U.S. Food and Drug Administration
Office of International Programs

Border Control & Food Imports

Christopher J. Hickey, PhD
FDA Country Director
Beijing, PRC

FDA and Food/Feed Safety

Office of Foods

- Center for Food Safety and Applied Nutrition (CFSAN)
  - works to assure that the food supply is safe, sanitary, wholesome, and honestly labeled
- Center for Veterinary Medicine (CVM)
  - regulates the manufacture and distribution of food additives and drugs that will be given to animals

Office of Regulatory Affairs (ORA)

- Inspection and compliance

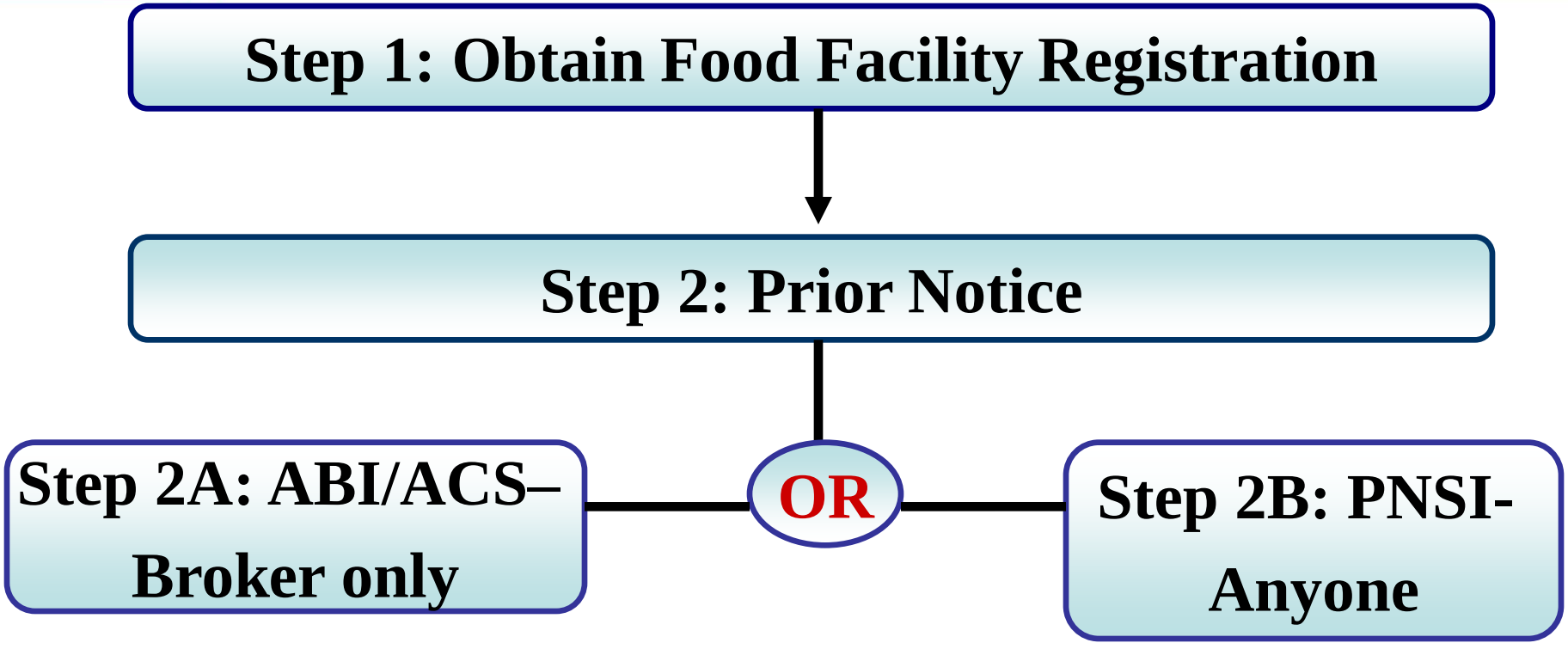
Step 1: Submit Food Facility Registration

Domestic and foreign facilities engaged in manufacturing, processing, packing, or holding food (subject to FDA's jurisdiction) for human or animal consumption in the U.S. must be registered. Food shipments from manufacturers who are not registered can be held at the port of entry until firm becomes registered.

- *NOTE: The requirement applies to each firm's location, not to firms or companies as a whole (site specific).*

Identify a U.S. Agent

- Foreign facilities are required to have a U.S. agent
  - can be any person that resides or maintains a place of business in the U.S. and is physically present in the U.S.
  - The U.S. agent acts as a communications link for both routine and emergency communications
  - FDA will contact a foreign facility's U.S. agent if an emergency occurs, unless the facility opts to designate a different emergency contact


Step 1: Obtain Food Facility Registration
Step 2: Prior Notice
Step 2A: ABI/ACS– Broker only
OR
Step 2B: PNSI- Anyone

Prior Notice of Imported Food

Prior Notice –Initial FDA Import Food Defense Review

Prior Notification must be submitted and confirmed electronically via:

- CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) (licensed brokers only),

  Or

- FDA's Prior Notice System Interface (PNSI) at http://www.access.fda.gov (anyone can use)

When Is Prior Notice Due?

Maximum Timeframe

- No more than 30 days before arrival if submitted via CBP's ABI/ACS (Automated Broker Interface of the Automated Commercial System)

Or

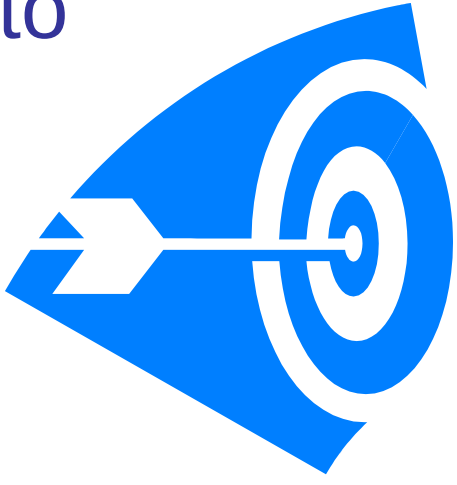
- No more than 15 days before arrival, if submitted via FDA's PNSI (Prior Notice System Interface)

Minimum timeframes, as specified by the mode of transportation, are no fewer than:

- 2 hours by land
- 4 hours by air or by rail
- 8 hours by sea

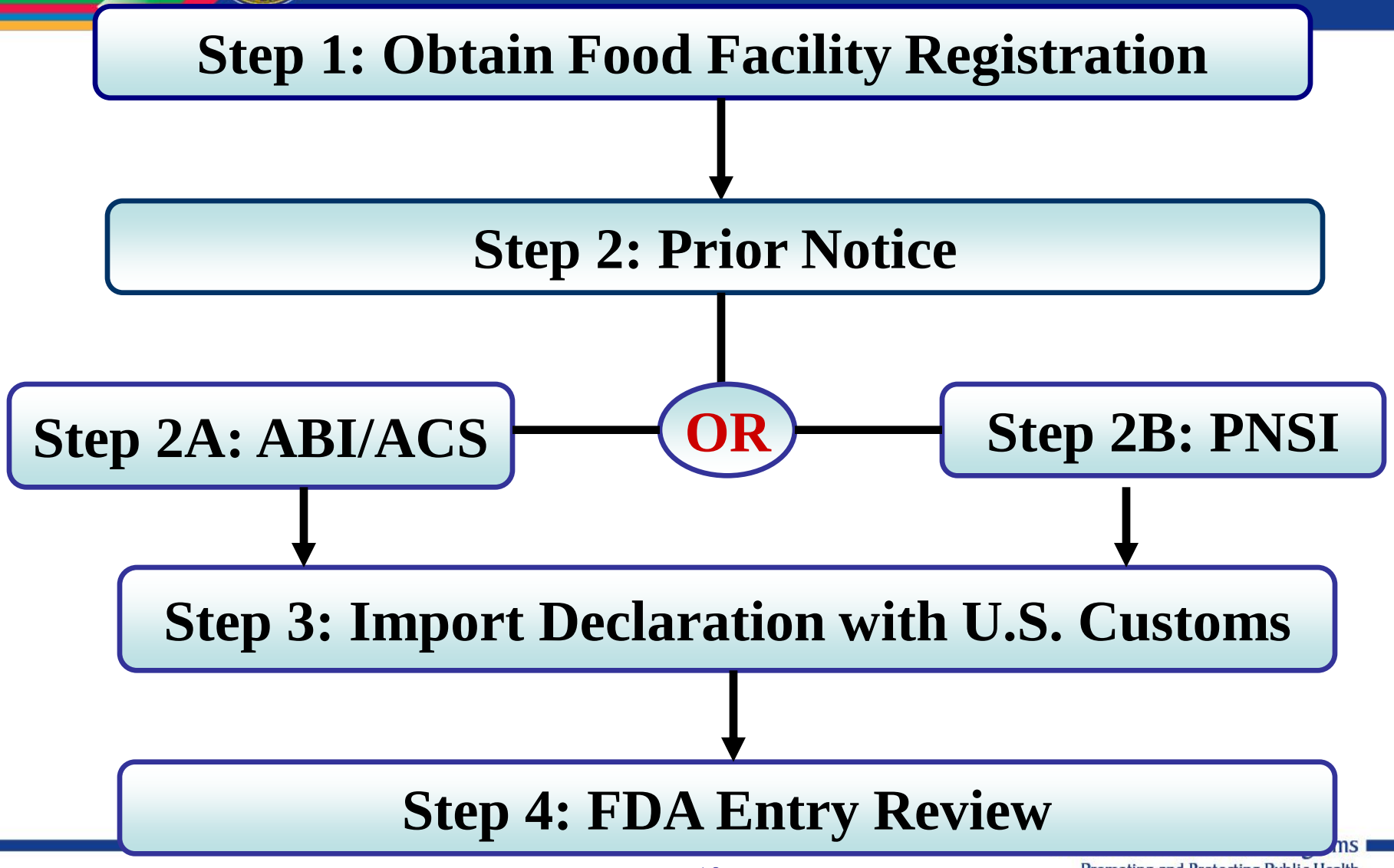
10,000,000 lines of food and feed offered for import every year in the U.S.

- How do we decide which to sample/examine/refuse?



Prior Notice Screening & Review

- Prior Notice can be electronically screened.
- Reviewers at the Division of Food Defense Targeting office personally examine Prior Notice submissions for shipments that are identified as highest risk for intentional contamination.
- After Prior Notice electronic or manual screening is satisfied, entry is reviewed for admissibility.

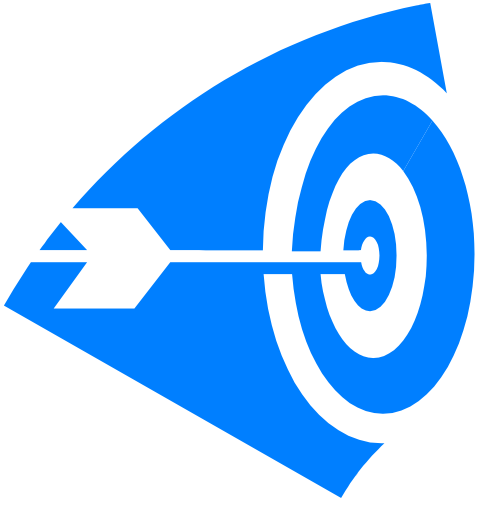

Step 1: Obtain Food Facility Registration
Step 2: Prior Notice
Step 2A: ABI/ACS
OR
Step 2B: PNSI
Step 3: Import Declaration with U.S. Customs
Step 4: FDA Entry Review

What Happens at the Port?

- CBP notifies FDA of shipments
- FDA reviewers have several options:
  - Release the product
  - Request examination of the product
  - Request additional information or documents
  - Recommend detention of the product
- CBP will release shipment only upon written notification by FDA

Admissibility screening & review

PREDICT



PREDICT

Purpose: Improve import screening and targeting to

- ✓ Prevent the entry of adulterated, misbranded, or otherwise violative goods
- ✓ Expedite the entry of non-violative goods

Method: Replace the admissibility screening portion of FDA's legacy electronic system for processing import entries.

PREDICT

- Use automated data mining and pattern discovery
- Utilize open-source intelligence
- Provide automated queries of Center databases where relevant (i.e., registration and listing, marketing approval status, low-acid canned food scheduled processes, etc.)

Examples of source data for PREDICT screening rules

- Results of field exams and sample analyses of previous entries
- Results of facility inspections (foreign and domestic)
- Ratings of inherent product risks
- Accuracy of product and facility coding by entry filers and importers
- Data anomalies within the current entry
- Admissibility history with respect to the firms associated with the imported product
- Open source intelligence pertaining to manufacturer(s), foreign locale(s), product(s), etc. that may pose potential health risks

What can you do?

- The quality of the data your broker or filer submits to FDA will count more than ever.
- You should work closely with the importer and filer to ensure data quality.
- Poor data quality or missing data will increase the targeting scores for your subsequent entry lines (importers and filers).
- Higher risk scores increase the likelihood of physical examination by FDA.

Import Regulatory Process

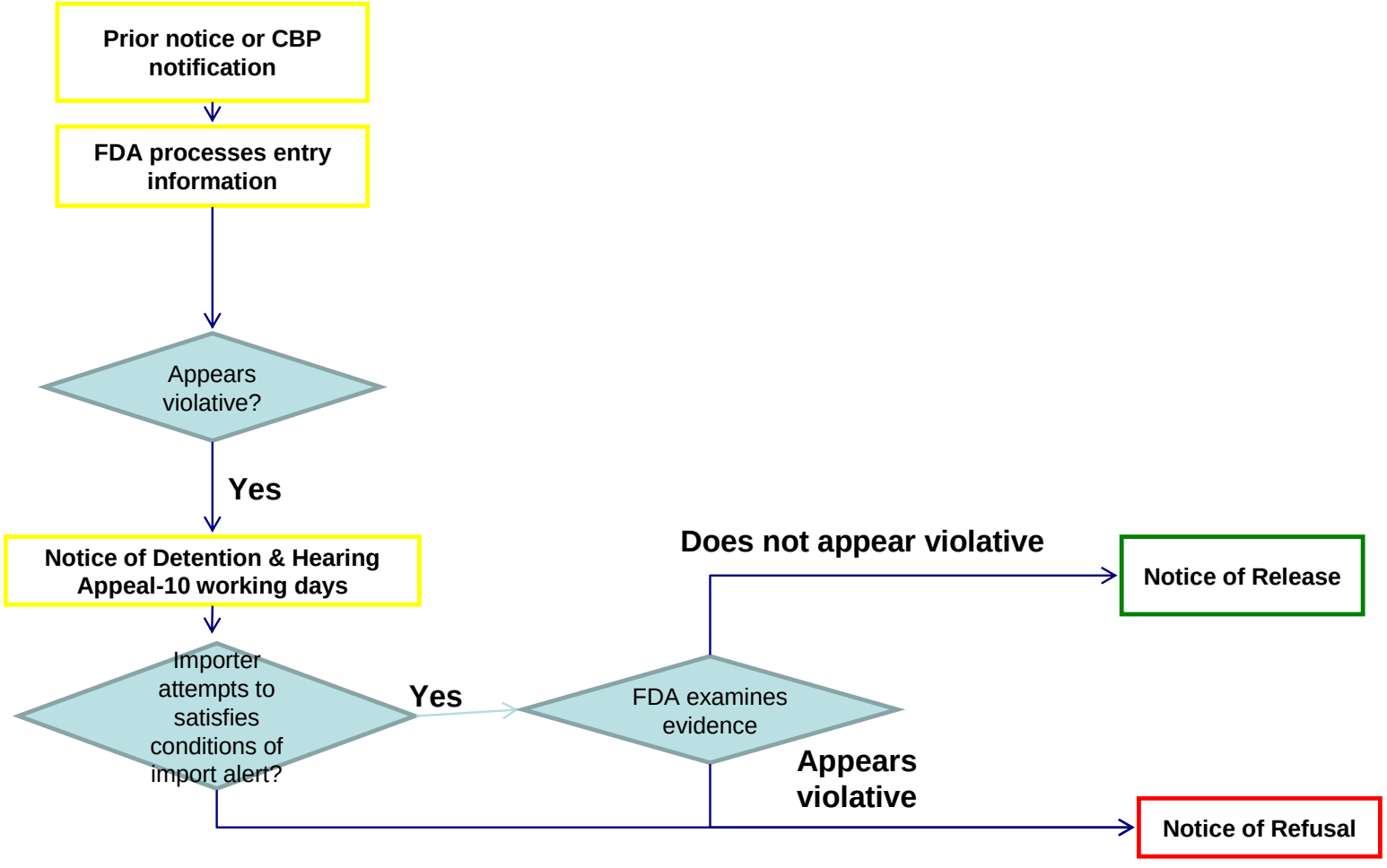
Product stopped and sampled

Product found in compliance - **shipment released**

Product out of compliance - **entry denied (refusal)**

- Reconditioning (bringing into compliance) may be considered under special circumstances
- Destruction or
- Re-export

Refusal and Import Alert



Types of Detention

DETENTION OF AN INDIVIDUAL ENTRY

Stopping a shipment of an individual entry (due to a sample collection or physical examination)

DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE) – Import Alerts

Stopping a shipment without collection of a physical examination by FDA

Detention of Individual Entry-Import Refusal

FDA can detain based upon "appearance" of a violation

"**Appearance**" can come from:

- Initial examinations of entry
- Sampling and laboratory analysis
- Historical data
- Facility Inspection
- Lack of required processes and/or approvals
- Other sources, e.g.. a disease outbreak involving an FDA regulated product
- Labeling
- Reports from verifiable sources e.g. other governmental and state agencies
- Import Refusals reported monthly @http://www.accessdata.fda.gov/scripts/importrefusals/
  - 25 Import Refusals for Taiwan in Sept 2012 (all product types)

Import Alert
Detention Without Physical Examination

Stopping a shipment without collection a physical evidence…

Recommendation based on:

- one violative sample
- establishment inspection
- information and historical data of non-compliance of individual processors, countries or geographical area
- active Import Alerts issued covering one or more firms or country or region
- Approximately 270 Active Import Alerts @ http://www.accessdata.fda.gov/cms_ia/countrylist.html
  - 45 Import Alerts for Taiwan (all product types)

Individual shipment release

Responsibility of importer to prove the product is in compliance

- Individual shipments may be released if:

- Each shipment is sampled and analyzed
- Analysis performed by a competent private laboratory in the US
- FDA reviews the lab results
- FDA may require additional documentation e.g. copies of current HACCP plans and monitoring records for those entries (in English)

DWPE Removal Requirements

Firm or importer (U.S. agent) **submits a petition for removal**

May be considered based on evidences that

- the violative practices or conditions have been fully corrected and
- future entries will be in compliance with the US law

FDA **needs assurance** that firms are compliant over a reasonable period

DWPE Removal Requirements

For specific product from individual manufacturer:

- At least five (5) consecutive non-violative shipments in a maximum six (6) month period (can be multiple ports)

For specific product from country or a specific geographic area:

- At least twelve (12) consecutive non-violative shipments in a maximum six (6) month period
- Shipments should include a representative number of manufacturers/shippers from the geographic area or country

For multiple products from specific manufacturer:

- At least twelve (12) consecutive shipments representing the range of products non-violative in a maximum six (6) month period

DWPE Removal Requirements

- At least one shipment audited by FDA to ensure analytical validity
- Shipments are individual, routine, commercial entries and represent separate production operations
- FDA may request additional documentation to ensure compliance with other provisions of U.S. laws and regulations (e.g. HACCP plan, monitoring, verification records)
- FDA may require an establishment inspection

What if a Non-compliant Food Passes Through the Import Screening?

- If imported product is found to be out of compliance after entry into the U.S. commerce, FDA can exercise normal domestic enforcement options
  - Seizure
  - Recall, usually by importer
- Future shipments will be more closely monitored and may require evidence that are in compliance

Informational Sources

Main web site for FDA – www.fda.gov

Importing food products into the U.S. -
www.fda.gov/Food/InternationalActivities/Imports/default.htm

Registration of Food Facilities –
www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm

Electronic Facility Registration at – www.access.fda.gov

Prior Notice of Imported Food -
www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/PriorNoticeofImportedFoods/default.htm

Import Refusal
http://www.accessdata.fda.gov/scripts/ImportRefusals/ir_index.cfm

Import Alerts
http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm