



**Food & Agriculture  
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**Import Process  
Prior Notice  
and  
Import Alerts**

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**FDA**

U.S. Department of Health and Human Services

**Food and Drug Administration**



# Overview of Presentation



- FDA Import Law
- FDA Importation Process
- Prior Notice
- Import Alerts



# FDA IMPORT LAW



- Covered by the FFD&CA section 801
- Allows for refusal of imported FDA-regulated products for appearing to be adulterated or misbranded based on evidence



## FDA Import Law 801(a) says:



- “If it appears from the examination of such samples *or otherwise* that...”
  - (1) such article has been manufactured, processed, or packed under insanitary conditions... or



## FDA Import Law 801(a) says:



- “If it appears from the examination of such samples *or otherwise* that...”
  - (2) such article is forbidden or restricted in sale in the country in which it was produced ... or



## FDA Import Law 801(a) says:



- “If it appears from the examination of such samples *or otherwise* that...”
  - (3) such article is adulterated, misbranded, or in violation of section 505 (New Drugs)



## FDA Import Law 801(a) says:



- “If it appears from the examination of such samples *or otherwise* that...”
  - (1)
  - (2)
  - (3)
- “then such article shall be refused admission...”



## FDA Import Law



- “appears” – gives us our standard of proof
  - We can refuse entry to goods that:
    - Appear to be adulterated or misbranded
    - Appear to be unapproved new drugs
    - Appear to have been manufactured not in accordance with GMPs



## FDA Import Law



“or otherwise” – allows us to make admissibility decisions using:

- Historical data
- Examinations (vs. sample collections)
- Information from other sources
- Other evidence



# FDA Imports



- ☞ There are approximately 320 ports of entry in the United States
  - ✓ Most ports have FDA personnel present
- ✓ FDA works with Customs & Border Protection (CBP)
  - ☞ CBP has the ultimate responsibility for protecting the borders
  - ☞ Responsible for collecting tariffs, duties, terrorism, facilitating trade, and enforcing other requirements of the Tariff Act
  - ☞ Controls the movement of goods offered for entry into the U.S.
  - ☞ Can seize products and issue fines under their own authorities
- ✓ Other U.S. regulatory agencies
  - ☞ A product is frequently regulated by multiple U.S. agencies
  - ☞ Each agency has different responsibilities and authorities
  - ☞ Actions may be conducted independently or jointly depending on the circumstances



# Prior Notice Final Rule



***Update on Status*** - Prior Notice of Imports [Sec 307- 801(m)]  
*Requires FDA to receive prior notice of all imported food shipments before entering the U.S.*

- Remains under DHHS/DHS Review
- Top Issues:
  - Requirement for providing of actual manufacturer and food facility registration numbers for foreign manufacturers
  - Submission timeframes, 2, 4, & 8 Hrs.





# NTC - Cargo



*Opened May 2007, the National Targeting Center for Cargo (NTC-C) is dedicated to National Cargo Targeting & includes the following components:*

- **CBP**
  - Cargo Targeters & Import Specialists
  - Laboratory and Scientific Services
  - Secure Freight Initiative
  - Container Security Initiative
  - Field Analysis Specialists/ATS Rule Targeters
  - Fraudulent Document Analysis Unit
- **FDA Prior Notice Center**
- **U.S. Dept of Agriculture**





## **PNC Mission/Activities**

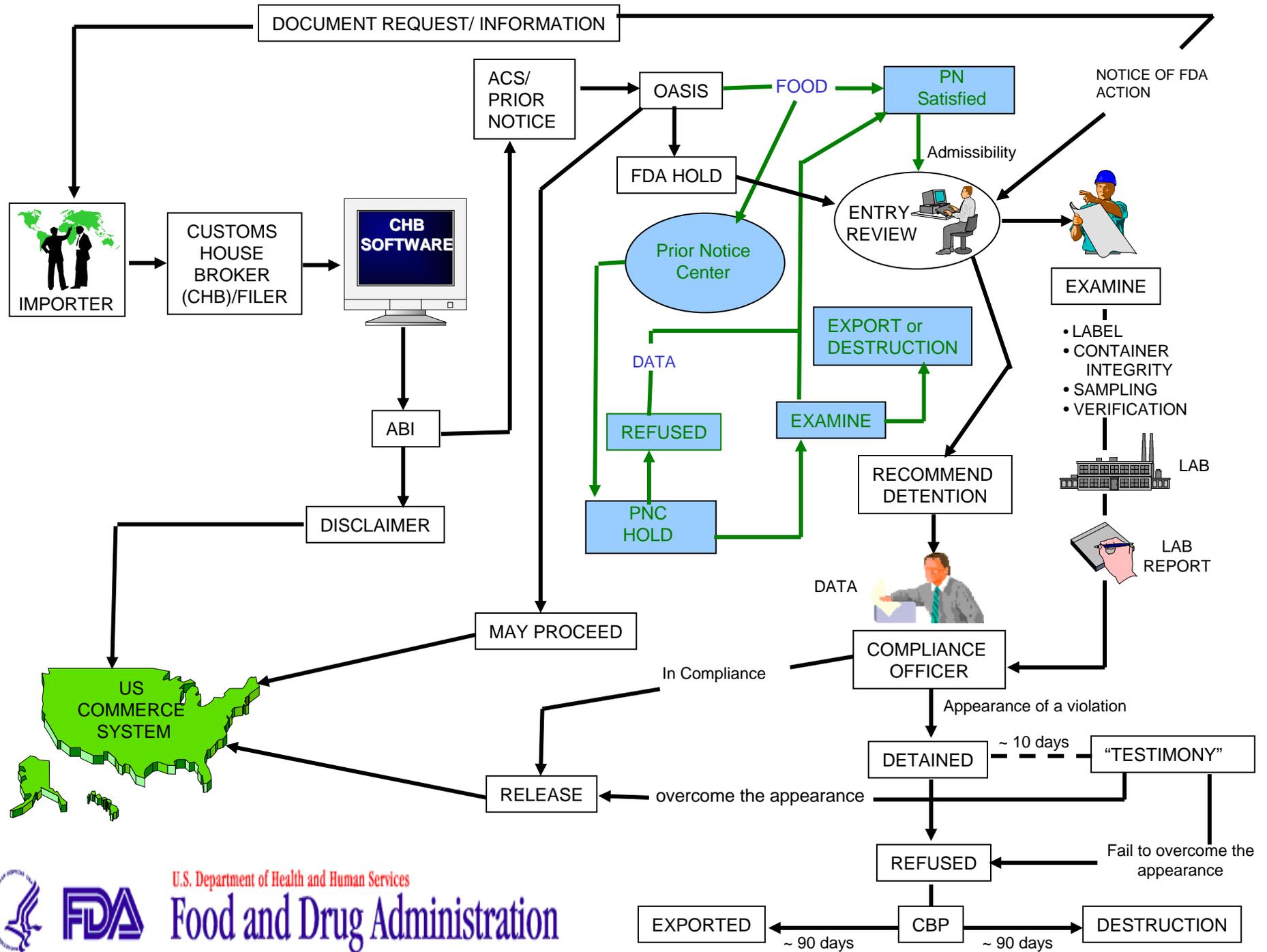


**Perform prior notice security reviews to hold food shipments deemed to pose a security risk to the U.S.**

**Refuse food shipments where prior notice is not submitted, is inaccurate, and/or is untimely.**

**Hold food shipments where foreign food facilities are not documented to be registered with FDA.**







# The Import Process



- ➔ An importer or a designated representative must file an entry notice and an entry bond with Customs pending a decision to allow the goods into the U.S.
- ➔ Notice must also be filed with FDA.
- ➔ FDA has trained individuals who review entry declarations and evaluate the admissibility of a product.
- ➔ Entry reviewers have several options:
  - ✓ Release the product
  - ✓ Request examination of the product
  - ✓ Request additional information or documents
  - ✓ Recommend detention of the product



# The Import Process



- ☞ If FDA allows the product to May Proceed
  - ✓ Product may be distributed
  - ✓ FDA still has jurisdiction
    - Import Status – Level of Proof only an “appearance”
    - vs.
    - Domestic Status – We need an actual violation
  - ✓ Does not preclude FDA action if a problem is found later



# The Import Process



☞ FDA can detain based upon “appearance” of a violation

✓ “Appearance” can come from:

- Facility Inspection
- Examinations
- Sampling
- Laboratory examination
- Historical Data
- Lack of required processes and/or approvals
- Other sources, eg. a disease outbreak involving an FDA regulated product
- Labeling
- Reports from other Governmental and State Agencies



# The Import Process



- ☞ Regardless of the nature of the detention:
  - ✓ Importer has the right to give evidence to refute the appearance of a violation
  - ✓ Based on the evidence, the detention will either stand (refusal) or be overturned (release)
  
- ☞ Importer can also petition to recondition the goods to bring them into compliance
  - ✓ Relabeling a misbranded product
  - ✓ Cleansing an adulterated product
  - ✓ Making a product not FDA regulated
  
- ☞ Reconditioning must be approved by FDA



# The Import Process



- ☞ If a product can not be brought into compliance, the product will be refused entry
- ☞ Refused product may be exported or destroyed
- ☞ A redelivery notice will be issued if products are not exported or destroyed
- ☞ FDA does have authority to seize product if certain criteria have been met



# Import Alert System:



1. It prevents potential violative products from being distributed into the United States
2. It frees up Agency resources to examine other shipments
3. Places the responsibility back on the importer
  - It is the responsibility of the importer to ensure that the products he is importing in the U.S. is in compliance with our laws and regs



# Import Alert System:



- ☞ **FDA Import Law on appearance” and “or otherwise”**
  - These form the basis for our Detention Without Physical Examination (DWPE)
  
- ☞ **Currently, 269 active Import Alerts**
  - [Http://WWW.FDA.GOV/ORA/RIARS/ORA\\_IMPORT\\_ALERTS.HTML](http://www.fda.gov/ora/riars/ora_import_alerts.html)
  
- ☞ **Import Alerts communicate information to the field:**
  - Field can detain goods without examining them
  - Field should examine or sample product
  - General Guidance about a product, firm, etc



# Import Alert System



## ☞ Violative history of:

- ✓ Commodities
- ✓ Manufacturers/shippers
- ✓ Growers
- ✓ Geographic area
- ✓ Countries of origin
- ✓ When warranted, Importers
- ✓ Or combinations of the above

## ☞ Adding a firm, product, or importer to DWPE:

- ✓ Based on evidence from our field offices
- ✓ Based on evidence from foreign inspections
- ✓ Other sources of information, e.g. foreign governments



# Import Alert System



- ☞ Removing a firm, product, or importer from DWPE:
  - ✓ Firms or importers may petition to be removed from DWPE
    - Industry submits the petition
    - FDA reviews the petition
  - ✓ Generally requires evidence of non-violative shipments but all depends on the Import alert
    - Firms with GMP violations may need an inspection to get off an IA
    - Analyzed by laboratory at importer expense
    - Documentation showing it isn't subject to the Alert
  - ✓ FDA needs assurance the cause of the violation has been corrected



**Thank you**

**Questions?**



**FDA**

U.S. Department of Health and Human Services

**Food and Drug Administration**