FDA Import Compliance Operations

Import Authority

- **Federal Food, Drug, & Cosmetic Act**
  Section 801 - "Administrative" procedure
  -Section 801(a) Detention/Refusal
  - Section 801(d)(1) PDMA
  - Section 801(d)(3) Import for Export
  - Section 801(m) BT provisions

- **MOU with U.S. Customs**

Burden of Proof for Imports

- Defined in FD&C Act in 801(a)

…if the article “appears” by “examination or otherwise” …to be violative…it “shall” be subject to refusal…

Compare and Contrast

How we regulate imports and domestics is different.

- Domestic- Inspectional authority §704
- Imports- “Appears” to be violative §801

Import vs. Domestic

	IMPORT	DOMESTIC
Control of Lot	• Detention/Refusal • "Appears"	• Seizure • "Preponderance of evidence"
Control of I.S. Shipment	• IA/DWPE • "Appears"	• Injunction • "Preponderance of evidence"
Criminal Charges	• Responsible Individual • "Beyond a reasonable doubt"	• Responsible Individual • "Beyond a reasonable doubt"

Compliance Operations

- Release
- Detention
- Refusal

Release

- Straight release
- Release with comment
- Release - Import for Export

Import for Export

- FD&C Act Section 801(d) – BT Act changed this section
- Additional requirements for Import for Export
  - Component of food, drug, dietary supplement, color additive, food additive, device, etc…
  - Intended for further manufacturing and re-export (warehouse/storage does not qualify for exemption)

Import for Export-Prior to Release

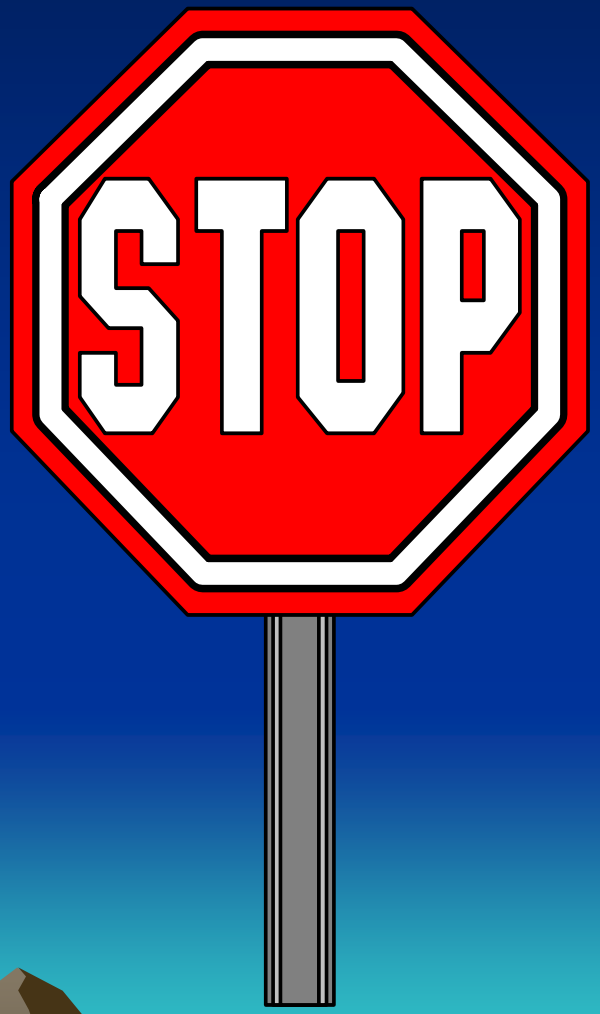
- Covered by CBP Temporary Importation Bond (TIB)
- Importer submits statement indicating further processed & chain of possession
- Provide Certificate of Analysis (drugs)

Import for Export – Release

- Firm must maintain records regarding manufacturing, export, etc.
- Follow up verification conducted during routine inspectional operations at responsible US establishment
- No time limit

Detention

- Written Notice of Detention and Hearing citing specific charge(s)
- 10 day response time (may be extended if requested)



Detention

- Based on
  - Violative label exam
  - Violative field exam
  - Violative lab results
  - DWPE
  - Lack of required documentation

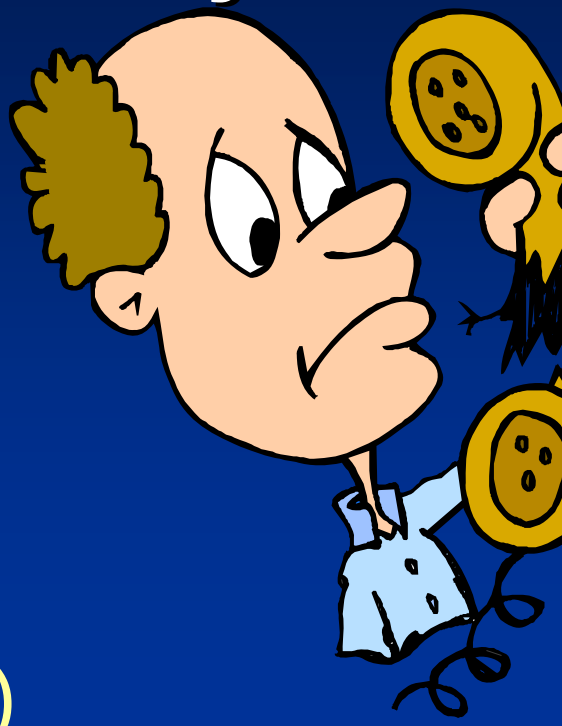
Importer's Options

- 10 day response time
  - Contest
    - Testimony/evidence to overcome the appearance of violation (evidence of registration, etc..)
    - Private lab analysis (subject to FDA review/audit)
  - Request authorization to recondition (submit Form FDA 766)
    - Supervision
    - Payment

Importer's Options

- Request refusal
- Does NOT respond (abandons entry). Results in Automatic refusal of admission

FDA Refusal of Admission
CBP Demand for Redelivery



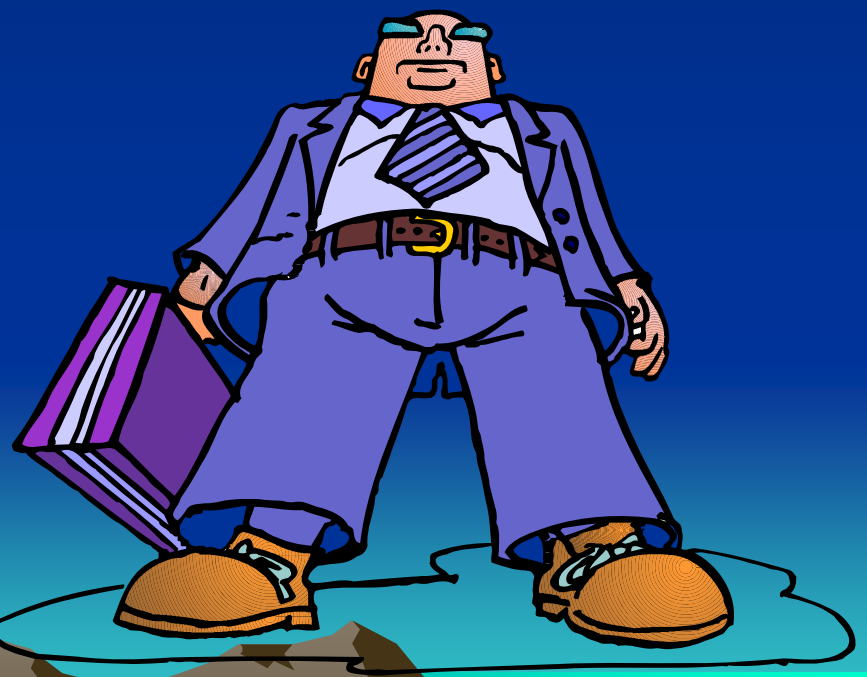
- FDA issues Notice of Refusal/ CBP issues Demand
- Redeliver to Customs custody-FDA may verify

Importer's options

- Destruction (Customs Form 3499)
- Exportation (Customs Form 7512)

Enforcement Actions

- FDA Detention/Refusal
- Place foreign manufacturer/ shipper/ product on DWPE
- FDA Initiated Recall
- Seizure (304)
- Injunction
- Prosecution



CBP Actions initiated at FDA request

- Bond Actions (i.e. liquidated damages)
  - Triple damages (3 x invoice value)
  - Domestic value
- CBP Seizure (contrary to law)
- Civil Money Penalty
- Cargo restrictions – withdrawal of cargo release privileges
- Penalty (i.e. suspension or revocation of filer's license; fines)

Criminal Activity

- Smuggling of violative FDA regulated articles
- False declaration
- Substitution
- False 3499/7512 (export/destruction)
- Re-importation of previously refused goods

Questions?