

Public Health Security and  
Bioterrorism Preparedness and  
Response Act of 2002  
(Bioterrorism Act-BTA)  
Public Law 107-188



U.S. Customs and  
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# Presentation Outline

- Overview
- Registration
- Prior Notice (PN)
- Submitting PN
- CBP Processing
- Resources



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# Bioterrorism Act (BTA)

## Purpose

To ensure the security of food for human or animal consumption imported or offered for import in the United States



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# BTA Key Dates

06/12/02	Signed by President
02/03/03	Notice of Proposed Rule Making (NPRM) issued (PN and Registration)
04/04/03	Comment period ends
05/09/03	NPRM (Detention and Recordkeeping)
07/08/03	Comment period ends
10/10/03	Final Interim PN and Registration Rule
10/16/03	FDA web portal available for registration
12/12/03	BTA implementation



# BTA Key Sections

Act contains

- 5 Titles

FDA Responsibilities:

- Title III
  - ◆ Subtitle A (Safety of Food)
    - Section 303 Detention
    - Section 305 **Registration**
    - Section 306 Records Management
    - Section 307 **Prior Notice**
  - ◆ Subtitle B (Drug Supply)



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and Response Act of 2002

# Changes in Interim Final Rule

There have been significant changes from the proposed regulations published in the Federal Register in February.

- Regulations on the disposition of shipments that fail to meet the requirements of the BTA have been modified
  - Language has changed from “shall be refused admission” to “may be subject to refusal of admission”



# Changes in Interim Final Rule (continued)

- The regulations will be published as an Interim Final Rule
  - Once the Interim Rule is published there will be a 75 day comment period
- Scope of the Act has been narrowed
- Time frames for PN have been shortened (separate slide)



# Changes in Interim Final Rule

(continued)

- ACS/ABI can be used for the submission of PN
- Flexibility as to who can submit PN
- Reduction in data elements required for PN
- Several more exclusions from PN requirements, including IEs
- Procedures outlined for shipments with no or inadequate PN submission



# Changes in Final Rule (continued)

- International mail: Homemade goods are excluded
- Secure facility is detailed
- Phase-In of requirements

Another major change in implementation is the commissioning of CBP officers to act on FDA's behalf to enforce BTA regulations



# BTA Scope

## How Is Food Defined?

- Covered under Title III, Subtitle A (Safety of Food)
- Food is defined in the BTA Interim Final Regulations as:
  - ◆ (1) articles used for food or drink for man or animals
  - ◆ (2) chewing gum, and
  - ◆ (3) articles used for components or any such article.
- Food imported or offered for import into the U.S. for human or animal consumption



# BTA Scope (continued)

## Extent of Food Coverage

- Approximately 2,000 HTS numbers
- 16% of all imports into the U.S. are food and animal feed as covered by the BTA



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# BTA Inclusions

## What Food Is Covered?

- All food as defined by FDA, “being imported or offered for import into the United States.”
- Food stored or distributed in the U.S.
- Gifts, trade, and quality assurance/control samples
- Transshipments through U.S. to another country
- Food imported for future export
- Food admitted into a U.S. Foreign Trade Zone (FTZ)



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# Registration



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# BTA Registration

## Who Must Register?

- Domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. are required to register with FDA.
  - ◆ Includes, but is not limited to, secure facilities e.g., G.O. warehouses and carrier facilities who perform these functions



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# BTA Registration Exemptions

## Which Facilities Are Excluded from Registering?

- Nonprofit facilities
- Retailers
- Farms
- Restaurants
- Fishing vessels, except those that engage in processing as defined in FDA's seafood HACCP regulations (21 CFR 123.3(k))
- Facilities subject to the exclusive jurisdiction of the U.S. Department of Agriculture



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# Registration Information

Registration is one-time process and must be done using Form 3537.

- Information required on the form includes:
  - Name and address of facility
  - Parent company name (if applicable)
  - Emergency contact information
  - Trade names
  - U.S. Agent
  - General product categories



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# Registration Information (continued)

- Form may be downloaded from the Bioterrorism Act page at [www.FDA.gov](http://www.FDA.gov)

## Registration Help:

- Tutorial registration available at [www.FDA.gov/furls](http://www.FDA.gov/furls)
- Toll-free number in U.S. is 1-800-216-7331



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# Registration Information (continued)

- Outside the U.S., the number is 301-575-0156 (not toll-free)
- Questions may be faxed to 301-210-0247 (not toll-free)
- Starting 10/16/03 these numbers will be staffed from 7 AM to 11 PM U.S. Eastern Time



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# Registration Information (continued)

- Changes to a facility's registration information must be reported to the FDA within 60 days of the change
- FDA can be notified through the same means as initial registration was done (see next graphic)



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# BTA Registration

## How To Register

- Registration may be via:
  - ◆ FDA web portal E-mail address: [www.FDA.gov/FURLS](http://www.FDA.gov/FURLS)
  - ◆ Submitting paper copy of Form 3537 or CD-ROM to:
    - Mailing address: (see [www.FDA.gov](http://www.FDA.gov))
    - Fax Number: 1-877-FDA-3882



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# BTA Registration

## Registration Deadlines

- Domestic and foreign firms that manufacture, process, pack, or hold articles or food for human or animal consumption may begin registration on October 16, 2003
- As of December 12, 2003, must be registered prior to importation



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# U.S Agent

Any facility that registers with the FDA must appoint a U.S. agent who resides and maintains a place of business in the U.S. and be physically present in the U.S.

The agent will act as the emergency contact for the FDA



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# Prior Notice



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# Prior Notice (PN): Overview

## Why Is PN Required on Importation of Food?

- Intent is to provide FDA with advance information to target potentially high risk shipments that could threaten Public Health and the Security of the food chain by an act of Bioterrorism



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# BTA Exemptions-Prior Notice

## What Food Commodities Are Excluded?

- Personal use food accompanying a traveler
- Food immediately exported (IE) (without leaving the port of arrival)
- Meat, poultry, and egg products (subject to USDA)
- Homemade goods shipped by international mail



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# Prior Notice (PN): Overview (continued)

## Who Submits a PN?

- Any person with knowledge of the required information may submit PN or have it transmitted on their behalf
  - ◆ *Submitter:* Person submitting PN
  - ◆ *Transmitter:* Individual filer submitting PN on behalf of submitter



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# Prior Notice (PN): Overview (continued)

## What Information is Provided in the PN (Data Elements)

- **Article Identity**

- ◆ FDA product code, common name, trade or brand name, quantity, lot/code identifier

- **Manufacturer, Shipper, All Growers** (if known, currently provided as manufacturer)

- ◆ Firm name and address, e-mail address, telephone and fax numbers, registration number



# Prior Notice (PN): Overview (continued)

## What Information is Provided in the PN (Data Elements)

- The country from which the article originates
- The country from which the article is shipped
- Anticipated Customs' port of arrival
  - ◆ Date and time of arrival
- Customs ACS entry type and date
- In the event of a hold, the information about where it is being held



# Prior Notice (PN): Overview (continued)

## What Information is Provided in the PN (Data Elements)

### ▪ **Submitter, Importer, Owner, Consignee**

- ◆ Individual (for submitter)
  - Information for submitter is currently provided by the filer as broker identity
- ◆ Firm name and address
- ◆ E-mail address
- ◆ Telephone and Fax numbers
- ◆ Registration number



# Prior Notice (PN): Overview (continued)

## What Information is Provided in the PN (Data Elements)

### ▪ **All carriers**

- ◆ Firm name and address
- ◆ E-mail address
- ◆ Telephone and Fax numbers
- ◆ Registration number
- ◆ Standard carrier abbreviation code



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# Prior Notice (PN): Overview (continued)

## When is a PN Required?

- A PN is required for:
  - ◆ Merchandise covered under the BTA and imported or offered for import into the U.S. [801(m) ]
  - ◆ Every entry item that has a separate FDA product code



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# Prior Notice (PN): Overview (continued)

## Failure to Register/Provide PN

- FDA can bring civil and criminal action against a party that is not registered
- FDA can bring about debarment (prohibits further trade activity) of any person convicted of a felony violation of the BTA
- Merchandise can be:
  - ◆ Held at Port
  - ◆ Sent to a Secure Facility
  - ◆ Returned to Country of Export
- CBP can Issue Penalties



# Prior Notice (PN): Overview (continued)

## Inadequate PN

“No, Inadequate, or Untimely Notice...”

- Article may be subject to refusal and, unless immediately exported with CBP concurrence, may be held within the port of arrival or removed to a secure facility

Article can not go to the importer, owner or consignees premises.



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# Prior Notice (PN): Overview (continued)

Amendments to PN

No substantial amendments.

Filer must cancel PN and cancel/delete entry.

New PN must be filed.



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# PN Timeframes

## Timeframes for Submitting PN

Land Border *2 hours prior to arrival at U.S. port*

- Trucks, all vehicles, pedestrians

Rail *4 hours prior to arrival at U.S. port*

Air *4 hours prior to arrival in the U.S.*

Vessel *8 hours prior to arrival at U.S. port*

International Mail *At time of mailing*



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# Commissioning CBP Officers

- Memorandum of Understanding (MOU) between FDA and CBP
- Perform FDA BTA 801(m) work at locations with limited or no FDA presence
- Receive training in FDA examination, sampling, and document review prior to December 12, 2003
- FDA to provide 24x7 hotline 800-number to assist CBP officers



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# Submitting PNs

## How PNs Are Submitted

- Via ABI/ACS
- Via FDA web portal
- Via e-mail (when web portal is unavailable)
- Via fax (when web portal is unavailable)



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# Submitting PN

## ACS/ABI/OASIS Changes

- PN submission will be done using several new or enhanced components of FDA's and CBP's existing electronic systems
  - ◆ CBP's ACS to FDA's OASIS system will be enhanced to support PN
  - ◆ ABI software changes will be required to support PN information
  - ◆ New ABI/ACS/OASIS interface, modeled after existing process, will be available to submit PN for entering the U.S. as automated in-bond or FTZ entry



# Submitting PN via ABI / ACS (Entry)

## How to Submit PN

- PN supplied along with ABI entry data
- 80% of BTA entries processed via ABI/ACS
- FDA provides PN confirmation number electronically to CBP and CBP advises filer
- PN results matched to the ABI entry and electronically provided to CBP officers



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# Submitting PN via ACS (No Entry): “ACS 2-Step”

- Known as 2 step process
  - Electronic transmission through ACS—no consumption entry information.
  - Required information:
    - ◆ In-bond number
    - ◆ Complete AWB/Master Airway Bill
    - ◆ Bill of Lading number
  - Working on a Wanding Bar Code on FDA PN Form



# BTA Entries Not Processed Via ABI/ACS

- Any transaction involving a BTA regulated article can be input through FDA web portal
- Non-automated and/or paper entries
  - ◆ Mail
  - ◆ FTZ admissions
- In-bonds unable to be filed through ACS/ABI 2-step process



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# Submitting PN via Web Portal

## How to Submit PN

- Filer submits PN request via the FDA web portal and receives PN confirmation number which filer then adds to paper entry submissions
- Inspectors may need to query new database file for PN results
- A paper copy of the PN will be required for release, if requested by CBP

FDA Web Portal ([www.access.FDA.gov](http://www.access.FDA.gov))



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# Submitting PNs: Alternative Methods

## How to Submit PN When FDA Web Portal Is Unavailable

- Use the alternative methods listed below to submit PN:
  - ◆ E-mail address: TBD [www.access.fda.gov](http://www.access.fda.gov)
  - ◆ Fax number: TBD (see [www.fda.gov](http://www.fda.gov))



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# FDA Process – 801(a) & 801 (m)

## PN and the FDA Interface: Overview

- 801(a) (Normal FDA Process)
  - ◆ Required by the full range of FDA related laws and regulations covering foods, drugs, medical devices, and cosmetics
  - ◆ Not a new requirement
  - ◆ Continues normal CBP/FDA processing
  
- 801(m): (BTA Requirement)
  - ◆ Required by BTA of 2002
  - ◆ A new requirement that focuses on anti-terrorism
  - ◆ Focus for CBP purposes is on Prior Notice (PN)
  - ◆ If PN requirement not satisfied, will result in refusal of admission



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# FDA Process: 801 (a): Normal FDA Procedures

- BTA requirements do not eliminate general FDA non-bioterrorism responsibilities under 801(a)
- 801(a) applies to all FDA regulated commodities (except radiation emitting electronic products) including foods, drugs, medical devices, and cosmetics



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# FDA Process: 801 (a): Normal FDA Procedures (continued)

- Calls for refusal of admission to any covered product which (or which appears to)
  - ◆ Contain any unsafe ingredient
  - ◆ Has been manufactured under unsanitary conditions
  - ◆ Lacks necessary pre-approval for sale in the U.S. (mainly drugs/medical devices)



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# FDA Process: 801 (a): Normal FDA Procedures (continued)

- Requires that refused product be reconditioned or destroyed unless exported within 90 days of refusal
- Allows product to be delivered (under bond) to the owner or consignee pending an admissibility decision by FDA



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# FDA Process: 801 (m): BTA Procedures

## Effect of BTA Requirements

- Added to Food, Drug, and Cosmetic Act as part of the BTA 2002
- Covers only “articles of food” as defined by the BTA
- Calls for refusal of admission for any covered article for which adequate notice of importation (PN) has not been supplied to FDA prior to the “arrival” of the article



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# FDA Process: 801 (m): BTA Procedures (continued)

## Effect of BTA Requirements

- Requires that any covered article for which PN has not been satisfied be held at the port of arrival or sent to a secure facility. The regulations will also allow the shipment to be returned to the country of export
- Prohibits delivery to the importer, owner, or consignee until satisfactory PN has been supplied to the FDA



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# Merchandise with Inadequate or No PN is Subject to Refusal

At the Port Director's discretion in consultation with FDA, based on availability of storage and resources merchandise subject to refusal may be:

- Held at the port
  - ◆ For seaports, airports, and courier hubs, the terminal facility of the arriving carrier is considered to be within the port of arrival
- Directed to secure facility. Must be done under bond
- Exported



# Status of Merchandise with No PN or Inadequate PN

- Legal status is G.O. merchandise
- If carrier has a terminal facility, it will be held in “constructive G.O.” at the terminal facility until final disposition (entry, export, sale, or destruction)
- If no terminal facility available, Port Director will send it to nearest G.O. warehouse or suitable facility, which may be inside or outside the port limits



# Procedures for Merchandise Retained at Port of Arrival

- Is held under “constructive G.O.”
- The Port Director will make an operational decision if and when a G.O. number should be assigned to the shipment



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# Procedures for Movement of Goods to a Facility Not Within the Port of Arrival

## Documentation Required

- Requires the appropriate CBP control documentation
  - ◆ CBP 6043 – Permit to Transfer – for movements within CBP limits
  - ◆ CBP 7512 “Restricted in-bond” for movements outside of port entities
  - ◆ No documents needed for movement of merchandise to terminal facility of carrier within the port of arrival



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# Procedures for Merchandise Held in Secure Facility

- Merchandise held under G.O. procedures for each port
- Perishable shipments, or where no suitable G.O. facility exists, will be held under “constructive G.O.” or directed by the Port Director to a suitable facility; will be destroyed or sold after 3-days’ public notice
- Carrier will assume cost of destruction. Storage costs are between carrier and importer



# Secure Facility Definition

## What Is a Secure Facility?

- A bonded facility designated by the CBP Port Director (may include G.O. warehouses or other suitable facilities)
- Facilities must be registered with the FDA
- Facilities outside the immediate vicinity of the port, suitable for the storage of food
- May not be the importer's facility
- (Merchandise) may be sent to a suitable facility in another port if no other options exist



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# Procedures for Merchandise Held in Secure Facility (continued)

## What Happens to Merchandise

- Merchandise under “constructive G.O.” will stay at the carrier’s facility until final disposition of the merchandise
- If eventually sold, it will be for:
  - ◆ Export only (PN not required) and shipped directly (Immediate Export) out of the port in which it is being held



# Registration of Facilities with FDA

## Which Facilities Must Register?

- All facilities that hold merchandise subject to the BTA must be registered with the FDA
  - ◆ This includes:
    - Terminal facilities
    - Container freight stations (CFS)
    - Bonded warehouses
    - Centralized examination stations (CES)
    - G.O. warehouses
    - Customs approved storage rooms (CASR)



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# Procedures for Merchandise Returned to Country of Export

- Shipper, importer, or carrier may decide to return merchandise to country of export with CBP concurrence
- Should be under physical control and custody of CBP
- May be documented using an Immediate Export (IE) in-bond



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# Procedures for Abandoned Goods

- BTA abandoned goods will be considered G.O. merchandise and will follow normal G.O. guidelines



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# Procedures for Segregation of BTA Refused Foods

## What Happens to Refused Foods?

- Food refused under 801(m)
  - ◆ Commingled foods within same container or truck
  - ◆ Commingled goods, e.g., goods that are “PN satisfied” and “PN not satisfied”



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# Procedures for Segregation of BTA Refused Foods (continued)

## What Happens to Refused Foods?

- Goods must be segregated, in accordance with local procedures and in coordination with the secure facility and carrier, so that “PN satisfied” foods may enter
- “PN not satisfied” handled as refused entry and held at port, moved to a secured facility, or returned to country of export
- The carrier must bear all costs



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# Entry Types Impacted by BTA

- BRASS
- Permit Ports
- Customs Form 3461 Entry/Immediate Delivery
- In-bond Filing Trade Requirements
- FTZ admissions
- Express consignment
- Non-automated informal/walk-up
- International mail
- Carnets



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# BRASS

Entries under BRASS will no longer be permitted for goods subject to the BTA



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# BTA Role for Permit Ports

It is expected that Permit Ports will be able to run ACS/ABI selectivity by effective date of BTA, 12/12/03



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# ABI/ACS Customs Form 3461 Entry/Immediate Delivery

## PN Requirements/How to Process

- For merchandise to be released from CBP custody and entered into the commerce of the U.S. or for export (includes warehouse)
- All BTA requirements must be satisfied prior to release



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# BTA In-Bond Filing Trade Requirements

## PN Requirements/How to Process

- PN submission (through ABI/ACS or FDA web portal) must include in-bond number and bill number (if applicable)
- Unless an immediate security risk, transportation (IT) in-bond shipments may be allowed to travel to the port of entry for satisfaction of PN
- Transhipped merchandise (T&E) must satisfy notice requirements at port of arrival in the U.S.



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# BTA In-Bond Filing Trade Requirements

## PN Requirements/How to Process

- In-bond (electronic or paper) must include indicator of PN compliance
- Capability to provide a 6-digit HTS on in-bonds is under development
- For in-bonds filed through the web portal, a paper copy of the PN confirmation may be required if requested by CBP



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# In-Bond Processing with PN Indicator

## PN Requirements/How to Process

- Automated in-bonds will query ACS PN database and return status messages to AMS/ABI
- Paper in-bonds will require manual input of PN indicator; ACS PN database will be queried automatically and return status messages to processing officer



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## PN Requirements/How to Process

- No automated system for goods admitted to an FTZ
- PN requirements must be met prior to movement of goods to the FTZ
- Paper copy of PN confirmation number shall be submitted with admission document
- Direct delivery only permitted if PN requirements, including time frames are satisfied
  - ◆ 48-hour reporting time disallowed



## PN Requirements/How to Process

- All other movement to the FTZ done as follows:
  - ◆ Under dray or delivery ticket
  - ◆ By CF214
    - (FDA web portal used to submit PN)
    - In-bond permitted if PN satisfied (ACS 2-step)



# Express Consignment

## PN Requirements/How to Process

- PN is required for all Express Consignment Courier Facility (ECCF) BTA covered shipments
- This represents fundamental change in business practices
- Consolidated entries for BTA merchandise will not be allowed. Separate entries will be required



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# Express Consignment

## PN Requirements/How to Process

- No Section 321 release(on manifest) for BTA merchandise. Consumption entry must be made.
- ECCF will not be considered “importer of record”; this will permit the BTA shipment to be held at the ECCF as it will be viewed as a secure facility under the BTA



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Bioterrorism Preparedness  
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# Non-Automated Informal Entries/ Walk-ups

## PN Requirements/How to Process

- Unless excepted, these goods must be manufactured in an FDA registered facility
- PN must be filed on each item by product code
- Paper copy of PN confirmation number must accompany the shipment
- Failure to have PN confirmation number will result in a refusal of admission



# Non-Automated Informal Entries/ Walk-ups

## PN Requirements/How to Process

- Inspector will query PN database to determine status
- Most of these will not have a bond and as a result will not be able to move their goods to a secure facility
- Most will not be able to meet PN requirements and shipment will most likely be returned to country of export



# International Mail

## PN Requirements/How to Process

- BTA applies to food as defined in the Act imported through international mail
- Food shipment must have PN confirmation number on Postal Declaration Form CN22 or CN23



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# International Mail (continued)

## PN Requirements/How to Process

- If there is no PN confirmation number, shipment will be held for 72 hours for FDA review and disposition
- If no FDA response, shipment is stamped with BTA Refusal stamp and returned to sender if there is a return address
- If there is no return address, shipment will be destroyed at FDA expense
- If shipment contains food and non-food items, shipment will be treated as commingled goods and returned or destroyed



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# Carnets

## PN Requirements/How to Process

- Definition
  - ◆ An international customs document that facilitates temporary imports into foreign countries and is valid up to 1 year
- Foreign facilities exporting BTA food products to the U.S. using carnets must register with the FDA; PN requirements also apply



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# Carnets

## PN Requirements/How to Process

- Process normally except CBP inspectors must query PN documents (PN confirmation) and database.
  - ◆ Paper copy of PN confirmation number shall be submitted with carnet



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# Help Resources

- FDA registration help:
  - ◆ U.S. Toll-free: 1-800-216-7331
  - ◆ Outside U.S.: 301-575-0156
  - ◆ Fax: 301-210-0247
  - ◆ Registration tutorial: [www.fda.gov/furls](http://www.fda.gov/furls)
- Federal Register: [www.gpoaccess.gov/fr](http://www.gpoaccess.gov/fr)
- Legislation: [www.thomas.loc.gov](http://www.thomas.loc.gov)
- CBP web site: [www.CBP.gov](http://www.CBP.gov)



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# Help Resources

- FDA web site: [www.FDA.gov](http://www.FDA.gov)
- FDA regional points of contacts
- Each CBP field office will have 2 BTA trained experts
- FDA Publication “What Do I Need To Know About FDA’s New Bioterrorism Rules” will available through trade associations, state agencies, U.S. embassies, and at the FDA website



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