Enforcement

Introduction to Drug Law

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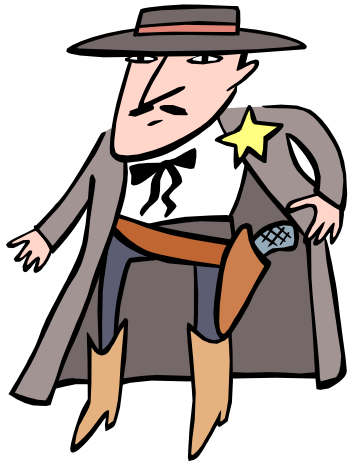
General Disclaimers

- Any Opinion Expressed in here is mine and neither FDLI's nor Duane Morris's
- Nothing in here constitutes legal advise
- I am not your lawyer
- Please ask questions If I know the answer I provide. If not, I will make something up

Violations and Enforcement

- Jurisdiction
  - Presumed
  - Includes drugs not already in the United States



Violations and Enforcement

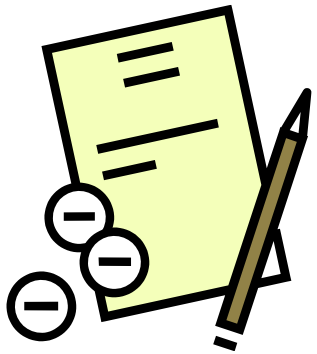
- Prohibited Acts
  - Adulterated
  - Misbranded
  - Unapproved new drugs
  - Wholesale distribution without proper licensure or registration
  - Failure to implement approved risk evaluation and mitigation strategy
  - Off-label promotion
  - Diversion
  - Fraudulent Price Reporting
  - Others

Violations

- Adulteration
  - Not compliant with good manufacturing practices ("CGMP")
  - Strength, quality, purity
  - Mixed, packed improperly

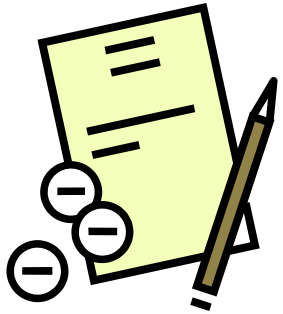
Violations

- Misbranding
  - Labeling
    - Very broad



Violations

- Unapproved "New" Drugs
  - Drug or Biologic
  - Does Not Comply With NDA, ANDA, Biologics License
- No NDA, ANDA, Biologics License
- OTC Drugs No Compliant Monograph, NDA, or ANDA



Violations and Enforcement

- Wholesale Distribution
  - 21 U.S.C. § 353(e)
    - Required to be licensed in a state
    - *United States v. Segredo*
  - State requirements
    - Most require out of state wholesalers/manufacturers/distributors to register
    - Colorado, Indiana, other states
      - Verified – Accredited Wholesale Distributors (VAWD) inspection or state inspection last two years
    - Many states separate Registration for Controlled Substances

Violations and Enforcement

- Risk Evaluation and Mitigation Strategy (REMS) containing Elements to Assure Safe Use (ETASU)
- Secretary can require
  - Pre-Approval
  - Post-Approval

Violations and Enforcement

- Off label promotion
  - *Caputo*
  - *Allergan*
  - *Caronia*
- Metatags
- Social Media
- Safe Harbor - Distribution peer reviewed articles

Violations and Enforcement

- Diversion
- DEA
- Reporting requirements

Enforcement

- Inspections
  - 21 U.S.C. 374
- VAI
- FDA Form 483
  - Not final agency action
  - Pattern of Conduct
  - Repeated Violations
  - Written Response 15 business days
  - Follow-on Responses

CTP -- Compliance Check Inspections

- Undercover Retailer Buy Inspections
- Trained Minor
- Results Sent to FDA
- Violation?
- 1st time – WL
- 2nd Time WL, CMP, No Tobacco Sale Order
- Results Posted FDA website

CTP CMPs

- **Number of Regulation Violations** **CMP Amount**
- 1 $0 (CTP will send a Warning Letter)
- 2 within a 12-month period $320
- 3 within a 24-month period $638
- 4 within a 24-month period $2,559
- 5 within a 36-month period $6,397
- 6 within a 48-month period $12,794

CTP – No Tobacco Sale Orders

- 5 or more violations in 36 months
- Complaint
  - Settlement
  - Hearing before and ALJ

Enforcement

- Warning letters
  - Not final agency action
  - Regional Offices
  - Written Response(s)
- Import Alerts (Detain without Inspection)
- Establishment Inspection Report

Inspections-Risk Based

- "Any establishment"
- Regular business hours
- "All things therein," "adulterated or misbranded"
- Not financial data or sales data except in limited situations
- Have person in charge
- Photos or video?
- Questioning by FDA

Enforcement

- Voluntary recalls
  - Not really voluntary
  - Shadow Recall

Enforcement

- Conducting a recall
  - Plan in place
    - Level (i.e. to whom to send notice)
    - Follow-up
    - Tracking
    - Post-Receipt handling
    - Media
  - FDA Input

Enforcement

- Civil penalties / disgorgements
  - Fines
  - Profit disgorgement
  - Contempt
    - Civil
    - Criminal

Enforcement

- Civil seizures
  - *In rem*
  - Supplemental Rules of Civil Procedure (Rules of Admiralty)
  - FDA or DEA must provide timely notice
  - You must assert claim
  - Potential counter-claims
    - Fees
    - Value of Product

Enforcement

- Expiration date may moot claim

Enforcement

- Injunctions
  - Temporary restraining orders
  - Preliminary & Permanent injunctions
  - Consent decrees
  - Deferred prosecution agreements
  - Ongoing monitoring
  - Contempt
    - Civil
    - Criminal

Enforcement

- Criminal prosecutions
  - Strict liability
  - Knowing vs. unknowing
  - Responsible person - *U.S. v. Park*
    - The *Park* doctrine provides for criminal liability (first-time misdemeanor and possible subsequent felony) under the FDCA without proof that a corporate official acted with intent (even negligence) or knowledge. Factors are:
      - The corporate official's knowledge of and actual participation in the violation;
      - Whether the violation involves actual or potential harm to the public;
      - Whether the violation is obvious or reflects a pattern of illegal behavior and/or failure to heed prior warnings;
      - Whether the violation is widespread or serious;
      - The quality of the legal and factual support for the proposed prosecution; and
      - Whether the proposed prosecution is a prudent use of FDA resources.

Enforcement

- Criminal prosecutions (Cont.)
  - Potentially responsible for actions of contractors if acting on your behalf
  - Debarment
  - Exclusion

Other Issues

- Federal Trade Commission
  - Marketing Issues
  - False Advertising
  - Reverse Payments
- False Claims Act
  - Federal
  - State
  - Criminal and civil
  - Fines per claim

Other Issues

- Foreign Corrupt Practices Act
  - Reporting Requirements
  - Bribing foreign officials
- Sunshine Act
  - Reporting Requirements