



# Device Case Processing

Tara Goldman, M.Sc.  
CSO

Office of In Vitro Diagnostic Device  
Evaluation and Safety

April 21, 2010

# Tools Used in Support of Regulatory Actions



- Food, Drug and Cosmetic Act

- <http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm>

- Code of Federal Regulations (CFR)

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>

- Compliance Policy Guides (CPG)

- <http://www.fda.gov/ora/cpgm/default.htm>

- Regulatory Procedures Manual (RPM)

- [http://www.fda.gov/ora/compliance\\_ref/rpm/](http://www.fda.gov/ora/compliance_ref/rpm/)

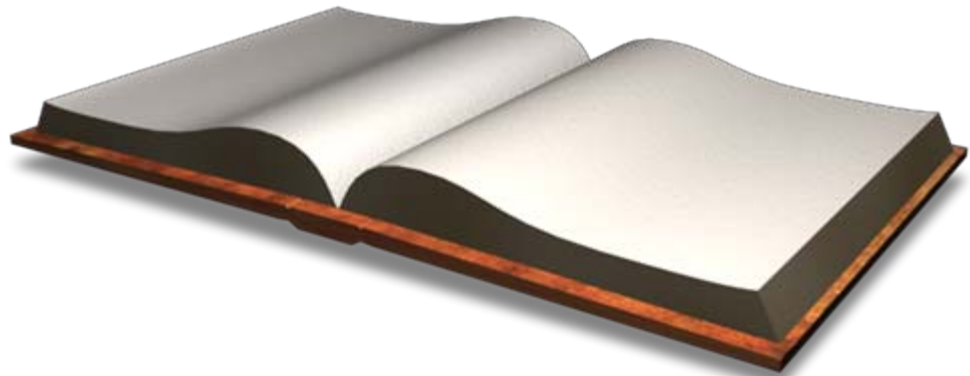
# Violative Devices

☑ Adulterated

(Section 501 FD & C Act)

☑ Misbranded

(Section 502 FD & C Act)





# Commonly Used Device Charges

## Adulteration Sections:

501(f)(1)(B) Unapproved class III device

501(c) Strength differs or purity or quality  
below claims

501(h) Not following GMP's (21 CFR 820)

501(i) Not following IDE regulations  
(21 CFR 812)

# Commonly Used Device Charges

(Continued)

## Misbranding Sections:

502(a) Label false or misleading

502(b) Missing device name, firm name,  
and address

502(f)(1) Inadequate directions for use

502(f)(2) Lack of adequate warnings

In Vitro Labeling 21CFR 809.10

# Commonly Used Device Charges

(Continued)

## Misbranding Sections (continued):

502(o) No Premarket Notification [510(k)],  
No Registration and Listing

502(j) Danger to Health

502(t)(2) Failure to report MDR's and/or  
Corrections or Removals (21CFR  
803 and 806)

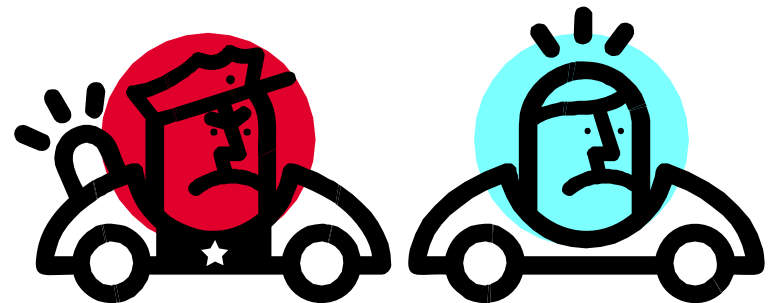
# Types of Enforcement Actions

- ☑ Administrative

FDA Acts on its own to exercise authority

- ☑ Judicial

FDA acts in coordination with legal system



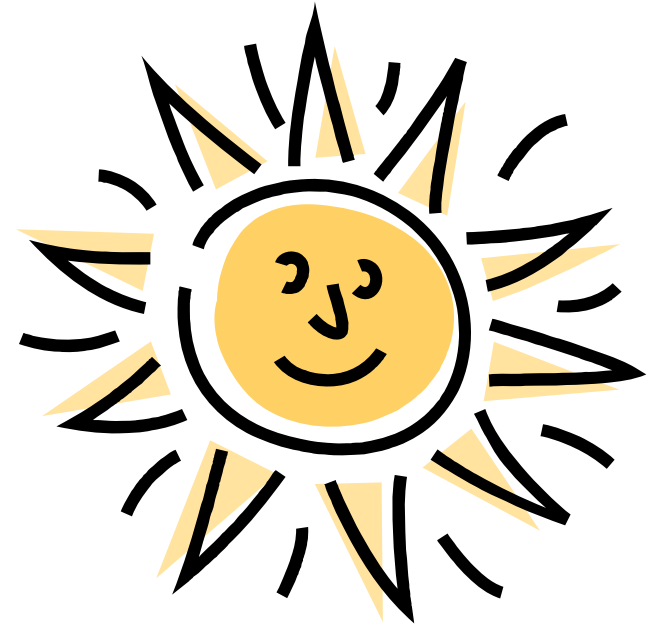
# Enforcement Action Considerations

- Jurisdiction
- Adequate evidence and documentation
- Action of choice
- Prior warning or absence of prior warning
- Action consistent with current policy/resources
- Shortage concerns



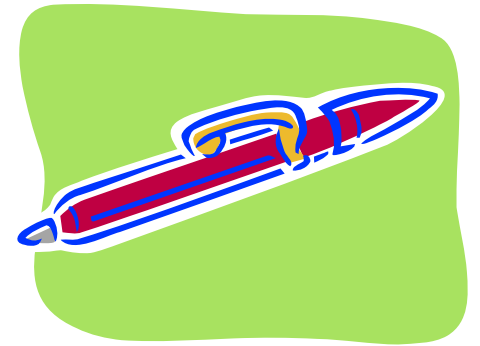


Except in most significant/unusual circumstances, FDA provides firm's/individuals an opportunity to voluntarily correct violations!



# Administrative Actions

- Warning Letter
- Civil Money Penalty
- Administrative Detention
- Section 518 Actions [FDA Recalls]
- Import Alert
- Automatic Detention



# Administrative Actions (continued)

## **WARNING LETTER**

- Written communication to firm or individual(s)
- Products, practices, processes, etc. to be in violation of the Act
- Failure to take appropriate and prompt action to correct the violations may result in regulatory action being initiated without further warning.
- ESTABLISHES PRIOR WARNING; ALLOWS FOR VOLUNTARY COMPLIANCE.

# Administrative Actions (Continued)

## **CIVIL \$ PENALTY (Devices only)**

Action which can go to a hearing conducted by an administrative law judge for most violations of the Act; penalty may not exceed \$15,000 for each violation and may not exceed \$1,000,000 for all violations in a single proceeding.



# Administrative Actions (Continued)

## **ADMINISTRATIVE DETENTION**

The temporary (30 days maximum) detention of devices believed to be adulterated or misbranded, until the agency has had time to consider what action it should take concerning the devices, and to initiate legal action, if appropriate.

# Administrative Actions (Continued)

## **SECTION 518 ACTIONS**

Section 518(a) Notification

Section 518(b) Repair, Replacement, or  
Refund

Section 518(e) Recall Authority



# Judicial Actions

- Seizure
- Injunction
- Citation
- Prosecution
- Grand jury investigation





# Most Common Judicial Actions

## **Seizure**

- Action against a device (section 304)
- Product(s) – may be lot/model specific
- May include raw materials, labeling, packaging, finished devices



# Most Common Judicial Actions

(Continued)

## **INJUNCTIONS (Section 302)**

- An order issued by the court requiring a defendant to do or refrain from doing a specified act
- Action against firm and/or individuals who control the manufacture/movement of devices



# Most Common Judicial Actions

(Continued)

## **CONSENT DECREE (Seizures and Injunctions)**

- Assures compliance with the Act
- May have “Sunset Clause” (releases injunction in approximately 5-6 years)

# Most Common Judicial Actions

(Continued)

## PROSECUTIONS

■ Criminal action directed against firm and/or responsible individuals

- **Misdemeanor** – Sentence of imprisonment is not more than one year; sentence of fine is not more than \$5,000; or both
- **Felony** – Sentence of imprisonment is not more than five year; sentence of fine is not more than \$10,000; or both

# Most Common Judicial Actions

(Continued)

## **TITLE 21 PROSECUTION**

- Food and Drug violations
- Requires Cite hearing – Section 305
- Violations of prohibited act(s)
  - Misdemeanor or felony



# Most Common Judicial Actions

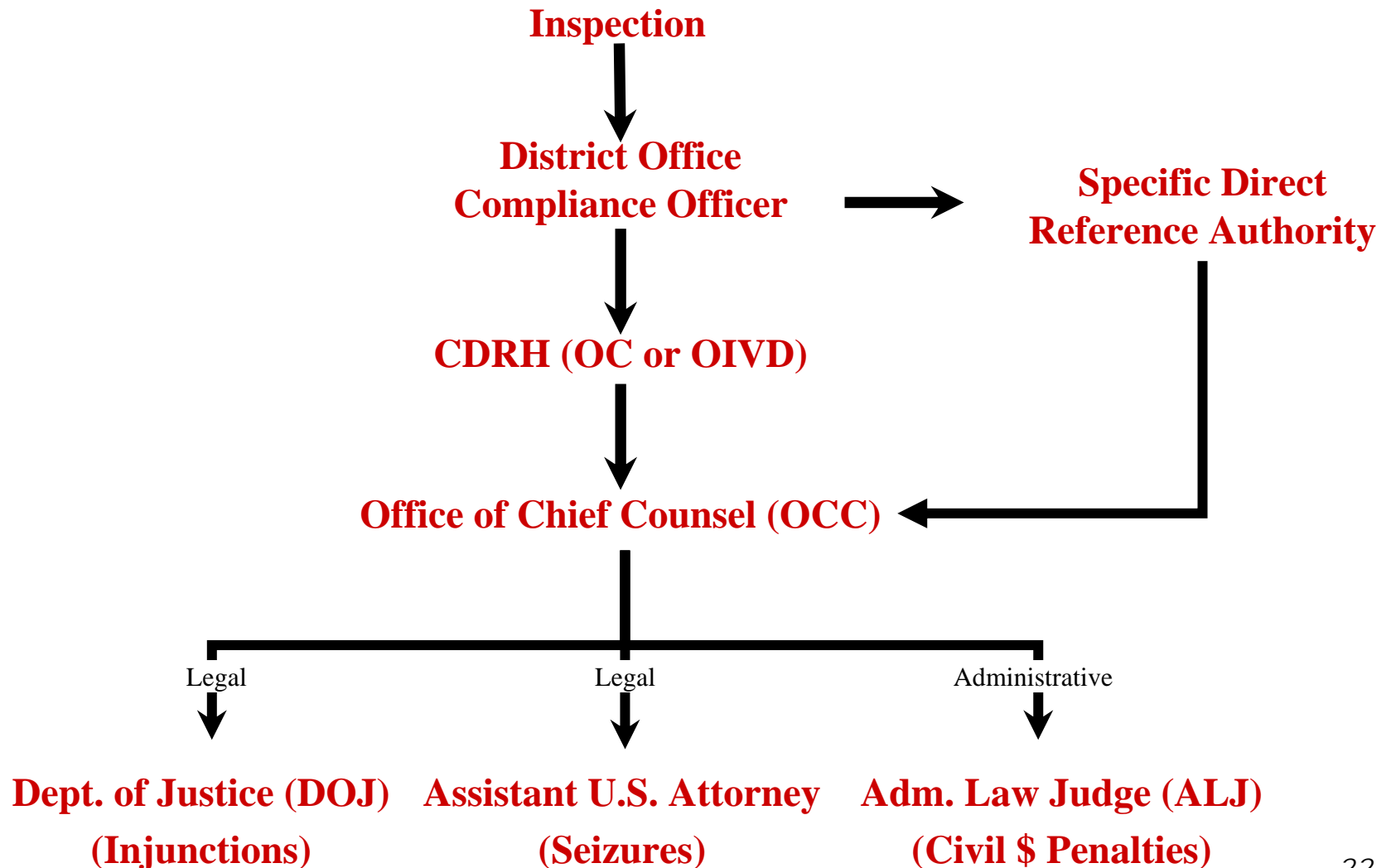
(Continued)

## **TITLE 18 PROSECUTION** (Typically Referred to OCI)

- False statements to the Government
  - Felony



# Case Action Flow



# Questions?

