1992 (“PDUFA”)
  - Generic Drugs Enforcement Act of 1992
  - Dietary Supplement Health and Education Act (“DSHEA”) (1994)
  - Food and Drug Administration Modernization Act (“FDAMA”) (1997)
  - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act”)
Legal Authority

- FD&C Act of 1938 (cont.)
  - Medical Device User Fee and Modernization Act of 2002 (“MDUFA”)
  - Project Bioshield Act of 2004
  - Food and Drug Administration Amendments Act of 2007 (“FDAAA”)
  - Food and Drug Administration Safety and Innovation Act of 2012 (“FDASIA”)
- Public Health Service Act of 1944
  - Biologics Price Competition and Innovation Act of 2009
Legal Authority

- Sec. 301 of The Federal Food, Drug and Cosmetic Act (FD&C Act) prohibits:
  - (a) The introduction or delivery for introduction into interstate commerce any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
  - (b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.
Sec. 301 of The FD&C Act prohibits:

- (c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
- (d) the introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505 [New Drug Application] or 564.