



U.S. Department of Health and Human Services

Food and Drug Administration

Overview of Prior Notice Final Rule and Draft CPG

Implementing the Bioterrorism Act

(73 FR 66294 (final rule)

73 FR 66411 (CPG); November 7, 2008)

Leslye M. Fraser, S.M., J.D., Director, ORPSS, CFSAN

May Nelson, Regulatory Counsel, ORPSS, CFSAN

Laura Draski, PhD., Director, Prior Notice Center

21 CFR 10.85

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Agenda

- **Regulatory background**
- **Overview of the final rule**
- **Highlights of the final rule**
- **Overview of the final rule draft CPG**
- **Question and answer**

Background: FDA's Regulatory Development Timeline



- **June 12, 2002:** Public Health Security and Bioterrorism Preparedness and Response Act (the Bioterrorism Act) enacted
 - Required prior notification of imported food to begin on Dec. 12, 2003
- **Feb. 3, 2003:** FDA and U.S. Customs and Border Protection (CBP) published proposed rule with 60 day comment period
 - FDA received over 470 comments
- **Oct. 10, 2003:** FDA and CBP published interim final rule (IFR) with 135 day comment period
 - FDA received over 320 comments
- **Dec. 12, 2003:** Prior Notice interim final rule became effective and draft Compliance Policy Guide issued
 - Prior Notice Center becomes operational

Background: FDA's Regulatory Development Timeline

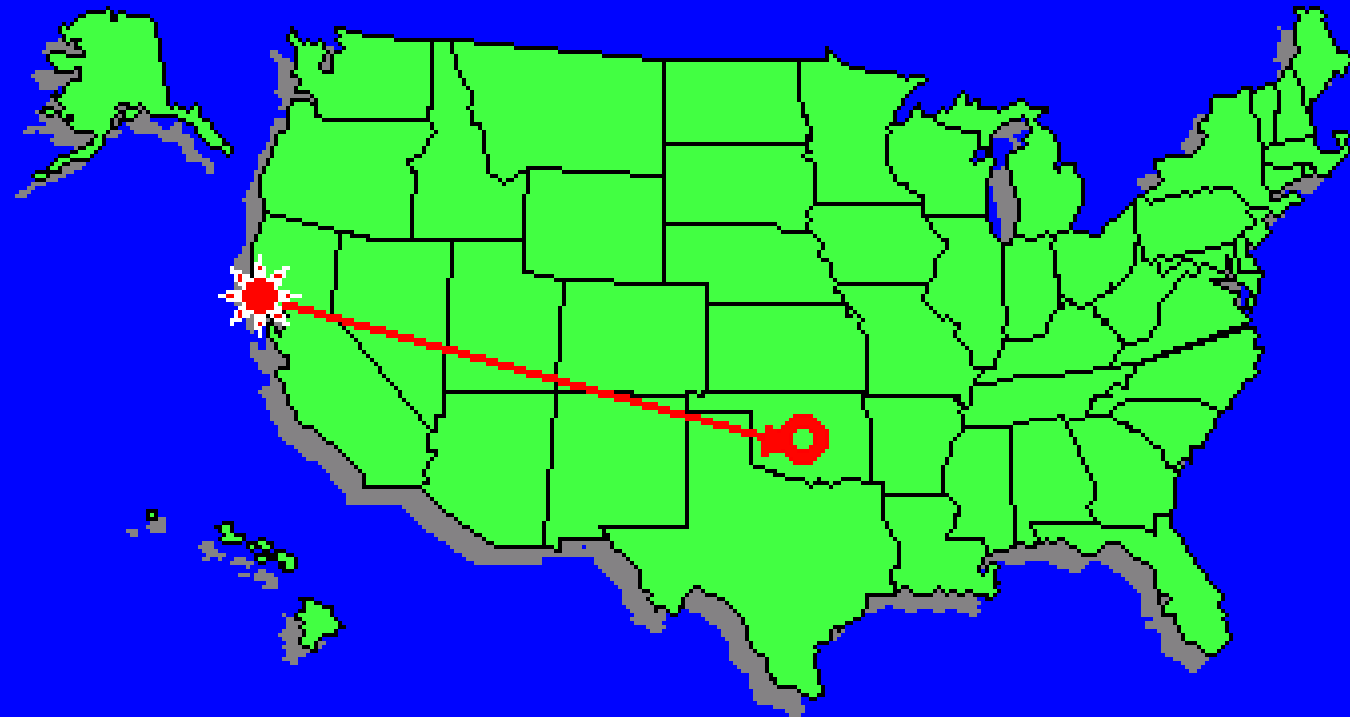


- **Nov. 7, 2008:** FDA and CBP published final rule and final rule draft compliance policy guide (CPG)
- **March 2009:** Final rule briefing to US agency staff and embassies
- **May 6, 2009:** Final rule becomes effective and final rule CPG to issue

FDA'S Prior Notice: Definitions

- **International Mail** – foreign national mail services
 - Does *not* include express carriers, express consignment operators, or other private delivery services
- **Port of Arrival** – water, air, or land port at which the article of food is imported or offered for import into the U.S. (i.e., the port where the article of food first arrives in the U.S.)
 - Note: May be different from the port where food is entered for CBP purposes

Port of Arrival vs. Port of Entry



**Crossing Location = Port of Arrival for Prior Notice;
may or may not be the port where entry is made for
CBP purposes**

FDA Country of Production (Originating Country)

- **For food in its natural state -- the country where the article of food was grown or collected, including harvested and readied for shipment to the U.S.**
 - **For wild fish or seafood caught or harvested outside the waters of the U.S. by a vessel that is not registered in the U.S.: the country in which the vessel is registered**
 - **For an article of food that was grown in a U.S. Territory: the U.S.**

FDA Country of Production vs. CBP Country of Origin

- **The “Bean Example”**: beans are grown and dried in the U.S., then rehydrated and canned in Country D
 - CBP identifies the country of origin as the U.S.
 - For purposes of prior notice, FDA identifies the “article of food” as canned beans, not dried beans
 - Thus, “FDA Country of Production” is Country D

FDA'S Prior Notice: Final Definitions (cont.)

- **Shipper** – the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the U.S.
- **United States** – the Customs territory of the United States (i.e., the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico, but not the Territories)

FDA'S Prior Notice: Final Definitions (cont.)

- **Manufacturer** – the last facility, as that word is defined in § 1.227(b)(2) of the registration rule, that manufactured/processed the food
 - *de minimis* processing:
labeling or other activities not related to manufacturing, e.g., storing

Multiple facilities: Who is the PN manufacturer?

- **Wine example**

- wine produced and bottled at winery “X”
- sent to winery “B” for labeling
- wine sent to facility “S” for storage
- wine then transferred to freight forwarder “F” who stores and consolidates the wine with others for shipment to U.S.

→ for PN purposes, winery X is the mfr.

What Food Imports are Subject to Prior Notice?

- **Unless excepted, all food for humans and animals that is imported or offered for import into the United States for *use, storage, or distribution in the U.S.*, including:**
 - **Food for gifts and trade**
 - **Quality assurance/quality control samples**
 - **Food for future export**
 - **Food for transshipment through the U.S. to another country**
 - **Food for use in a U.S. Foreign Trade Zone (FTZ)**
 - **Food sent by mail**
 - **Food sent by express couriers**

What Definition of “Food” Applies?

- **With some exceptions, the definition in section 201 (f) of the Federal Food, Drug, and Cosmetic Act applies:**
 - *i.e., “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”*

Examples of FDA-regulated Food Within Scope of the Rule

- Dietary supplements and dietary ingredients**
- Infant formula**
- Beverages (including alcoholic beverages and bottled water)**
- Fruits and vegetables**
- Fish and seafood**
- Dairy products and shell eggs**

Examples of FDA-regulated Food Within Scope of the Rule

- Raw agricultural commodities for use as food or components of food**
- Canned and frozen foods**
- Live food animals**
- Bakery goods, snack food, candy, and chewing gum**
- Animal feeds and pet food**

What is Excluded from the Prior Notice Food Definition

- **Food contact substances**, as defined in § 409(h)(6) of the FD&C Act
- **Pesticides regulated by EPA**, as defined in 7 U.S.C. § 136(u)
- **Meat, poultry and egg products** that at the time of importation are subject to **USDA's *exclusive* jurisdiction**

What Kinds of Food Imports are Not Subject to Prior Notice?

- **Food carried by or otherwise accompanying an individual for personal use (i.e., consumption by self, family, or friends, not for sale or other distribution)**
- **Food made by an individual at home sent as a personal gift (i.e., not for business reasons) to an individual in the U.S.**
- **Food shipped as baggage or cargo constituting the diplomatic bag/pouch**

Who is Authorized to Provide Prior Notice?

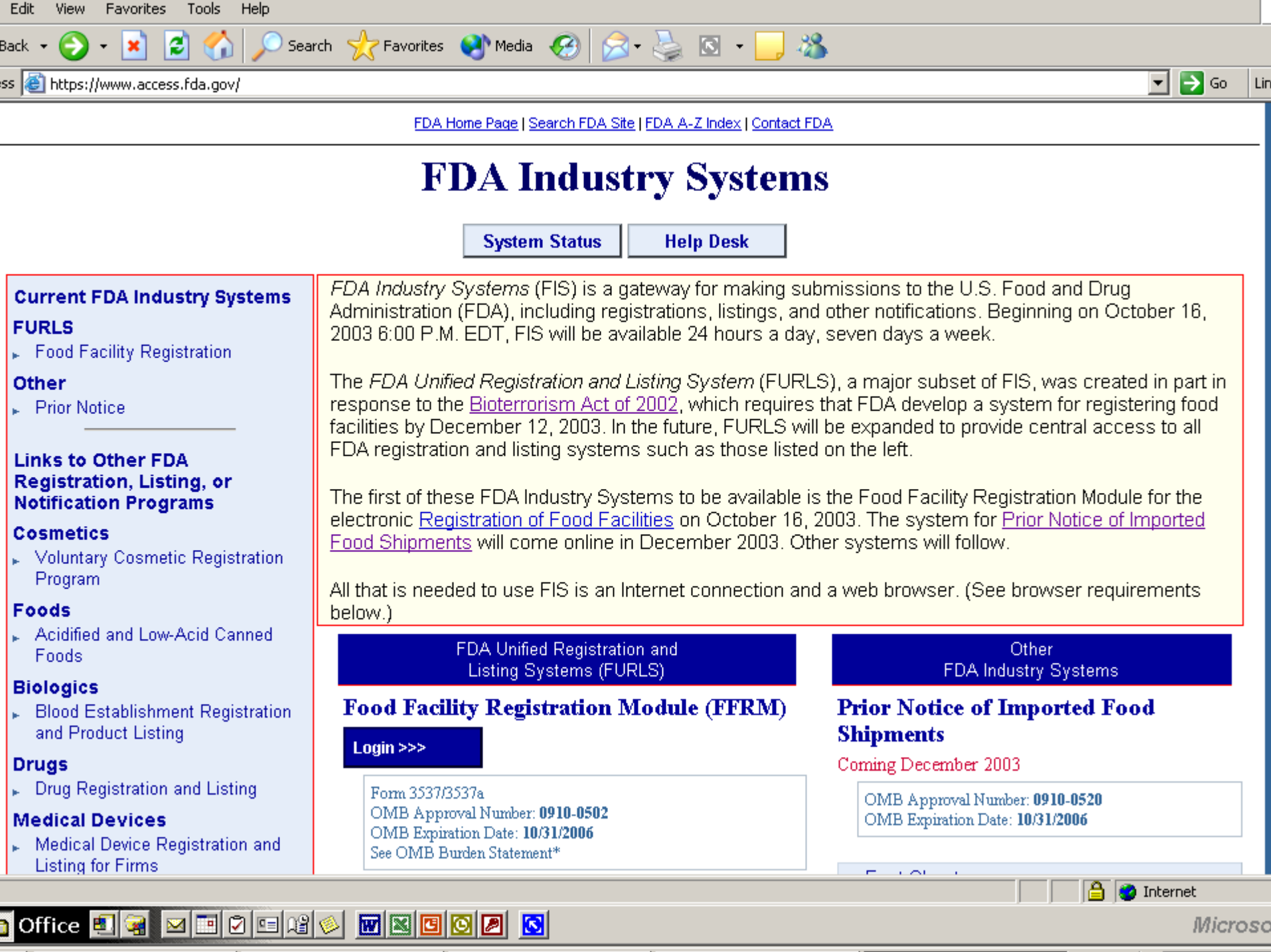
- **“Submitter”** can be any person with knowledge of the required information
- **“Transmitter”** is a person who transmits the required information to FDA for the submitter

How Do I Submit Prior Notice?

- All prior notice information must be in the English language using the Latin (Roman) alphabet, except:
 - individual's name, the name of a company, and the name of a street may be submitted in a foreign language
- Must be submitted electronically through:
 - CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS), or
 - FDA's PN System Interface (PNSI) at <http://www.access.fda.gov>

Submitting Prior Notice (cont.)

- **NOTE: PNSI submission is required for:**
 - **Articles of food imported or offered for import by international mail**
 - **Transaction types that cannot be made through ABI/ACS**
 - **Articles of food that have been refused for inadequate prior notice**



FDA Industry Systems

[System Status](#)

[Help Desk](#)

Current FDA Industry Systems

FURLS

- ▶ [Food Facility Registration](#)

Other

- ▶ [Prior Notice](#)

Links to Other FDA Registration, Listing, or Notification Programs

Cosmetics

- ▶ [Voluntary Cosmetic Registration Program](#)

Foods

- ▶ [Acidified and Low-Acid Canned Foods](#)

Biologics

- ▶ [Blood Establishment Registration and Product Listing](#)

Drugs

- ▶ [Drug Registration and Listing](#)

Medical Devices

- ▶ [Medical Device Registration and Listing for Firms](#)

FDA Industry Systems (FIS) is a gateway for making submissions to the U.S. Food and Drug Administration (FDA), including registrations, listings, and other notifications. Beginning on October 16, 2003 6:00 P.M. EDT, FIS will be available 24 hours a day, seven days a week.

The *FDA Unified Registration and Listing System* (FURLS), a major subset of FIS, was created in part in response to the [Bioterrorism Act of 2002](#), which requires that FDA develop a system for registering food facilities by December 12, 2003. In the future, FURLS will be expanded to provide central access to all FDA registration and listing systems such as those listed on the left.

The first of these FDA Industry Systems to be available is the Food Facility Registration Module for the electronic [Registration of Food Facilities](#) on October 16, 2003. The system for [Prior Notice of Imported Food Shipments](#) will come online in December 2003. Other systems will follow.

All that is needed to use FIS is an Internet connection and a web browser. (See browser requirements below.)

FDA Unified Registration and Listing Systems (FURLS)

Food Facility Registration Module (FFRM)

[Login >>>](#)

Form 3537/3537a
OMB Approval Number: **0910-0502**
OMB Expiration Date: **10/31/2006**
See OMB Burden Statement*

Other FDA Industry Systems

Prior Notice of Imported Food Shipments

Coming December 2003

OMB Approval Number: **0910-0520**
OMB Expiration Date: **10/31/2006**

Submitting Prior Notice (cont.)

If this isn't working . . .	Then file here	In this form:
Customs broker's or self-filer's system, or ABI/ACS	FDA PNSI	Electronically
PNSI or OASIS (FDA will post notice at http://www.fda.gov)	FDA (see http://www.fda.gov – see Prior Notice for locations)	In the format it deems appropriate during outage

How Far in Advance Can I submit Prior Notice?

- **Maximum time frames for submitting PN:**
 - Increased time frames from the IFR
 - Dependent on mode of submission:
 - **Via ABI/ACS: Submit PN no more than *30-calendar days* before arrival**
 - **Via PNSI: Submit PN no more than *15-calendar days* before arrival**
- **Does not apply to food arriving by international mail**
(must submit PN before food is sent to U.S.)

When Is My Prior Notice Due?

- **Arrival by land via road:**
PN must be given no less than 2 hours before the food arrives at the port of arrival
- **Arrival by air and land via rail:**
PN must be given no less than 4 hours before the food arrives at the port of arrival
- **Arrival by water:**
PN must be given no less than 8 hours before the food arrives at the port of arrival

When Is My Prior Notice Due?

(cont.)

- **Food carried by or accompanying an individual**
 - time is based on manner of transportation
- **Food arriving by international mail**
 - prior notice must be submitted before the food is mailed

What Information is Required in a Prior Notice?

Note: * indicates that if a corresponding registration number is provided, then the city and country can be submitted in lieu of the full address.

- **Submitter*** (name, address, phone, e-mail)
- **Transmitter*** (name, address, phone, e-mail)
- **CBP Entry type** (e.g., Consumption entry, Warehouse entry, Transportation and Exportation entry)
- **CBP Entry Identifier** (e.g., entry number or in-bond number)

What Information is Required in a Prior Notice?

- **Identity of the article of food**

- Complete FDA product code

- Common or usual name or market name

- Estimated Quantity

- Lot or code numbers, if required by FD&C Act or FDA regulations

- E.g., low acid canned foods, infant formula, acidified foods

What Information is Required in a Prior Notice?

- **For food no longer in its natural state – identity of the manufacturer: name and then 2 options:**
 1. Registration number, city, and country OR
 2. Full address and reason the registration number is not provided, e.g., out of business, private residence, unable to determine
- **For food in its natural state -- grower, if known**
- **FDA Country of Production**

What Information is Required in a Prior Notice?

- **Shipper name and full address**
- **Country** from which the article is **shipped**
- **Anticipated arrival information**
 - **Port of arrival**
 - **Date of arrival**
 - **Time of arrival**

What Information is Required in a Prior Notice?

Anticipated Time of Arrival and Express Shipments:

- **The tracking number provided by the express consignment operator or carrier may substitute for the anticipated arrival information if:**
 - **food is arriving by express consignment operator or carrier,**
 - **neither the submitter nor transmitter is the express consignment operator or carrier, and**
 - **PN is submitted via PNSI**

What Information is Required in a Prior Notice? (cont.)

Note: † indicates not required for an article of food imported or offered for import for transshipment, storage, and export, or further manipulation and export

- **Name and full address of importer †**
- **Name and full address of owner (if different than importer or ultimate consignee) †**
- **Name and address of ultimate consignee†**

What Information is Required in a Prior Notice? (cont.)

- **Mode of transportation**
- **Carrier** - Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code carrying the food from the country from which it is shipped

What Information is Required in a Prior Notice? (cont.)

- **Planned shipment information:**

- **All:** airway bill number or bill of lading number and container number if containerized cargo
- **Ocean Vessel:** vessel name and voyage number
- **Air:** flight number
- **Truck/Bus/Rail:** trip number
- **Rail:** car number

→ **Express consignment operator or carrier *tracking number* may substitute for airway bill number or bill of lading number and flight number when conditions are met**

Requirements for Food Arriving by International Mail

- **All information previously listed, *except*:**
 - Entry identifier
 - Anticipated port, date, and time of arrival
 - Importer, owner, or ultimate consignee
 - Mode of transport
 - Carrier and planned shipment information
- **Additional information required:**
 - Anticipated date of mailing
 - U.S. recipient

Requirements for Food Refused for Inadequate Prior Notice

- **All information previously listed, *except*:**
 - Anticipated and planned shipment information
- **Additional information required:**
 - Actual quantity
 - Actual shipment information, e.g., bill of lading/airway bill, flight number, etc.
 - Actual arrival information: port, date, and time of arrival
 - Hold location and address
 - Identification of contact at that location

What Happens When FDA Accepts Your PN For Review?

- **FDA will notify you that your PN has been confirmed for review with a reply message containing a *PN Confirmation Number***
- **Prior Notice “clock” (for timeliness of notice) starts when FDA confirms PN**
- **Note: Receipt of confirmation does not mean that FDA has determined the PN to be either timely or accurate**

Prior Notice Confirmation Number Must Accompany . . .

- **... any article of food arriving by international mail;
number must be on Customs Declaration;**
- **... food brought in by individual for non-personal use; and**
- **... any article of food for which PN was submitted through PNSI when the article arrives in the U.S.;
number must be provided to CBP or FDA upon arrival**

What if the Information Changes After I Submit a Prior Notice?

- **Changes in the following fields require no action:**
 - *estimated quantity, anticipated arrival information, planned shipment information or estimated date of mailing*
- **All other changes** – new prior notice must be submitted unless the food will not be offered for import into the U.S.
 - Should also cancel PN previously submitted (PNSI or ABI/ACS depending on how PN was filed)
 - Timeframe will restart

What Happens to Food Without Adequate Prior Notice?

- **No or inaccurate prior notice**
 - food is subject to refusal

- **Untimely prior notice**
 - food is subject to refusal, unless FDA has already reviewed the notice and notified CBP of its response

What Happens to Food Without Adequate Prior Notice?

- **If refused, food must be held at the port of entry, unless:**
 - **CBP concurrence is obtained for export and food immediately is exported from the port of arrival under CBP supervision; or**
 - **Directed to another location by CBP or FDA**
- **Must notify FDA of hold location**
 - **FDA and CBP are *not* liable for transportation, storage or other expenses resulting from any hold**

What Happens to Food Without Adequate Prior Notice?

- **Refused food** is general order merchandise (19 U.S.C. 1490) and must be moved under appropriate custodial bond
- **Refused food must not be entered with CBP; it *must not* be delivered to importer, owner, or ultimate consignee until prior notice requirements are met**

Consequences of Failure to Submit Adequate Prior Notice

- **Prohibited act to import or offer for import food without providing prior notice:**
 - **FDA can bring a civil or criminal action in federal court**
 - **FDA can seek to debar persons under section 306 of the Bioterrorism Act**

Consequences of Failure to Register If Required

- If the failure relates to the **manufacturer**:
the food is subject to **refusal** for failure
to provide adequate prior notice
 - (Identity of facility is incomplete)
- Same consequences for inadequate
prior notice apply

Consequences of Failure to Register If Required (cont.)

- If the failure relates to **another facility** associated with the food that is not registered: **food is subject to hold** at the port of entry or other location if directed by FDA or CBP
- Food remains under hold until facility is registered and number provided to FDA

Prior Notice vs. 801(a) Admissibility

A determination that an article of food is no longer subject to hold for a prior notice or registration violation:

- Is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws**
- Does not mean that it will be granted admission under other provisions of the FD&C Act or other U.S. laws.**

Final Rule Highlights

- Revises the IFR in only a few key areas.
- Until final rule and CPG take effect, the IFR and IFR CPG remain in effect.
- **UNCHANGED: Minimum time frames for submitting PN** – retains the IFR time frames: no less than
 - 8 hours (for food arriving by water),
 - 4 hours (for food arriving by air or land/rail), and
 - 2 hours (for food arriving by land/road)
before the food arrives at the port of arrival

Final Rule Highlights: Time Frames

- **Increases the maximum time frames for submitting prior notice from 5 days to:**
 - **via PNSI:**
 - no more than 15 calendar days before anticipated date of arrival
 - **via ABI/ACS:**
 - no more than 30 calendar days before anticipated date of arrival
- **Changes in maximum time frames previously handled in CPG**

Final Rule Highlights: Manufacturer

- **Adds definition for “manufacturer”**
 - the last facility, as defined in registration rule, that manufactured/ processed the food
- **Required for identity of manufacturer:**
 - name of manufacturer and either
 - the registration number, or
 - the full address of site-specific facility and valid reason why no registration number is submitted.

Final Rule Highlights:

Moved from CPG to Final Rule

- **Additional exemption from PN:**
Diplomatic bag / pouch
- **Allow express consignment operator or carrier tracking number as substitute for:**
 - **anticipated arrival information**
 - **Bill of Lading or Airway bill number**
 - **flight number**

Draft CPG Highlights:

Enforcement Discretion (ED)

- **No graduated enforcement period**
- **Provisions retained as is:**
 - **Non-commercial shipments (no PN)**
 - **Non-commercial gift packs (single PN)**
 - **Imported food arriving from/exiting to the same country (no PN)**
- **New areas of enforcement discretion:**
 - **Foreign-to-foreign mail and courier shipments by individuals (no PN)**
 - **U.S. government shipments (no PN)**
 - **Seed for cultivation (no PN)**

Draft CPG Highlights

Revised Areas of ED

- **Manufacturer:**
 - **Eliminated ED for providing an alternate facility when the actual manufacturer and registration number were not known**
 - **Now site-specific manufacturer registration number or full address must be provided**
- **Samples**
 - **ED on samples for testing only (no PN)**

Draft CPG Highlights:

Removed or Moved to Final Rule

- **HTS Code**
 - No longer required (removed from CPG and FR)
- **Submission of PN greater than 5 days out (moved to FR):**
 - Previous CPG allowed submission up to 10 days out
 - Final rule now allows for PN submission up to 15 days for PNSI and 30 days for ABI/ABS prior to arrival.
- **Express carrier tracking numbers (moved to FR):**
 - Allow express consignment operator or carrier tracking number as substitute for:
 - anticipated arrival information
 - Bill of Lading or Airway bill number
 - flight number

Where Can I Find a Copy of the Final Rule?

Go to <http://www.fda.gov/>

Choose “Prior Notice of Imported Food” link

Outreach documents:

- Constituent Update with summary of final rule and final rule draft CPG

<http://www.cfsan.fda.gov/~dms/cfsup189.html>

- Prior Notice Fact Sheet (coming soon)
- “What You Need to Know About Prior Notice of Imported Food Shipments” booklet (coming soon)

