

# OMB Burden Statement FDA Form 3540

\*Public reporting burden for this collection of information is estimated to take one hour each time an import entry is submitted on form 3540. An import entry, on average, constitutes 2.6 different articles of food; with a prior notice submitted for each article. Therefore we estimate that submitting prior notice for each article of food will take 23 minutes to complete, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Paperwork Reduction Act Office  
Director, JonnaLynn Capezutto  
8455 Colesville Road, Room 14526  
Silver Spring, MD 20910  
[PRASStaff@fda.hhs.gov \(mailto:PRASStaff@fda.hhs.gov\)](mailto:PRASStaff@fda.hhs.gov)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

**[More in Importing Food Products into the United States](#)**  
**[\(/Food/GuidanceRegulation/ImportsExports/Importing/default.htm\)](#)**

**[Prior Notice of Imported Foods](#)**  
**[\(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm\)](#)**

**[Filing Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm\)](#)**

**[Historical Information about Prior Notice](#)**  
**[\(/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm\)](#)**

[Check System Status \(http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm161883.htm\)](http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm161883.htm)

FDA Industry Systems (FIS) was created to facilitate making submissions to the U.S. Food and Drug Administration (FDA), including registrations, listings, and other notifications. FIS has been available 24 hours a day, seven days a week, since October 16, 2003 6:00 p.m. EDT.

[Log-In \(https://www.access.fda.gov/oaal/ogonFlow.htm?execution=e2s1\)](https://www.access.fda.gov/oaal/ogonFlow.htm?execution=e2s1)

[Create Account \(https://www.access.fda.gov/oaal/createNewAccountflow.htm?execution=e2s1\)](https://www.access.fda.gov/oaal/createNewAccountflow.htm?execution=e2s1)

FIS was created, in part, in response to the **Bioterrorism Act of 2002** (<http://www.fda.gov/regulatoryinformation/legislation/ucm148797.htm>), which gave high priority to improved information management to help protect the food supply. The Act requires that FDA develop two systems: one to support the registration of facilities that manufacture, process, pack, or hold food products intended for consumption in the United States and one to receive prior notice before food is imported or offered for import into the United States. Under the law, facilities must be registered by December 12, 2003 when Prior Notice went into effect.

### Systems Index

**FURLS Acidified/Low Acid Canned Foods (LACF)**

Form **2541/2541d/2541e/2541f/2541g**  
 OMB Approval Number **0910-0037**  
 OMB Expiration Date **09/30/2017**  
 See **OMB Burden Statement**  
<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm151742.htm>

[Info \(http://www.fda.gov/oc/omb/burden/Registration/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm)

**FURLS Biologics Export Certification Application & Tracking System (BECATS)**

FDA **3613**  
 OMB Approval Number **0910-0498**  
 OMB Expiration Date **03/31/2018**  
 See OMB Burden

[Info \(http://www.fda.gov/oc/omb/burden/Registration/BECATS/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/BECATS/default.htm)

**FURLS Dairy Listing Module (DLM)**

FDA **3972**  
 OMB Approval Number **0910-0509**  
 OMB Expiration Date **09/30/2017**  
 See OMB Burden

**FURLS CDER Export Certification Application & Tracking System (CDEReCATS)**

FDA **3613**  
 OMB Approval Number **0910-0498**  
 OMB Expiration Date **03/31/2018**  
 See OMB Burden

[Info \(http://www.fda.gov/oc/omb/burden/Registration/CDEReCATS/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/CDEReCATS/default.htm)

**FURLS CDRH Export Certification Application & Tracking System (CECATS)**

FDA **3613**  
 OMB Approval Number **0910-0498**  
 OMB Expiration Date **03/31/2018**  
 See OMB Burden

[Info \(http://www.fda.gov/oc/omb/burden/Registration/CECATS/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/CECATS/default.htm)

**FURLS CFSAN Certificate Application Process (CAP)**

FDA **3613d/3613e**  
 OMB Approval Number **0910-0793**  
 OMB Expiration Date **05/31/2018**  
 See OMB Burden

[Info \(http://www.fda.gov/oc/omb/burden/Registration/CAP/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/CAP/default.htm)

**FURLS Device Registration & Listing Module (DRLM)**

Form **3673(03/08)**  
 OMB Approval Number **0910-0625**  
 OMB Expiration Date **06/30/2019**  
 See **OMB Burden Statement**  
<http://www.fda.gov/MedicalDevices/DeviceRegistrationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

[Info \(http://www.fda.gov/oc/omb/burden/Registration/DeviceRegistrationandListing/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/DeviceRegistrationandListing/default.htm)

**FURLS Food Facility Registration Module (FFRM)**

Form **3537/3537a**  
 OMB Approval Number **0910-0502**  
 OMB Expiration Date **08/31/2019**  
 See **OMB Burden Statement**  
<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm151633.htm>

[Info \(http://www.fda.gov/oc/omb/burden/Registration/FoodFacilityRegistration/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/FoodFacilityRegistration/default.htm)

**FURLS New Dietary Ingredient Notification (NDIN) (Dietary Supplements)**

Form **3880**  
 OMB Approval Number **0910-0330**  
 OMB Expiration Date **03/31/2018**  
 See OMB Burden Statement

[Info \(http://www.fda.gov/oc/omb/burden/Registration/NDIN/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/NDIN/default.htm)

**FURLS Shell Egg Producer Registration Module (SEPRM)**

Form **3733**  
 OMB Approval Number **0910-0660**  
 OMB Expiration Date **08/31/2016**  
 See **OMB Burden Statement**  
<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ShellEggProducerRegistration/ucm210764.htm>

[Info \(http://www.fda.gov/oc/omb/burden/Registration/ShellEggProducerRegistration/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/ShellEggProducerRegistration/default.htm)

**FURLS Structure/Function Claims Notification (SFCN) (Dietary Supplements)**

FDA **TBA**  
 OMB Approval Number **0910-0331**  
 OMB Expiration Date **06/30/2019**  
 See OMB Burden

[Info \(http://www.fda.gov/oc/omb/burden/Registration/SFCN/default.htm\)](http://www.fda.gov/oc/omb/burden/Registration/SFCN/default.htm)

**FURLS Tobacco Registration and Product Listing (TRLM)**

FDA **3741**  
 OMB Approval Number **0910-0650**  
 OMB Expiration Date **01/31/2019**  
 See OMB Burden

**Prior Notice System Interface (PNSI)**

Form **3540**  
 OMB Approval Number **0910-0502**  
 OMB Expiration Date **06/30/2017**  
 See **OMB Burden Statement**  
<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm151675.htm>

[Info \(http://www.fda.gov/oc/omb/burden/Registration/ImportsExports/Importing/ucm2006837.htm\)](http://www.fda.gov/oc/omb/burden/Registration/ImportsExports/Importing/ucm2006837.htm)

**Help Desk**

**FDA Industry Systems / FDA Unified Registration and Listing Systems (FURLS) / Technical Help**

*Electronic Submissions Gateway Approved Production Transaction Partners, Food Facility Registration Module, Prior Notice, Low Acid & Acidified Canned Foods, and Account Management.*

Phone: 1-800-216-7331 or 240-247-8804 7:30 a.m.-11:00 p.m. Eastern Time  
 Fax: 301-436-2804 or 1-866-673-0846

To e-mail questions about the Bioterrorism Act [use this form](#)  
<http://www.accessdata.fda.gov/scripts/email/cfsan/bioterrorismact/helpf2.cfm>

[Account Management Help \(http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073725.htm\)](http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073725.htm)

[Electronic Submissions Gateway Help \(http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm\)](http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm)

Effective January 14, 2004: The FDA Industry System Help Desk is available for technical assistance with online registration and listing systems, Prior Notice, and regulated electronic submissions on U.S. Government business days (Monday to Friday, excluding U.S. government holidays) from 7:30 a.m. to 11:00 p.m. Eastern Time (see [Federal Holidays \(https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/federal-holidays/\)](https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/federal-holidays/) and [Federal Government Operating Status \(http://www.opm.gov/Operating\\_Status\\_Schedules/\)](http://www.opm.gov/Operating_Status_Schedules/)).

You may leave a message or send e-mail at other times. These will be addressed on the next business day.

**Prior Notice / Policy Help**

Phone: 1-866-521-2297

The Prior Notice Center staff can answer questions about Prior Notice policies, procedures, and interpretations 24 hours a day, 7 days a week.

**Electronic Submissions Gateway / Pre-Production Help**

If you want to become a trading partner, or have a question about becoming a trading partner, for the Electronic Submissions Gateway, please visit the [FDA Electronic Submissions Gateway \(http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm\)](http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm)

**FURLS Tobacco Registration and Product Listing (TRLM) Help**

Email: [CTPRegistrationandListing@fda.hhs.gov](mailto:CTPRegistrationandListing@fda.hhs.gov)

The Registration and Listing staff can assist with answering your questions about Tobacco Registration and Product Listing.

**Additional Information**

**FDA Registration, Listing, or Notification Programs**

- [Voluntary Cosmetic Registration Program \(http://www.fda.gov/cosmetics/registrationprogram/ucm2005171.htm\)](http://www.fda.gov/cosmetics/registrationprogram/ucm2005171.htm)
- [Blood Establishment Registration and Product Listing \(http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/RegulationoftheBloodSupply/default.htm\)](http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/RegulationoftheBloodSupply/default.htm)
- [Human Cell and Tissue Establishment Registration and Product Listing \(http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm\)](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm)
- [Drug Registration and Listing \(http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm)
- [Medical Device Registration and Listing for Firms \(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm\)](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm)

**System Requirements**

1. **Internet Access** Internet access is widely available, including at public libraries and Internet cafes.
2. **Web Browser** The following web browsers are supported by FURLS/PNSI applications.
  - FURLS
    - Microsoft Internet Explorer (Version 11)
    - Mozilla Firefox 43.0 or newer
    - Google Chrome 49.0 or newer (except TRLM)
  - PNSI
    - Microsoft Internet Explorer (Version 9.0)
    - Mozilla Firefox 43.0 or newer
    - Google Chrome 49.0 or newer

**Other FDA Industry Information**

- [Information for FDA-Regulated Industry \(http://www.fda.gov/ForIndustry/default.htm\)](http://www.fda.gov/ForIndustry/default.htm)
- [Information Materials for the Food and Cosmetics Industries \(http://www.fda.gov/Food/ResourcesForYou/Industry/default.htm\)](http://www.fda.gov/Food/ResourcesForYou/Industry/default.htm)
- [ORA Industry Assistance \(http://www.fda.gov/Food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/default.htm\)](http://www.fda.gov/Food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/default.htm)
- [Small Business Guide to FDA \(http://www.fda.gov/ForIndustry/SmallBusinessAssistance/SmallBusinessGuidetoFDA/default.htm\)](http://www.fda.gov/ForIndustry/SmallBusinessAssistance/SmallBusinessGuidetoFDA/default.htm)
- [Cosmetics - Information for Industry \(http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/default.htm\)](http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/default.htm)
- [Food Ingredients and Packaging - Information for Industry \(http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm\)](http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm)
- [Over the Counter Drug Products - Industry Information \(http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm\)](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm)
- [Medical Devices and Radiation-Emitting Electronic Products \(http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm\)](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm)
- [Food Labeling and Nutrition - Information for Industry \(http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm\)](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm)

# Prior Notice of Imported Foods

**[Login/Create Account \(https://www.access.fda.gov/oa/\)](https://www.access.fda.gov/oa/)**

OMB Approval Number: **0910-0520**

OMB Expiration Date: 06/30/2017

See **[OMB Burden Statement \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm151675.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm151675.htm)**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

Along with other provisions, the Act requires that FDA receive prior notification of food, including animal feed that is imported or offered for import into the United States. Advance notice of import shipments allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect that nation's food supply against terrorist acts and other public health emergencies.

The **[FDA Food Safety Modernization Act \(/Food/GuidanceRegulation/FSMA/default.htm\)](/Food/GuidanceRegulation/FSMA/default.htm)** (FSMA) signed January 4th, 2011 aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. On May 5, 2011 the FDA published an interim final rule requiring that a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. The new information can help FDA make better informed decisions in managing potential risks of imported food into the United States.

**[Additional Overview and Background \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm114217.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm114217.htm)**

For Instructions on the Prior Notice System Interface, see **[Filing Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm)**, which includes the following resources and more:

- **[Quick Start Guide \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm121048.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm121048.htm)** (also available in **[Spanish \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm170358.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm170358.htm)**)
- **[Step by Step Web System Instructions \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm074936.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm074936.htm)**
- **[PNSI "Wizards" Step by Step Instructions \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm075108.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm075108.htm)**

- [Product Code Builder Tutorial \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm125839.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm125839.htm)
- [Find, Copy and Cancel Web Entries and Prior Notices \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm074912.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm074912.htm)
- [HTS Codes \(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/ucm170031.htm\)](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/ucm170031.htm)

**Guidance Documents and Rules**

- [Guidance for Industry: Prior Notice of Imported Food Questions and Answers \(Edition 3\) \(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm078911.htm\)](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm078911.htm)
- [Final Rule: Information Required in Prior Notice of Imported Food \(https://www.federalregister.gov/articles/2013/05/30/2013-12833/information-required-in-prior-notice-of-imported-food\)](https://www.federalregister.gov/articles/2013/05/30/2013-12833/information-required-in-prior-notice-of-imported-food)
- [Guidance for Industry: Enforcement Policy Concerning Certain Prior Notice Requirements \(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm261080.htm\)](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm261080.htm)
- [Guidance for Industry: Entry Types and Entry Identifiers; Prior Notice of Imported Food \(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm082677.htm\)](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm082677.htm)
- [Guidance for Industry: Prior Notice of Imported Food Contingency Plan for System Outages \(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm078888.htm\)](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm078888.htm)
- [Compliance Policy Guide, Guidance for FDA and CBP Staff: Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 \(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm153055.htm\)](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm153055.htm)

[More Guidance Documents and Rules](#)

[\(/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/default.htm\)](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/default.htm)

**International Mail and Gifts**

- [Importing Gift Packs and Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm086159.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm086159.htm)
- [Sending Gifts to Your Friends and Family: Prior Notice Policy \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm086165.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm086165.htm)
- [Prior Notice for Food Articles Step-by-Step Instructions for PNSI: Food Articles sent by International Mail \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm125924.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm125924.htm)

**Contact FDA**

**System Help Desk**  
**800-216-7331**  
**301-575-0156 INTL**

Contact for questions regarding PNSI account creation, management, password reset, and technical

computer questions. (Mon–Fri 7:30 am - 11:00 pm EST)

Division of Food Defense Targeting  
(formerly Prior Notice Center)

**866-521-2297**

**571-468-1488 INTL**

**571-468-1936 Fax**

**[prior.notice@fda.hhs.gov](mailto:prior.notice@fda.hhs.gov) (<mailto:prior.notice@fda.hhs.gov>)**

Contact for questions regarding prior notice policies, procedures, and interpretations. (24/7)

Division of Import Operations & Policy

**301-796-0356**

Contact for import questions not related to prior notice.

#### Resources for You

- **[What You Need to Know about Prior Notice of Imported Food Shipments](/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm267673.htm)**  
(</Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm267673.htm>)
- **[FDA Industry Systems User Guide: Account Management](/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073725.htm)**  
(</Food/GuidanceRegulation/FoodFacilityRegistration/ucm073725.htm>)
- **[Registration of Food Facilities](/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm)** (</Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>)

**[More in Importing Food Products into the United States](/Food/GuidanceRegulation/ImportsExports/Importing/default.htm)**  
(</Food/GuidanceRegulation/ImportsExports/Importing/default.htm>)

- ▶ **[Prior Notice of Imported Foods](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm)**  
(</Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm>)

**[Filing Prior Notice](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm)** (</Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm>)

**[Historical Information about Prior Notice](/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm)**  
(</Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm>)

# Filing Prior Notice

## Getting Started

- [Prior Notice System Interface \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm114217.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm114217.htm) (Overview and Background)
- [Prior Notice for Food Articles Quick Start Guide \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm121048.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm121048.htm)
- [Step-by-Step Instructions for PNSI \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm074936.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm074936.htm)
  - The Prior Notice Concept: Terms
  - Accessing the Prior Notice System Interface (PNSI)
  - Creating a New Web Entry
  - Creating and Submitting a Prior Notice
  - Completing a Web Entry
- [Additional Capabilities for PNSI Version 2.0 \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm074912.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm074912.htm)
- [Time Saving Tips from the FDA Prior Notice Center for PNSI \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm125894.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm125894.htm)
- [PNSI Wizards: Step-by-Step Instructions \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm075108.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm075108.htm)

## Tutorials

- PNSI Animated Tutorial (Coming Soon!)
- [Product Code Builder Tutorial \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm125839.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm125839.htm)
- [Prior Notice for Food Articles Quick Start Guide \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm121048.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm121048.htm)

More in [Importing Food Products into the United States \(/Food/GuidanceRegulation/ImportsExports/Importing/default.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/default.htm)

[Prior Notice of Imported Foods \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm)

▶ [Filing Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm)

[Historical Information about Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm)

# Historical Information about Prior Notice

See all [current information on Prior Notice](#)

[\(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm\)](#).

- **[Final Rule: Information Required in Prior Notice of Imported Food \(https://www.federalregister.gov/articles/2013/05/30/2013-12833/information-required-in-prior-notice-of-imported-food\)](https://www.federalregister.gov/articles/2013/05/30/2013-12833/information-required-in-prior-notice-of-imported-food)** May 2013
  - Interim Final Rule: **[Information Required in Prior Notice of Imported Food \(http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0179-0001\)](http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0179-0001)** May 2011
  - Fact Sheet: **[FDA'S Interim Final Rule - Information Required in Prior Notice of Imported Food \(http://wcms.fda.gov/FDAgov/Food/GuidanceRegulation/ImportsExports/Importing/ucm153720.htm\)](http://wcms.fda.gov/FDAgov/Food/GuidanceRegulation/ImportsExports/Importing/ucm153720.htm)** August 2011
- **[Final Rule: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 \(http://www.gpo.gov/fdsys/pkg/FR-2008-11-07/pdf/E8-26282.pdf\)](http://www.gpo.gov/fdsys/pkg/FR-2008-11-07/pdf/E8-26282.pdf)** November 7, 2008
- Fact Sheet: **[FDA's New Food Bioterrorism Regulation: Interim Final Rule - Prior Notice of Imported Food Shipments \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm082069.htm\)](#)** October 2003
- Flyer: **[Notice to Truckers: New FDA Regulations Will Affect Imported Food Shipments \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm211002.htm\)](#)** November 2003
- Flyer: **[Notice to Importers and Filers: New FDA Regulations Will Affect Imported Food Shipments \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm189558.htm\)](#)** November 2003
- Flyer: **[Prior Notice Information Sheets: Shipments of Food that Appear to be for Commercial Purposes \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm191730.htm\)](#)** December 2004
- Joint Plan: **[Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm205576.htm\)](#)** August 2004
- International Mail: **[Sending Food Through International Mail \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm082154.htm\)](#)** October 2004
- Information on Gift Packs: **[Importing Gift Packs and Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm086159.htm\)](#)** November 2004



- Information on Sending Gifts: **[Sending Gifts to Your Friends and Family: Prior Notice Policy \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm086165.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm086165.htm)** December 2004
- Information Sheets: **[Shipments of Food that Appear to be for Commercial Purposes \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm191730.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm191730.htm)** December 2004

#### Resources for You

- **[Filing Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm)**

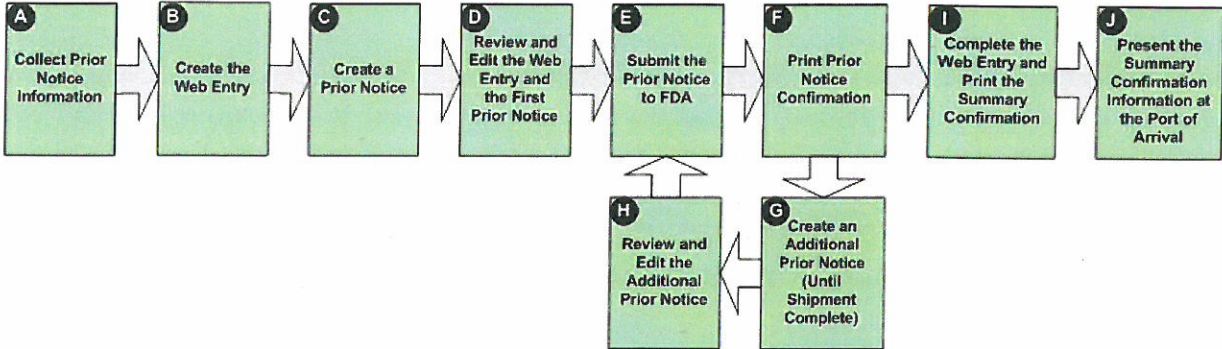
**[More in Importing Food Products into the United States \(/Food/GuidanceRegulation/ImportsExports/Importing/default.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/default.htm)**

**[Prior Notice of Imported Foods \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm)**

**[Filing Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006837.htm)**

▶ **[Historical Information about Prior Notice \(/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm\)](/Food/GuidanceRegulation/ImportsExports/Importing/ucm153853.htm)**

**Prior Notice Submission Process**





## Welcome to the Prior Notice System Interface

The Prior Notice System Interface enables you to submit Prior Notices for Imported Food Articles to the Food and Drug Administration (FDA).

<b>Get Started</b>	▶ Overview of how to submit a Prior Notice for Food Importation.
<b>Learn New Features</b>	▶ Overview of New Features available in this version of the Prior Notice System Interface.
<b>Create New Web Entry</b>	▶ Creating a Web Entry is the first step in creating Prior Notices. A Web Entry contains information that one or more food articles you intend to import share (e.g., arrival information). After Creating a Web Entry, create, review, and submit Prior Notices. Prior Notices include information about the Product, its Quantity and Packaging, and other related information, such as the Manufacturer or Grower/Consolidator and the Shipper.  <b>You must complete the Web Entry after you have submitted all Prior Notices that you are planning to submit as part of this Web Entry. This will allow U.S. Customs and Border Protection to receive the Prior Notice review decisions in time from the U.S. Food and Drug Administration (FDA) for all articles in the Web Entry. The system automatically "Completes" Web Entries with submitted Prior Notices when the Prior Notice submission timeframe elapses (see the "Complete Web Entry" Help topic).</b>
<b>Find Existing Web Entry</b>	▶ Use this feature to find Web Entries that you have already created.
<b>Find Existing Prior Notice</b>	▶ Use this feature to find Prior Notices that you have already created. To submit Holding Facility information for a Prior Notice submitted via PNSI by this account or another account within the same company, search for the Prior Notice and click the Submit Holding Facility button.
<b>View/Submit Holding Facility</b>	▶ To submit Holding Facility information for a Prior Notice that has been submitted via the U.S. Customs' and Border Protection (CBP) Automated Commercial System (ACS) or by another PNSI user of a different company click on the View/Submit Holding Facility button.
<b>Manage Favorites</b>	▶ Use this feature to maintain Favorite Facilities that you have already created.

Copyright © 2003-2017 U.S. Food and Drug Administration

Prior Notice v11.2.0, April 28, 2017

0, Thu Jun 01 11:09:01 EDT 2017



[Home](#) | [Contact Us](#) | [Help](#) | [Logoff](#)

Hung Le, PNM1

## 1 Web Entry (Create)

Select the Entry Type for the Web Entry and click on the Next button. Refer to the Help for the descriptions of the entry types.

\*Entry Type:

Copyright © 2003-2017 U.S. Food and Drug Administration  
Prior Notice v11.2.0, April 28, 2017  
0, Thu Jun 01 11:11:05 EDT 2017



### 1 Web Entry (Create)

To create a new Web Entry, enter the information on this page and then click on the Save button. Required items are marked with an asterisk (\*).

#### Entry Information

Enter all Entry Information marked with an asterisk (\*). If you do not have an Entry Identifier, leave the Entry Identifier blank and enable the Not Known checkbox to request the system to assign you one.

\*Entry Identifier:   Not known. (Requests a system-generated identifier.)

\*Entry Type: Consumption

\*How many Prior Notices do you or your company intend to submit for this Web Entry?

#### Port of Arrival

Enter the Port Code for the Port of Arrival and the Arrival Date and Time. Please note if the Arrival Date and Time is in the past then this Date and Time is considered the Actual Date and Time. If the Arrival Date and Time is in the present/future then the Date and Time is considered the Anticipated Arrival Date and Time. The time should be in the time zone of the Port of Arrival. If you do not know the Port Code, select the state and click on the Find Port Code button.

Port:

State:

[Find Port Code](#)

OR \*Port Code:

\*Anticipated Arrival Date:  (MM/DD/YYYY)

\*Anticipated Arrival Time:   (24-hour clock HH:MM)

#### Submitter

The Submitter is the person with knowledge of the required Prior Notice information submitted to FDA. The Transmitter is the person who is logged into the system and who transmits the information either as the Submitter or on behalf of the Submitter. If you are the Submitter, answer Yes to the question below.

Are you the Submitter for this Web Entry?

If you are NOT the Submitter, select the country containing the business location of the Submitter and then click on the Enter Submitter button to provide further information about the Submitter.

\*Country/Area:

[Enter Submitter](#)

#### Importer

Is the Importer the same as the Submitter?

If the Importer is not the same facility as the Submitter, select the country containing the business location of the Importer and click on the Enter Importer button to provide further information about the Importer.

\*Country/Area:

[Enter Importer](#)

#### Carrier

The Carrier is the transporter of the food from the "Country from which the article is shipped" into the United States. Select the applicable Mode of Transportation and then click on the Enter Carrier button to provide information about the Carrier.

\*Mode of Transportation:

[Enter Carrier](#)

[Save](#)

[Cancel](#)



[Home](#) | [Contact Us](#) | [Help](#) | [Logoff](#)

Hung Le, PNM1

[1 Create Web Entry](#) [2 Create Prior Notice](#)

### 1 Web Entry (View)

[Copy](#) [Copy Prior Notice From Another Web Entry](#) [Cancel](#)

This page displays all known information about the Web Entry. You may edit information in the Web Entry or its related facilities by clicking on the appropriate Edit button, if there are no submitted Prior Notices associated with it. To create a new Prior Notice, click on the Create Prior Notice option above.

#### Web Entry

[Edit](#)

Entry Identifier: ###-4-8

Status: Open

Port of Arrival: Washington D.C., DC

Entry Type: Consumption

Anticipated Arrival Date and Time: 06/02/2017 00:01

Number of Intended Prior Notices: 1

#### Submitter

[Edit](#)

Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, Maryland 20903-1058  
UNITED STATES

Registration Number:  
Name: John Doe  
Phone: 999-999-9999  
Fax:  
e-mail: john.doe@.com

#### Importer

[Edit](#)

Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, Maryland 20903-1058  
UNITED STATES

Registration Number:

#### Carrier

The Carrier is the transporter of the food from the "Country from which the article is shipped" into the United States. Select the applicable Mode of Transportation and then click on the Enter Carrier button to provide information about the Carrier.

\*Mode of Transportation:

[Enter Carrier](#)

#### Prior Notices

None available.

[1 Create Web Entry](#) [2 Create Prior Notice](#)



## 2 Prior Notice: Article (Create)

To create a Prior Notice, enter the Article information. You must enter or select a value for each item marked with an asterisk, "\*".

Entry Identifier: ###-4-8

\*Country from which the Article is Shipped:

### Product Information

Enter the exact seven-character Product Code. Use the Search button to find the Product Code. Use "99", meaning "Not Elsewhere Classified", as the last two characters of the Product Code ONLY if a specific code for food does not exist.

\*FDA Product Code:  [Search >>](#)

FDA Product Description: BLUE FISH, Metal, ASEPTIC PACK

\*Common or Usual Name/Market Name:

### Production Identifiers

[Add](#)

Production Identifiers are the Lot Codes, Production Codes, or other identifiers associated with products. The production identifiers are mandatory if the product is required to bear such numbers by the FD&C Act or by FDA regulations. Use the Add and Delete buttons to add or remove Production Identifiers.

### Quantity and Packaging

You may invoke the wizard to build the Quantity and Packaging for this Article by clicking on this button. [Wizard](#)

For packaged food, enter the weight or volume of the smallest (Base) unit. For, example, 16 "ounces, weight (avdp)", if the smallest unit is a 16 oz can. If the product has no packaging, enter the net weight or volume as the Base Unit and check the Bulk-shipment checkbox. The system will ignore all Packaging information if the Bulk-shipment checkbox is checked.

**You must create a separate Prior Notice for each article of food with a different base unit.**

\*Base Unit (Number and Measure):    Bulk-shipment (no packages)

For packaged food, provide the estimated quantity of food that will be shipped, described from the largest container to smallest package size (up to five packaging levels may be provided). For example, 500 Cases, with 40 Cans per Case (The weight of the individual can is the base unit).

	Number	Package Type	
Largest Package to Smallest Package	<input type="text" value="10"/>	<input type="text" value="Box"/>	Total Quantity: 40 Gallons (US)
	<input type="text"/>	<input type="text"/>	<a href="#">Calculate</a>
	<input type="text"/>	<input type="text"/>	
	<input type="text"/>	<input type="text"/>	
	<input type="text"/>	<input type="text"/>	

### Refusal Information

This section only applies if the actual food in this current shipment (not previous shipments of the same food product) has been refused entry by any Country/Area, including the United States.

\*Has this article of food been refused entry by any Country/Area?

Country(s)/Area(s) of Refusal:  
To select more than one country hold the CTRL key and click on the desired countries



[Home](#) | [Contact Us](#) | [Help](#) | [Logoff](#)

Hung Le, PNM1

### 3 Submit Prior Notice?

**Please verify that the information contained within your Web Entry and Prior Notice is correct to the best of your knowledge. After you submit your first Prior Notice, you may no longer edit information in that Prior Notice or the associated Web Entry. Are you sure that you are ready to submit this Prior Notice?**

Transmitter: PNM1

#### Web Entry

Entry Identifier: ###-###-###-8

Status: Open

Port of Arrival: Washington D.C., DC

Anticipated Arrival Date and Time: 06/02/2017 00:01

Entry Type: Consumption

#### Submitter

Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, Maryland 20903-1058  
UNITED STATES

Registration Number:  
Name: John Doe  
Phone: 999-999-9999  
Fax:  
e-mail: john.doe@fda.gov

#### Importer

Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, Maryland 20903-1058  
UNITED STATES

Registration Number:

#### Carrier

Mode of Transportation: Land, Automobile

#### Article

Article Number: 0001

FDA Country of Production: United Kingdom (GB)

Country from which the Article is Shipped: United Kingdom (GB)

#### Product Information

FDA Product Code: 16AEF05

FDA Product Description: BLUE FISH, Metal, ASEPTIC PACK

Common or Usual Name/Market Name: Fish

#### Production Identifiers

#### Quantity and Packaging

Total Quantity: 40 Gallons (US)

Base Unit: 4 Gallons (US)

Packaging from largest to smallest package: 10 Box

#### Refusal Information

Country(s)/Area(s) of Refusal:

#### Related Facilities

##### Manufacturer

Jane Doe Fish Inc  
9999 Some Way

Registration Not Required  
Facility is non-processing fishing vessel (21 CFR 1.226(f))