Title I-Inspections and Enforcement in the Compounding World

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FDLI

TITLE I – INSPECTIONS AND ENFORCEMENT IN THE COMPOUNDING WORLD

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QUICK RECAP: COMPOUNDING QUALITY ACT – 503A VS 503B COMPOUNDERS

- 503A: Pharmacy compounding (majority of compounders)
  - Not subject to CGMP requirements, not required to register with FDA, and not routinely inspected by FDA
  - Primarily overseen by state regulatory authorities
  - Not exempt from the prohibition on preparing drugs under insanitary conditions
    - FDA has authority to inspect, within certain limitations
  - Procedure for inspections of 503A entities: "Preliminary assessment"

QUICK RECAP: COMPOUNDING QUALITY ACT – 503A VS 503B COMPOUNDERS

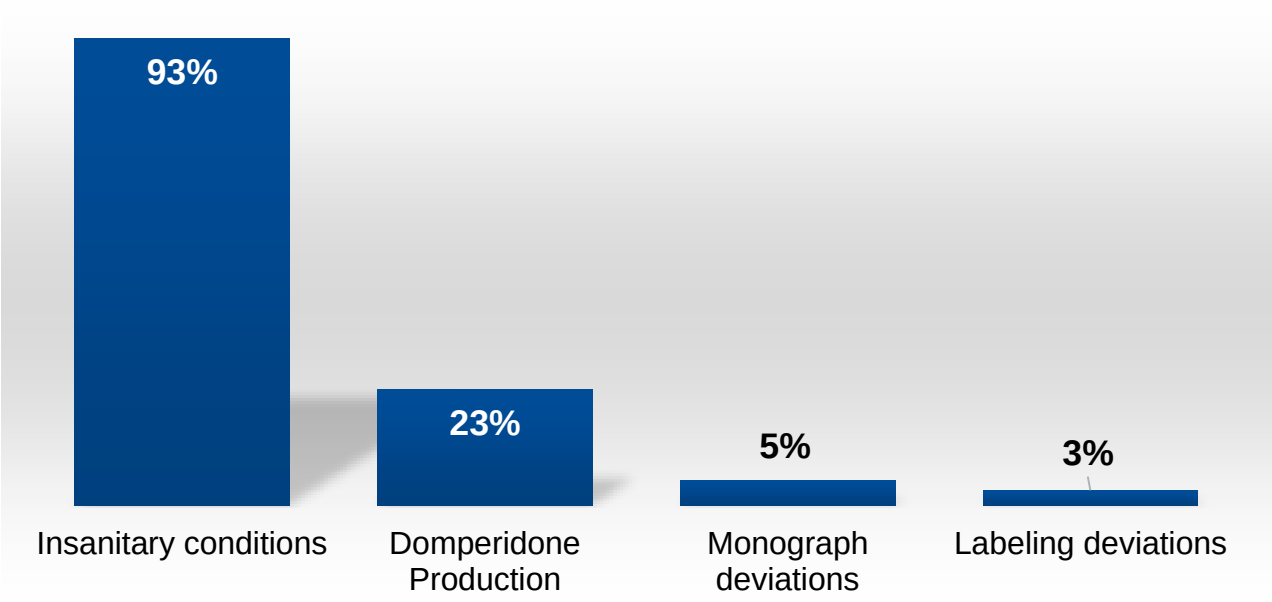
- 503B: Outsourcing facilities
  - A facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all the requirements of Section 503B
  - Not exempt from CGMP requirements
  - May compound drugs with or without a patient-specific prescription
  - Must compound sterile drugs / may compound nonsterile drugs
  - Inspected on a risk-based schedule

TRENDS: 503A & 503B FACILITY INSPECTIONS

As of November 27, 2016	As of September 30, 2017
>350 inspections (85 outsourcing facilities)	~500 inspections
>130 warning letters	>180 warning letters
>30 referral letters	>70 referral letters
~100 recalls overseen	>150 recalls overseen
“Number” of DOJ civil and criminal enforcement actions	

Inspections have resulted in recalls, temporary cessation of operations, warning letters, and civil or criminal enforcement actions

TRENDS: WARNING LETTERS ISSUED TO 503A FACILITIES



Letters issued between December 6, 2014 and December 8, 2016 (n=96) and publicly posted as of March 2, 2017

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"CRITICAL TRANSITION PERIOD": FDA FOCUS

503A

- Working with states to identify large-scale, multi-state distributors
- Identifying compounders distributing non-patient specific compounded drugs
- Targeting FDA oversight in a manner helpful to the states

503B

- Helping facilities comply with CGMP requirements
- Engaging in pre-operational inspections and meetings to provide advice
- Increasing frequency of post-inspection correspondence and regulatory meetings

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TRENDS: STATE INSPECTIONS – CALIFORNIA (EXAMPLE)

Triggering Event

- Consumer complaint
- Arrest notification
- Referral from other agency
- Inspection

Investigation

- Inspection
- Interviews
- Records assessment
- Report writing

Outcome

- No violations / insufficient evidence
- Findings determine outcome

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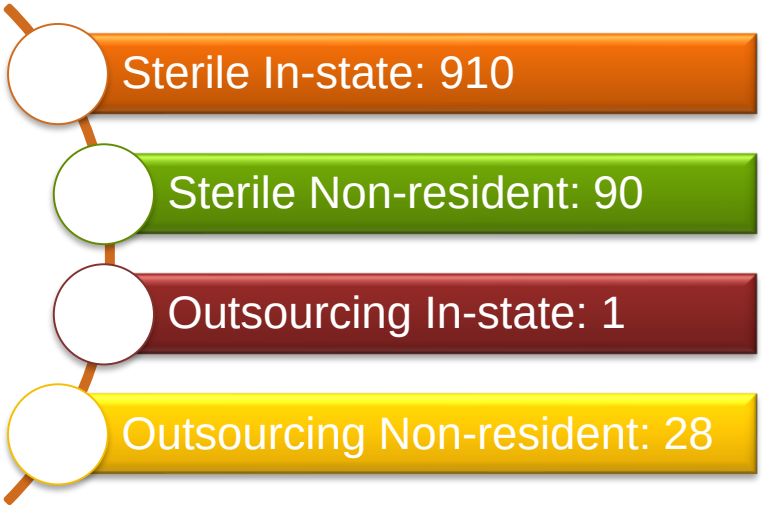
TRENDS: STATE INSPECTIONS – CALIFORNIA COMPOUNDING INSPECTIONS FY 2017-2018

- Sterile Compounding and Outsourcing Inspections: 1,029 Total



- Total violations identified

3,067

- Corrections ordered

2,401

- Violation notices issued

162

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TRENDS: STATE INSPECTIONS – CALIFORNIA COMPOUNDING INSPECTIONS FY 2017-2018

Top 5 Corrections Issued to Sterile or Outsourcing Facilities	
Compounding log	110
Germicidal detergent cleaning of sterile compounding area/equipment	95
Sterile compounding equipment/are made of materials easily cleaned and disinfected	64
Sterile compounding gloves and handwashing requirements	63
Pharmacy fixtures and equipment clean and orderly; hot and cold running water	46

Top 5 Violations Issued to Sterile or Outsourcing Facilities	
Compounding log	5
Maintain sterile compounding written policies and procedures	5
Viable surface and viable air sampling performed	4
Use of PEC that provides ISO Class 5 air or better	4
Non-shedding, segregated and dedicated cleaning materials for clean room	4

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INSPECTION READINESS: PREPARE, PRACTICE, PERFORM

- Know what you are and why
- Maintain a written plan easily available to responsible personnel
- Design and implement an effective compliance program
- Provide initial and on-going training for personnel regarding compliance requirements
- Ensure proper documentation and storage of records
- Engage in appropriate environmental controls and quality testing
- Foster a culture of compliance
- Routinely evaluate strength of program, identify and address weaknesses

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Compounding Enforcement
Recent DOJ Actions

John Claud
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch

Views and analysis expressed here are personal, and are not meant to impart any policy of the United States Department of Justice

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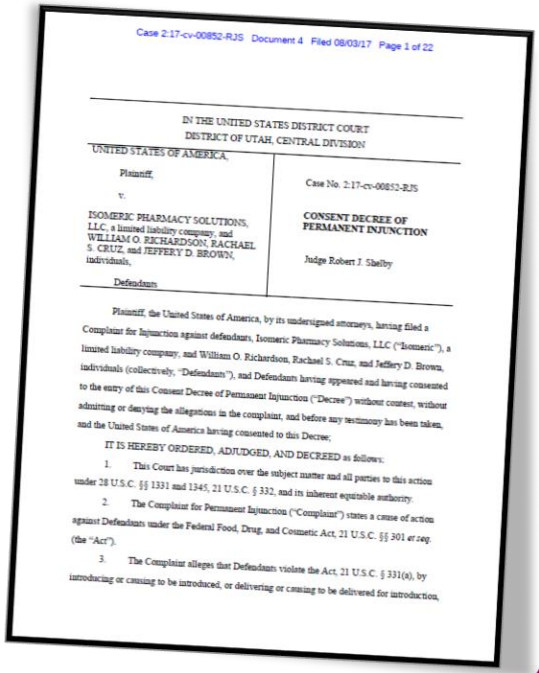
Recent DOJ Enforcement Actions

Isomeric Pharmacy Solutions (Civil – D. Utah)

- August 2017
- Civil consent decree of permanent injunction
- Sterile drugs, injectables
- Allegations: Microorganisms in air and on surfaces used for sterile processing
- Released over 100 batches of purportedly sterile products processed in areas violating environmental monitoring “action limit”



Case 2:17-cv-00852-RJS Document 4 Filed 08/03/17 Page 1 of 22

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ISOMERIC PHARMACY SOLUTIONS, LLC, a limited liability company, and WILLIAM O. RICHARDSON, RACHAEL S. CRUZ, and JEFFERY D. BROWN, individuals,

Defendants

Case No. 2:17-cv-00852-RJS

CONSENT DECREE OF PERMANENT INJUNCTION

Judge Robert J. Shelby

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Injunction against defendants, Isomeric Pharmacy Solutions, LLC ("Isomeric"), a limited liability company, and William O. Richardson, Rachael S. Cruz, and Jeffery D. Brown, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint for Permanent Injunction ("Complaint") states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction,

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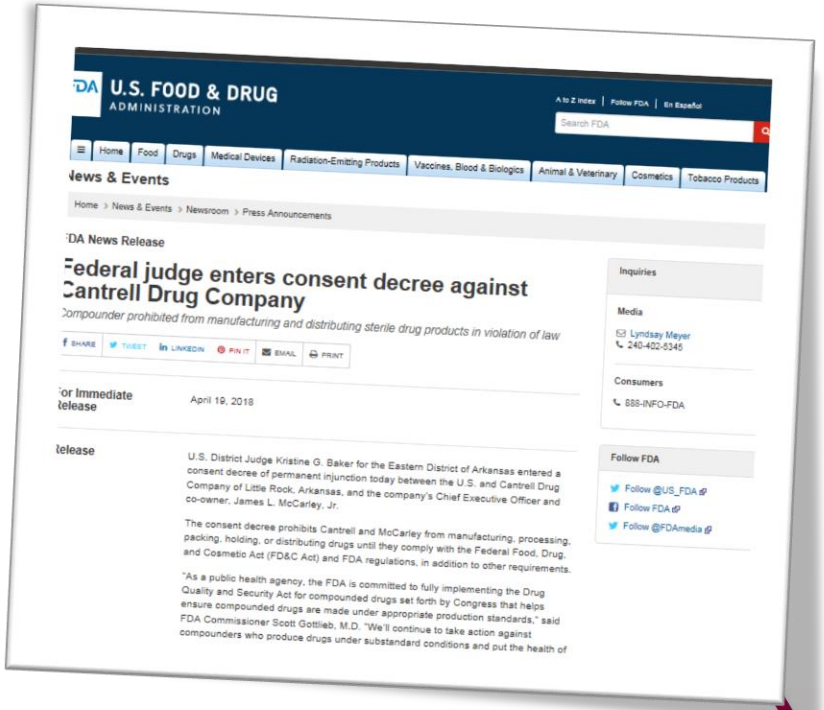
Cantrell Drug Company (Civil - E.D. Ark.)

- April 2018
- Civil consent decree, permanent injunction
- Sterile injectables
- Allegations: Insanitary conditions
- 503B outsourcing facility
- Case went through Bankruptcy Court



Delta Pharma, Inc. (Civil - N.D. Miss.)

- June 2018
- Civil permanent injunction
- Allegations: Insanitary conditions
- Deficiencies in sterile compounding procedures
- Pharmacy must take corrective measures, approved by FDA
- Prior inspections in 2013 (2014 Warning Letter) & 2016

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

DELTA PHARMA, INC., a corporation, and TOMMY T. SIMPSON and CHARLES MICHAEL HARRISON, individuals,

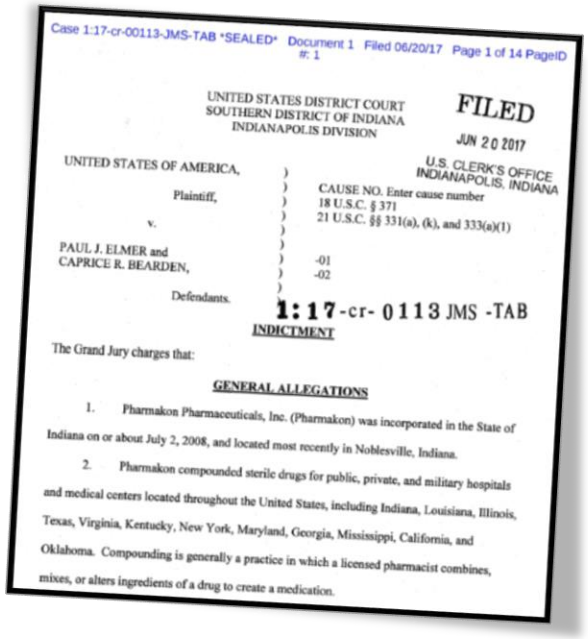
Defendants.

Civil Action No. 3:18-cv-127-NBB-JMV

CONSENT DECREE OF PERMANENT INJUNCTION

Pharmakon (Criminal - S.D. Ind.)

- **Paul Elmer trial scheduled for March 25, 2019**
- **Compliance director Caprice Bearden pleaded guilty**
- **Counts: Conspiracy (§ 371); Introduction of Adulterated Drugs (§ 331(a)); Adulterated Drugs While Held for Sale (§331(k)).**



Case 1:17-cr-00113-JMS-TAB *SEALED* Document 1 Filed 06/20/17 Page 1 of 14 PageID #: 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

FILED
JUN 20 2017
U.S. CLERK'S OFFICE
INDIANAPOLIS, INDIANA

UNITED STATES OF AMERICA,
Plaintiff,
v.
PAUL J. ELMER and
CAPRICE R. BEARDEN,
Defendants.

CAUSE NO. Enter cause number
18 U.S.C. § 371
21 U.S.C. §§ 331(a), (k), and 333(a)(1)
-01
-02

1:17-cr-0113 JMS -TAB

INDICTMENT

The Grand Jury charges that:

GENERAL ALLEGATIONS

1. Pharmakon Pharmaceuticals, Inc. (Pharmakon) was incorporated in the State of Indiana on or about July 2, 2008, and located most recently in Noblesville, Indiana.

2. Pharmakon compounded sterile drugs for public, private, and military hospitals and medical centers located throughout the United States, including Indiana, Louisiana, Illinois, Texas, Virginia, Kentucky, New York, Maryland, Georgia, Mississippi, California, and Oklahoma. Compounding is generally a practice in which a licensed pharmacist combines, mixes, or alters ingredients of a drug to create a medication.

- ***An indictment constitutes only charges. Every person or company charged is presumed innocent until guilt has been proven beyond a reasonable doubt.***

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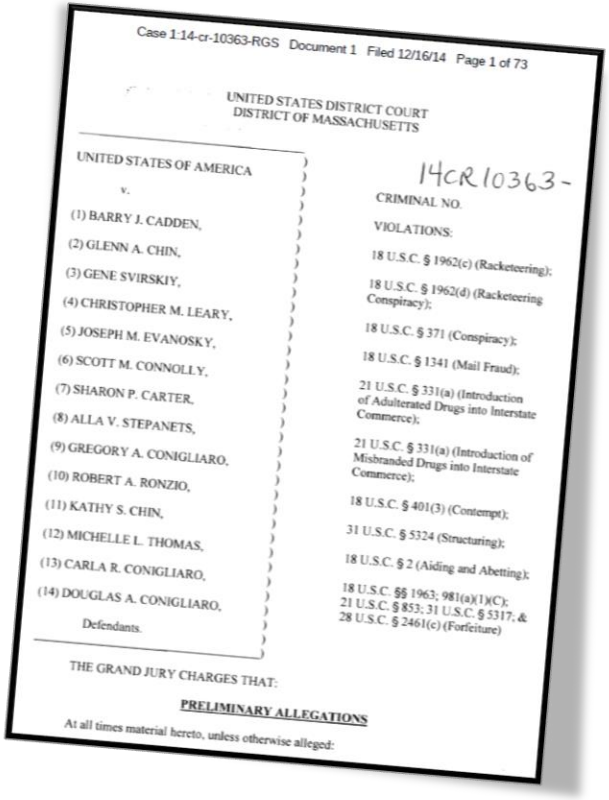
New England Compounding Center (Criminal, D. Mass.)

- Arising from the 2012 fungal meningitis outbreak
- 64+ people dead; 750+ infected
- Three trials to date; fourth trial currently schedule for March 25, 2019



Case 1:14-cr-10363-RGS Document 1 Filed 12/16/14 Page 1 of 73

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA
v.
(1) BARRY J. CADDEN,
(2) GLENN A. CHIN,
(3) GENE SVIRSKIY,
(4) CHRISTOPHER M. LEARY,
(5) JOSEPH M. EVANOSKY,
(6) SCOTT M. CONNOLLY,
(7) SHARON P. CARTER,
(8) ALLA V. STEPANETS,
(9) GREGORY A. CONIGLIARO,
(10) ROBERT A. RONZIO,
(11) KATHY S. CHIN,
(12) MICHELLE L. THOMAS,
(13) CARLA R. CONIGLIARO,
(14) DOUGLAS A. CONIGLIARO,
Defendants.

14CR10363-

CRIMINAL NO.

VIOLATIONS:

18 U.S.C. § 1962(c) (Racketeering);

18 U.S.C. § 1962(d) (Racketeering Conspiracy);

18 U.S.C. § 371 (Conspiracy);

18 U.S.C. § 1341 (Mail Fraud);

21 U.S.C. § 331(a) (Introduction of Adulterated Drugs into Interstate Commerce);

21 U.S.C. § 331(a) (Introduction of Misbranded Drugs into Interstate Commerce);

18 U.S.C. § 401(3) (Contempt);

31 U.S.C. § 5324 (Structuring);

18 U.S.C. § 2 (Aiding and Abetting);

18 U.S.C. §§ 1963; 981(a)(1)(C); 21 U.S.C. § 853; 31 U.S.C. § 5317; & 28 U.S.C. § 2461(c) (Forfeiture)

THE GRAND JURY CHARGES THAT:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

- ***An indictment constitutes only charges. Every person or company charged is presumed innocent until guilt has been proven beyond a reasonable doubt.***

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New England Compounding Center (Criminal, D. Mass.)

- **First trial: Barry Cadden – 108 mos. (9 years)**
- **Second Trial: Glenn Chin – 96 mos. (8 years)**
- **Third trial ongoing. Six defendants on trial for Racketeering, Mail Fraud, Klein Conspiracy against FDA, FDCA misbranding and adulteration charges**

- ***An indictment constitutes only charges. Every person or company charged is presumed innocent until guilt has been proven beyond a reasonable doubt.***

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Synergy/HealthRight (Criminal - E.D. Tenn.)

- October 2018
- Four defendants, seven companies
- Allegations: Nearly $1B in healthcare fraud
- Compounders paired with telemarketers to generate bogus prescriptions
- Billed to private insurers (not Tri-Care)

- *An indictment constitutes only charges. Every person or company charged is presumed innocent until guilt has been proven beyond a reasonable doubt.*

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Synergy/HealthRight (E.D. Tenn.)

- **Doctors approved prescriptions without knowing defendants were massively marking up the prices of the invalidly prescribed drugs**
- **Eluding the audit cycle by opening new pharmacies**
- **FDCA charges for bogus prescriptions, 18 U.S.C. § 353(b)**

- ***An indictment constitutes only charges. Every person or company charged is presumed innocent until guilt has been proven beyond a reasonable doubt.***

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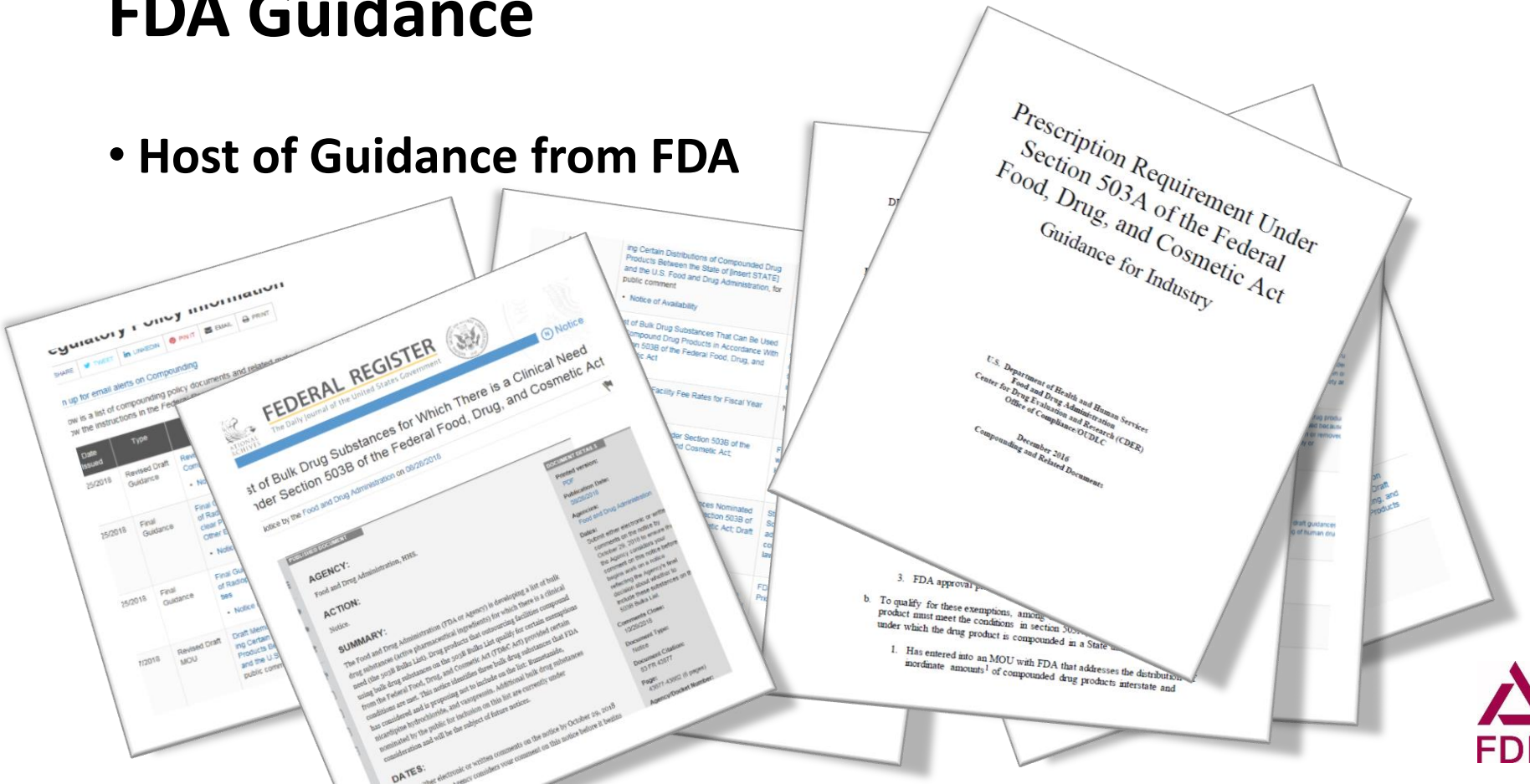
FDA Guidance

- **Host of Guidance from FDA**



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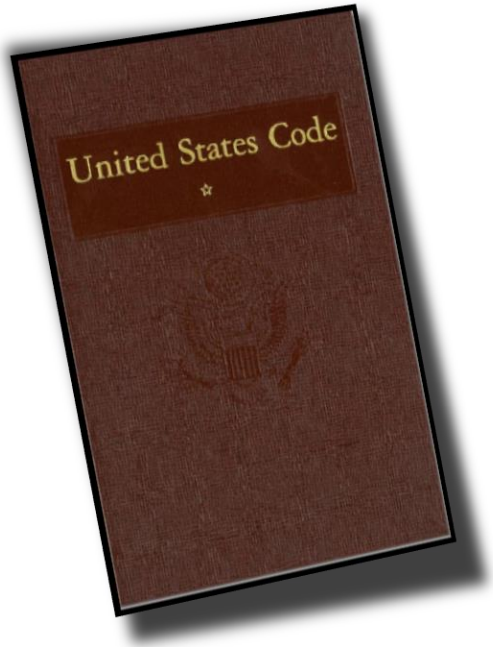
Enforcement Litigation



- DOJ will litigate based on violations of federal law
- Focus will be on adulterated or misbranded drugs
- Factors may include evidence of fraud based on marketing claims, healthcare fraud, smuggling, endangering patient safety

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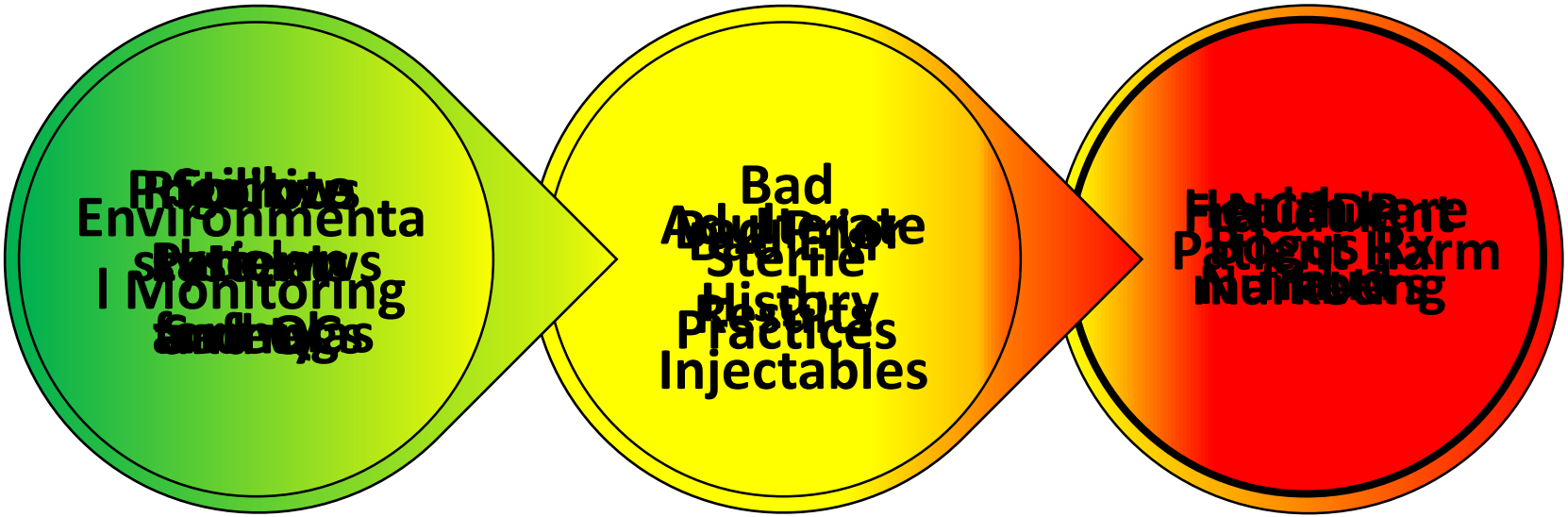
What Might Trigger Enforcement Action?



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