Regulaciones del FDA para exportar Alimentos a EEUU

Expositor:

Israel Sanguineti

Lima, Diciembre del 2009

Punto de Quiebre

FDA – Nuevas Regulaciones

Mayores controles de las importaciones de alimentos y puntos de desembarque de pasajeros y mercancías

Nuevas leyes y regulaciones:

USA Food And Drug Administration (FDA)

"The Bioterrorism Act of 2002"

Ley de Bioterrorismo

Ley de Seguridad de la Salud Pública y respuesta ante el Bioterrorismo

- Título I: Preparación nacional contra el bioterrorismo y otras emergencias en salud pública
- Título II: Incremento a los controles sobre agentes biológicos peligrosos y toxinas
- **Título III: Protección de la inocuidad y seguridad del suministro de alimentos y medicamentos**
- Título IV: Seguridad y garantía del agua potable
- Título V: Disposiciones adicionales

Titulo III

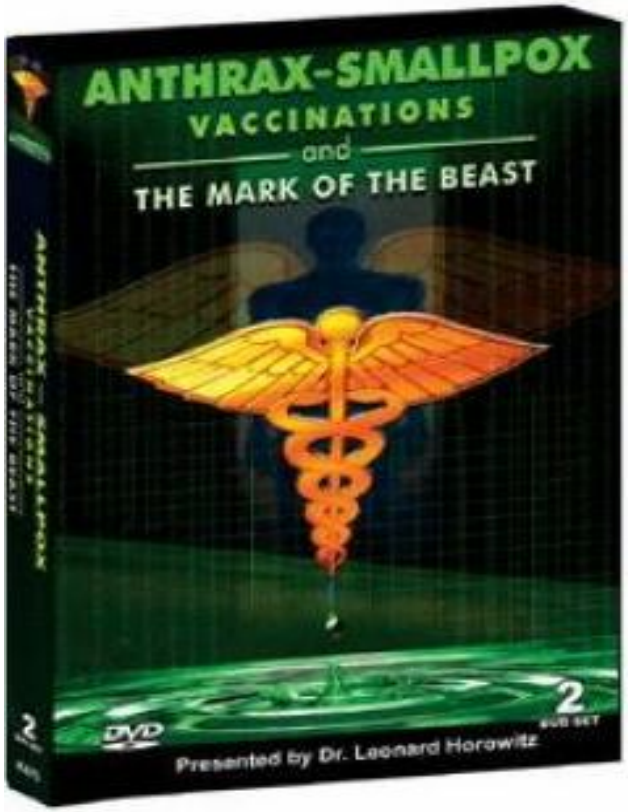
- Detención Administrativa (Sec303)

- **Registro de Instalaciones Alimenticias (Sec305) (Registro de Food Facility . Número de FDA)**

- Establecimiento y Mantenimiento de Registros (Sec306)

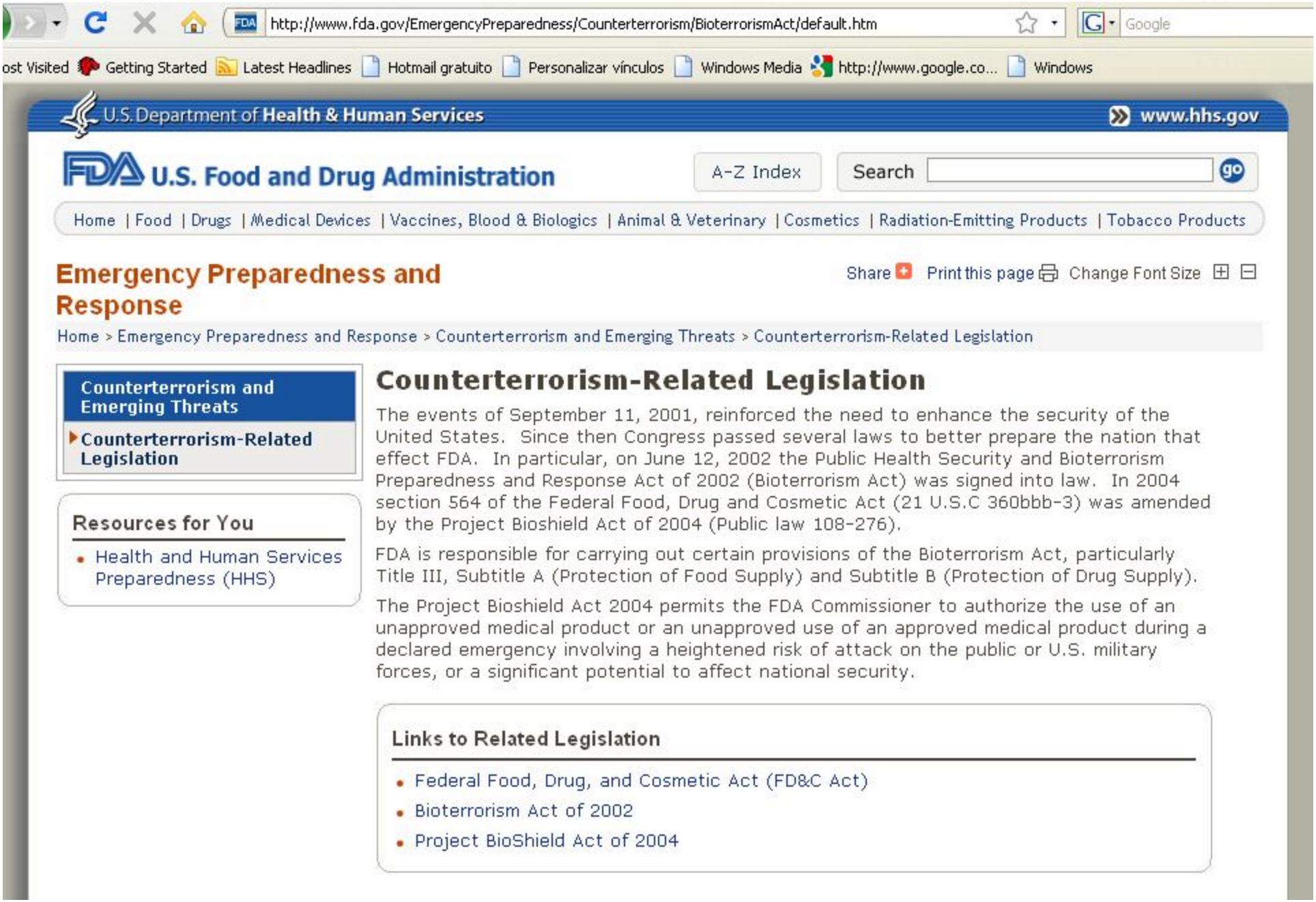
- **Notificación Previa de Alimentos Importados (Sec307) (Prior Notice)**

Bioterrorismo



BIOTERRORISMO:
Empleo criminal de agentes patógenos contra una población con el propósito de generar enfermedad, muerte, pánico y terror.

FDA - Información



Alimentos Regulados

Alimentos:

Definición en la sec. 201 (f) de la Ley Federal de Alimentos, Medicamentos y Cosméticos, se aplica:

(1) Artículos utilizados como comida o bebida para el hombre u otros animales,

(2) goma de mascar, y

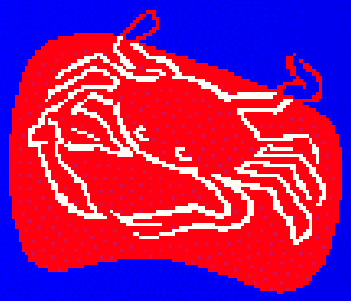
(3) Artículos utilizados como componentes de cualquiera de esos artículos".

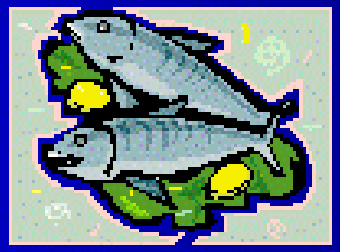
Alimentos Regulados

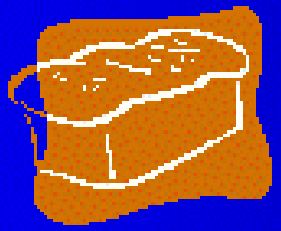
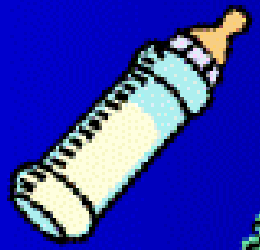
- Pescados y mariscos
- Leche y derivados
- Frutas y vegetales frescos o secos
- Productos de panadería
- Alimentos en conserva
- Refrescos
- Carnes, embutidos
- Huevos
- Cereales, granos y menestras
- Golosinas y confitería
- Bebidas alcohólicas
- Aditivos alimentarios
- Alimento para animales domésticos (inclusive mascotas)
- Café, té, infusiones
- Suplementos

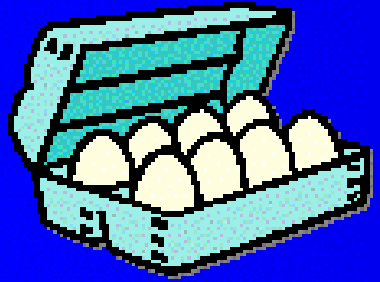
***TODOS AQUELLOS QUE FINALMENTE VAYAN A SER CONSUMIDOS EN EE.UU**

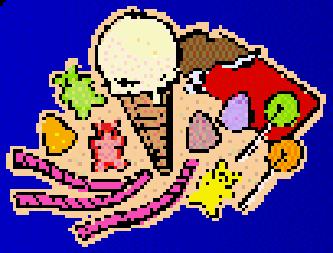
Examples of FDA-Regulated Food









FOOD FACILITY REGISTRATION

Food Facility

Establecimiento o estructura (fábrica, planta, packing, factoría, almacén, etc.) donde se fabrican, manufacturan, procesan, envasan, acondicionan o almacenan alimentos que vayan a ser exportados a EE.UU.

Food Facility

No es una instalación:

- Residencias particulares (garajes, patios, azoteas)
- Campos de cultivo o granjas de cría
- Vehículos de transporte (excepto los barcos-factoría de productos pesqueros)

Food Facility

Para llevar a cabo algunas disposiciones de la Ley de Bioterrorismo, la FDA ha establecido regulaciones que requieren:
Food facilities estén registradas ante la FDA, y la
La notificación con antelación al FDA acerca de los envíos de alimentos.

Los propietarios, operadores o agentes a cargo de instalaciones nacionales o extranjeras que fabrique, procesen, envasen o almacenen alimentos para el consumo en los EE.UU. están obligados a registrar la instalación en la FDA.

Registro de Food Facility

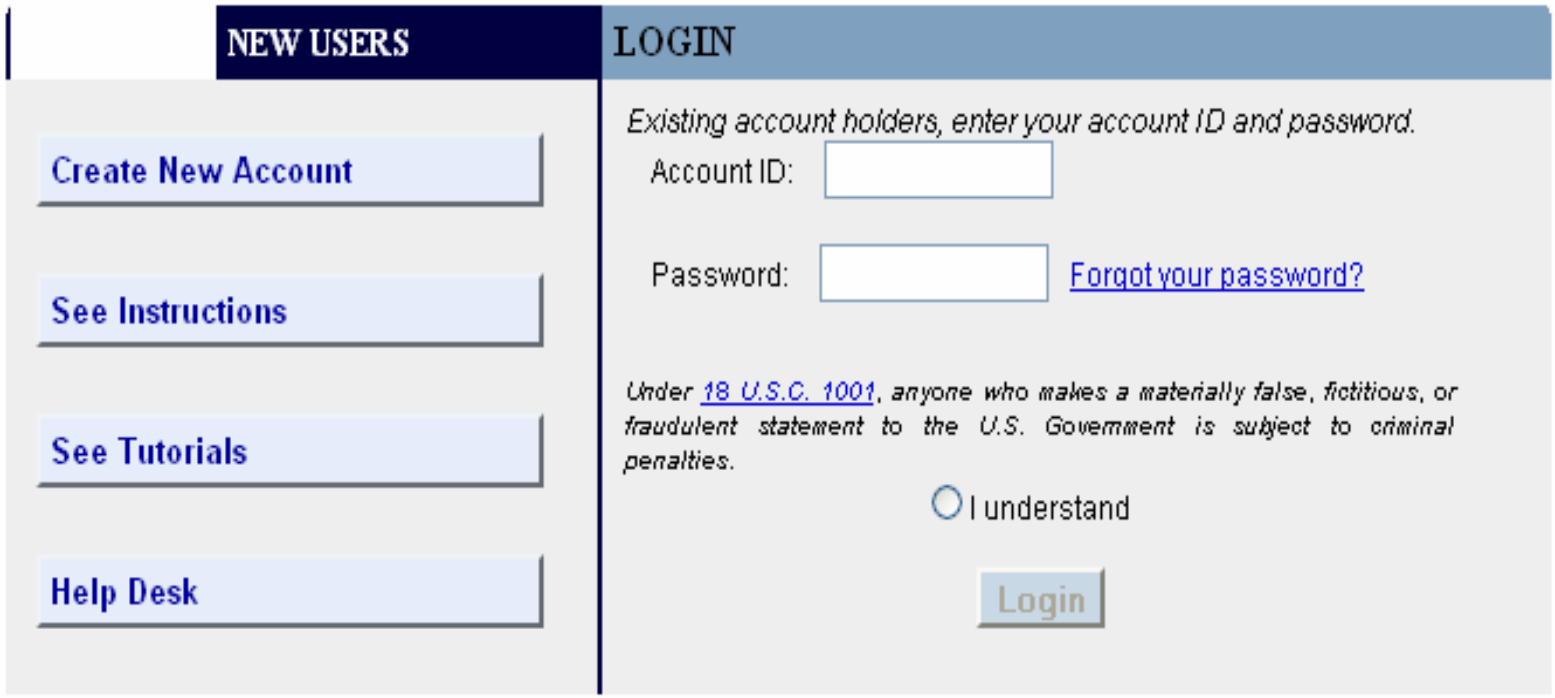
Registro de Food Facility

- **Llenando un formulario electrónico proporcionado por la FDA a través de su página WEB:** www.fda.gov
- **Enviando el formulario escrito por FAX o correo postal a la FDA** (en desuso por las ventajas que ofrece la vía electrónica)

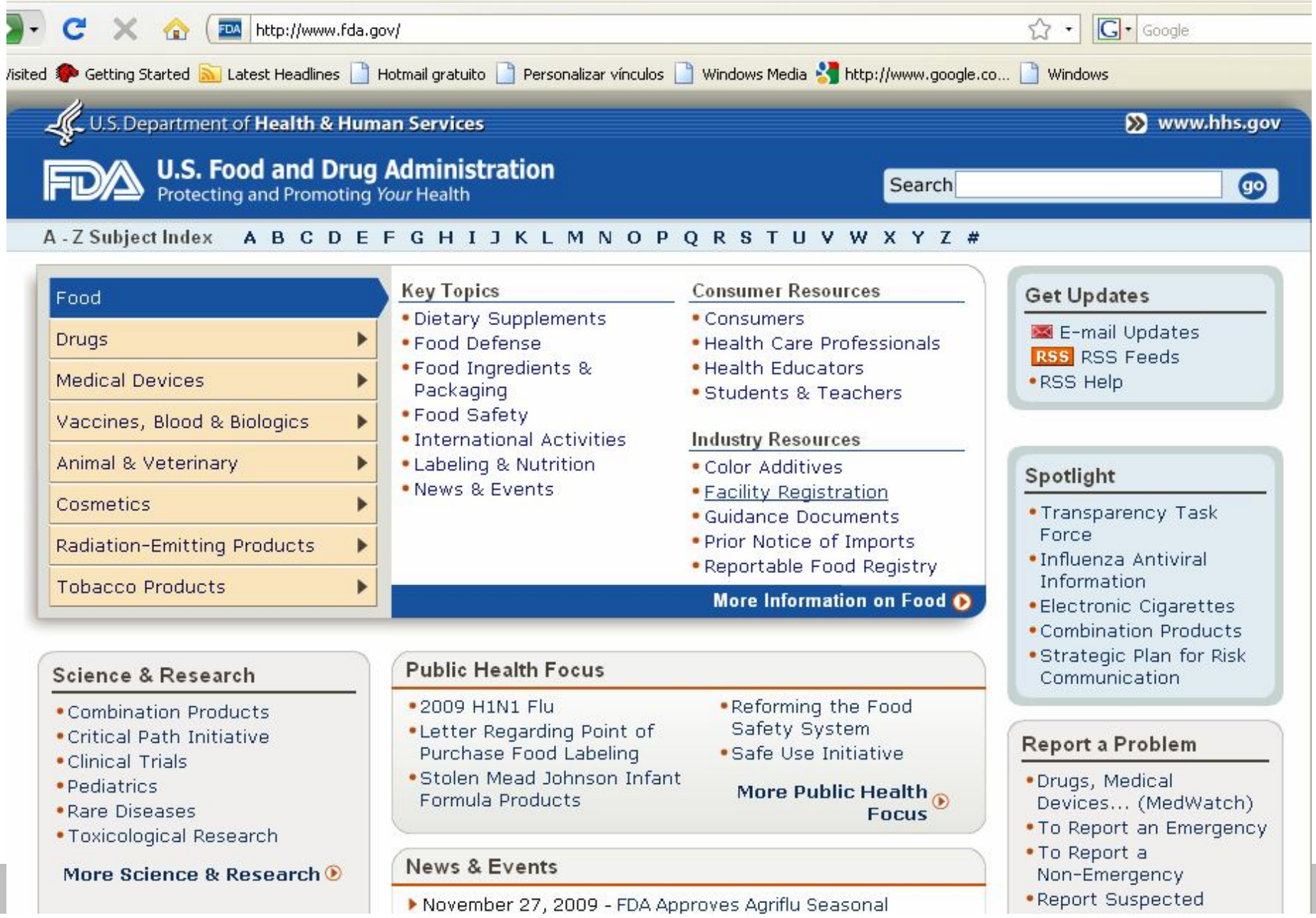
U.S. Food and Drug Administration (HFS-681)
5600 Fishers Lane
Rockville, MD, USA 20857
877 332-3882

Registro de Food Facility

Primero debemos generar una Cuenta FDA en la sección **FDA Industry Systems** de la Página Web de la FDA (https://www.access.fda.gov/oaa/)



Registro de Food Facility



Registro de Food Facility

U.S. Department of Health & Human Services www.hhs.gov

U.S. Food and Drug Administration

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Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Food

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Home > Food > Guidance, Compliance & Regulatory Information > Registration of Food Facilities

Guidance, Compliance & Regulatory Information

- Registration of Food Facilities
  - Registration/Cancellation by Paper (Mail or FAX) or CD-ROM
  - Online Registration

Resources for You

- Compliance Policy Guide - Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Registration of Food Facilities

Login / Create Account
OMB Approval Number: 0910-0502
OMB Expiration Date: 05/31/2010
See OMB Burden Statement.

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.

To carry out certain provisions of the Bioterrorism Act, FDA has established new regulations requiring that:

- Food facilities are registered with FDA, and
- FDA be given advance notice on shipments of imported food.

The Bioterrorism Act requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with the FDA by December 12, 2003.

Owners, operators, or agents in charge of domestic or foreign

Spotlight

- Notice To Industry: Reminder to Update Your Information in the FDA Food Facility Registration Database
- Important FDA Notice Regarding Firms Offering Registration Services
- Register a Food Facility Online Quick Start Guide
- New Features in the Food Facility Registration Module (FFRM)

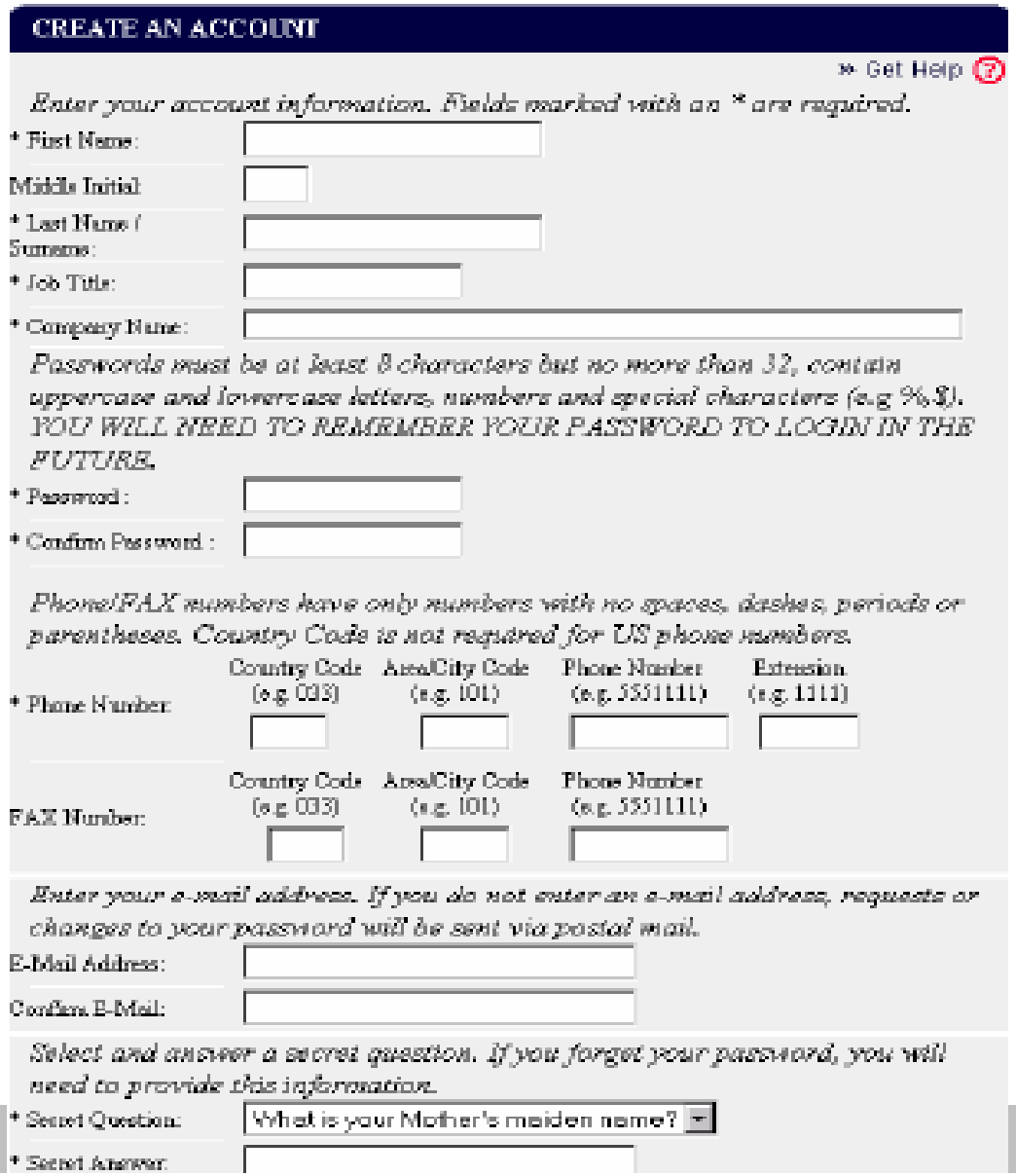
Compliance Info.

- Summary Report of the U.S. Food and Drug Administration's Initial Test of the Accuracy of the Emergency Contact/U.S. Agent Data in the Food

Registro de Food Facility

Registro de Food Facility

Ingreso de Información



CREATE AN ACCOUNT

» Get Help

*Enter your account information. Fields marked with an * are required.*

* First Name:

Middle Initial:

* Last Name / Surname:

* Job Title:

* Company Name:

Passwords must be at least 8 characters but no more than 32, contain uppercase and lowercase letters, numbers and special characters (e.g %,$). YOU WILL NEED TO REMEMBER YOUR PASSWORD TO LOGIN IN THE FUTURE.

* Password :

* Confirm Password :

Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country Code is not required for US phone numbers.

	Country Code (e.g. 033)	Area/City Code (e.g. 101)	Phone Number (e.g. 3331111)	Extension (e.g. 1111)
* Phone Number:				
FAX Number:				

Enter your e-mail address. If you do not enter an e-mail address, requests or changes to your password will be sent via postal mail.

E-Mail Address:

Confirm E-Mail:

Select and answer a secret question. If you forget your password, you will need to provide this information.

* Secret Question: What is your Mother's maiden name?

* Secret Answer:

Registro de Food Facility

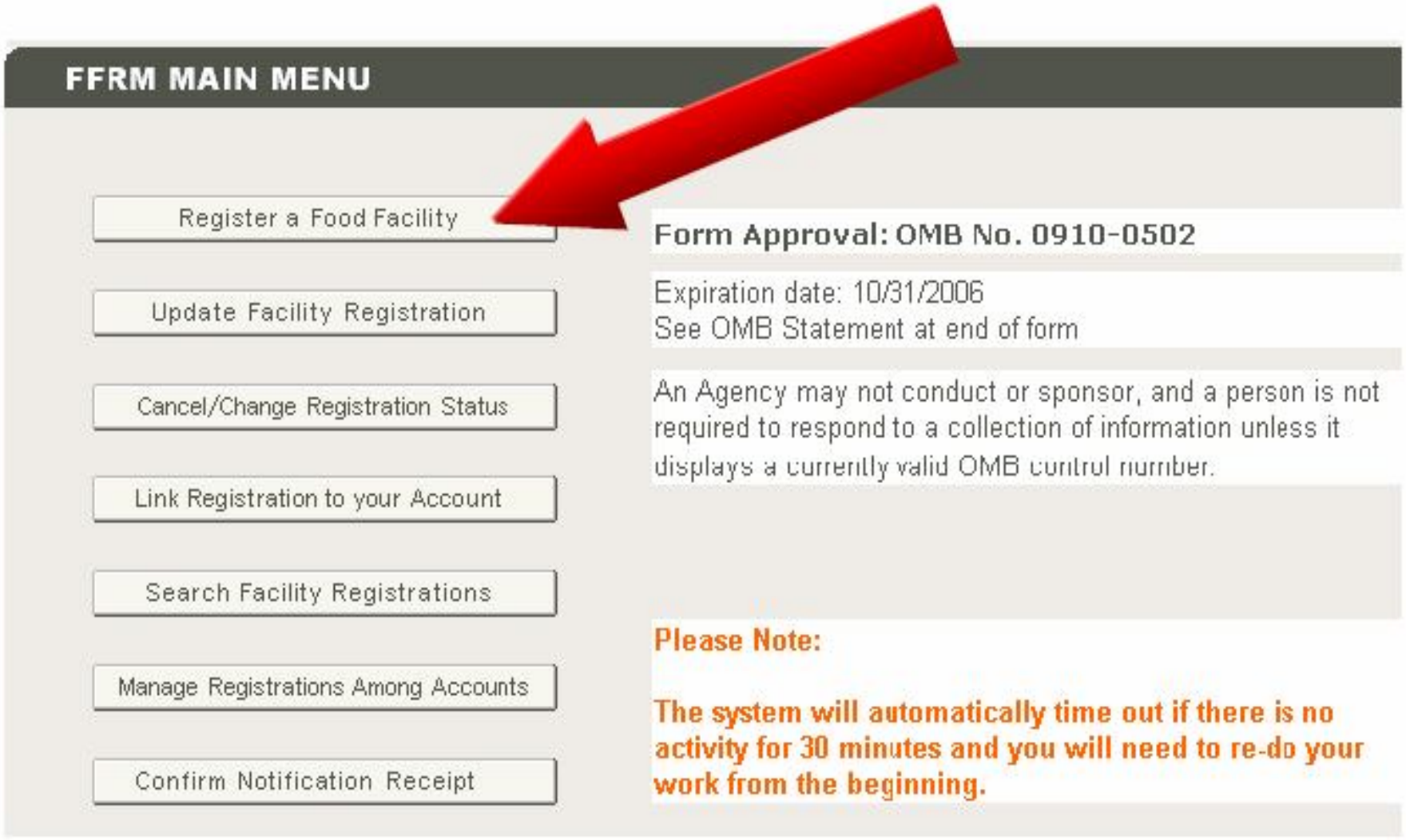
Nuevo usuario

Registro de Food Facility

Ingreso al registro de Instalaciones

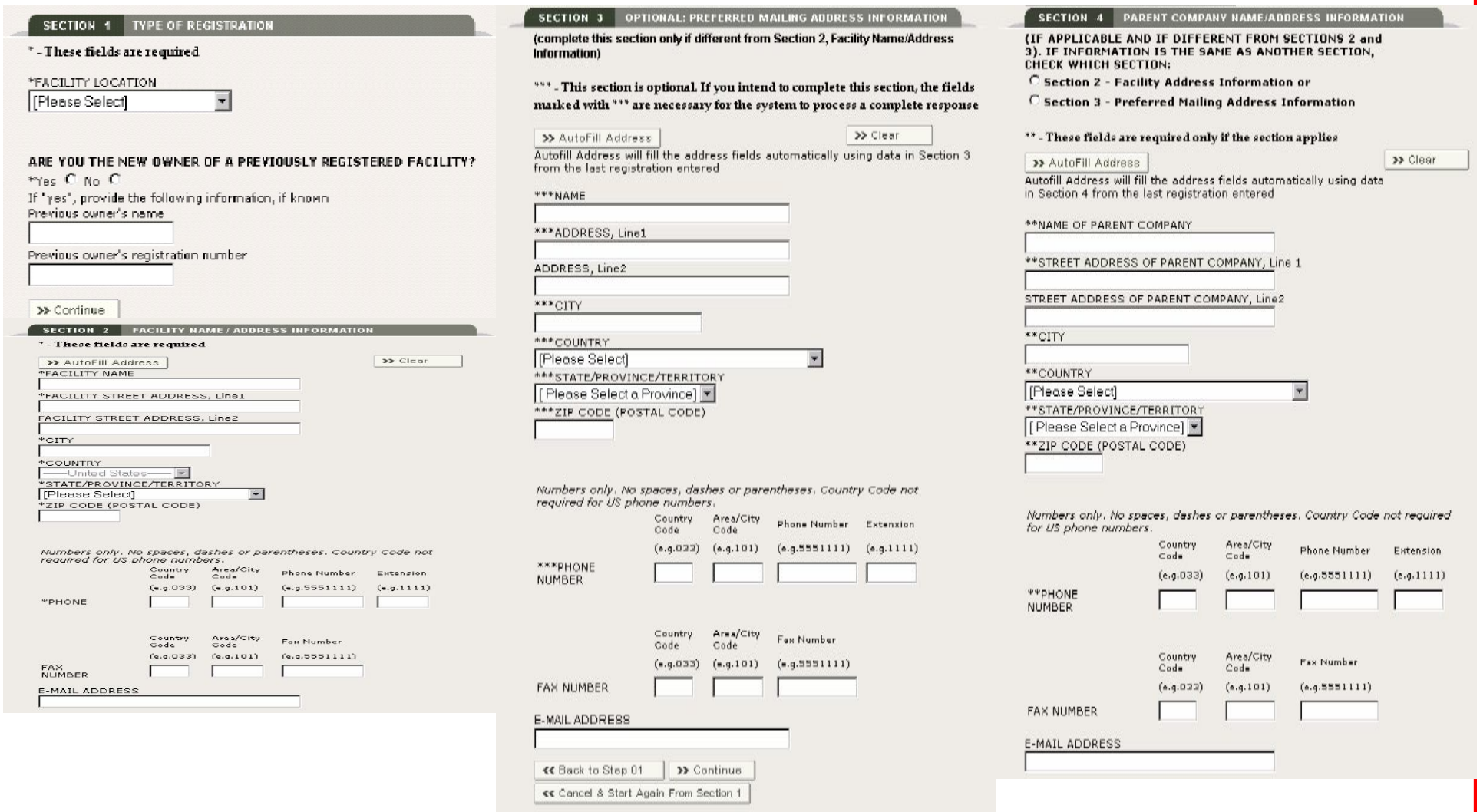
Registro de Food Facility

Ingreso al formulario del registro de Instalaciones



Registro de Food Facility

Completando el Formulario



SECTION 1 TYPE OF REGISTRATION

* - These fields are required

*FACILITY LOCATION
[Please Select]

ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY?
*Yes ○ No ○
If "yes", provide the following information, if known
Previous owner's name
Previous owner's registration number

>> Continue

SECTION 2 FACILITY NAME / ADDRESS INFORMATION

* - These fields are required

>> AutoFill Address >> Clear

*FACILITY NAME
*FACILITY STREET ADDRESS, Line1
FACILITY STREET ADDRESS, Line2
*CITY
*COUNTRY
——United States——
*STATE/PROVINCE/TERRITORY
[Please Select]
*ZIP CODE (POSTAL CODE)

Numbers only, No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
*PHONE				

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER			

E-MAIL ADDRESS

SECTION 3 OPTIONAL: PREFERRED MAILING ADDRESS INFORMATION

(complete this section only if different from Section 2, Facility Name/Address Information)

*** - This section is optional. If you intend to complete this section, the fields marked with "*" are necessary for the system to process a complete response

>> AutoFill Address >> Clear

Autofill Address will fill the address fields automatically using data in Section 3 from the last registration entered

***NAME
***ADDRESS, Line1
ADDRESS, Line2
***CITY
***COUNTRY
[Please Select]
***STATE/PROVINCE/TERRITORY
[Please Select a Province]
***ZIP CODE (POSTAL CODE)

Numbers only, No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
***PHONE NUMBER				

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER			

E-MAIL ADDRESS

<< Back to Step 01 >> Continue
<< Cancel & Start Again From Section 1

SECTION 4 PARENT COMPANY NAME/ADDRESS INFORMATION

(IF APPLICABLE AND IF DIFFERENT FROM SECTIONS 2 and 3). IF INFORMATION IS THE SAME AS ANOTHER SECTION, CHECK WHICH SECTION:

○ Section 2 - Facility Address Information or
○ Section 3 - Preferred Mailing Address Information

** - These fields are required only if the section applies

>> AutoFill Address >> Clear

Autofill Address will fill the address fields automatically using data in Section 4 from the last registration entered

**NAME OF PARENT COMPANY
**STREET ADDRESS OF PARENT COMPANY, Line 1
STREET ADDRESS OF PARENT COMPANY, Line2
**CITY
**COUNTRY
[Please Select]
**STATE/PROVINCE/TERRITORY
[Please Select a Province]
**ZIP CODE (POSTAL CODE)

Numbers only, No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
**PHONE NUMBER				

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER			

E-MAIL ADDRESS

Registro de Food Facility

Completando el Formulario

- Nombre, razón social, dirección y teléfono de la instalación.
- Nombre, dirección, teléfono y correo electrónico del propietario o persona a cargo de la instalación.
- Nombre, dirección, teléfono y correo electrónico del **agente en EE.UU.**
- Tipo de alimento procesado en la instalación (frutas, conservas, especias, etc.).
- Nombre, dirección teléfono y correo electrónico de la persona que llenó el formulario, en caso que el propietario lo haya designado.
- Declaración de autenticidad y exactitud de la información brindada.

Registro de Food Facility

Registro Completo

Prior Notice

U.S. Department of Health & Human Services
HHS.gov

Prior Notice

Es la notificación electrónica enviada al FDA indicando que un artículo alimentario, va a ser importado u ofrecido en los Estados Unidos.

Los prior notices deben ser enviados antes de que los artículos de los alimentos crucen la frontera de los EE.UU.

Prior Notice - Timing

La Notificación Previa del FDA deberá enviarse entre 5 días y:

•**Ocho Horas Antes,** si arribara a EE.UU por vía marítima.

•**Cuatro Horas Antes,** si arribara por vía aérea o férrea.

• **Dos horas antes,** si ingresara por vía terrestre.

Prior Notice

El lanzamiento de prior notices del FDA será de carácter obligatorio para los siguientes productos, además de las exportaciones comerciales:

- Muestras comerciales y regalos.
- Alimentos que transitan a través de EE.UU hacia otro país.
- Alimentos enviados por correo o servicio de Courier.
- Alimentos enviados para análisis de calidad.

Prior Notice

Envíos exentos de notificación previa:

•Muestras de alimentos para análisis fisicoquímicos destructivos o que los imposibilita para un posterior consumo

•Alimentos para consumo personal de los viajeros.

•Alimentos preparados en casa de un viajero o familiares y transportados en el equipaje para obsequiar en EE.UU

Prior Notice

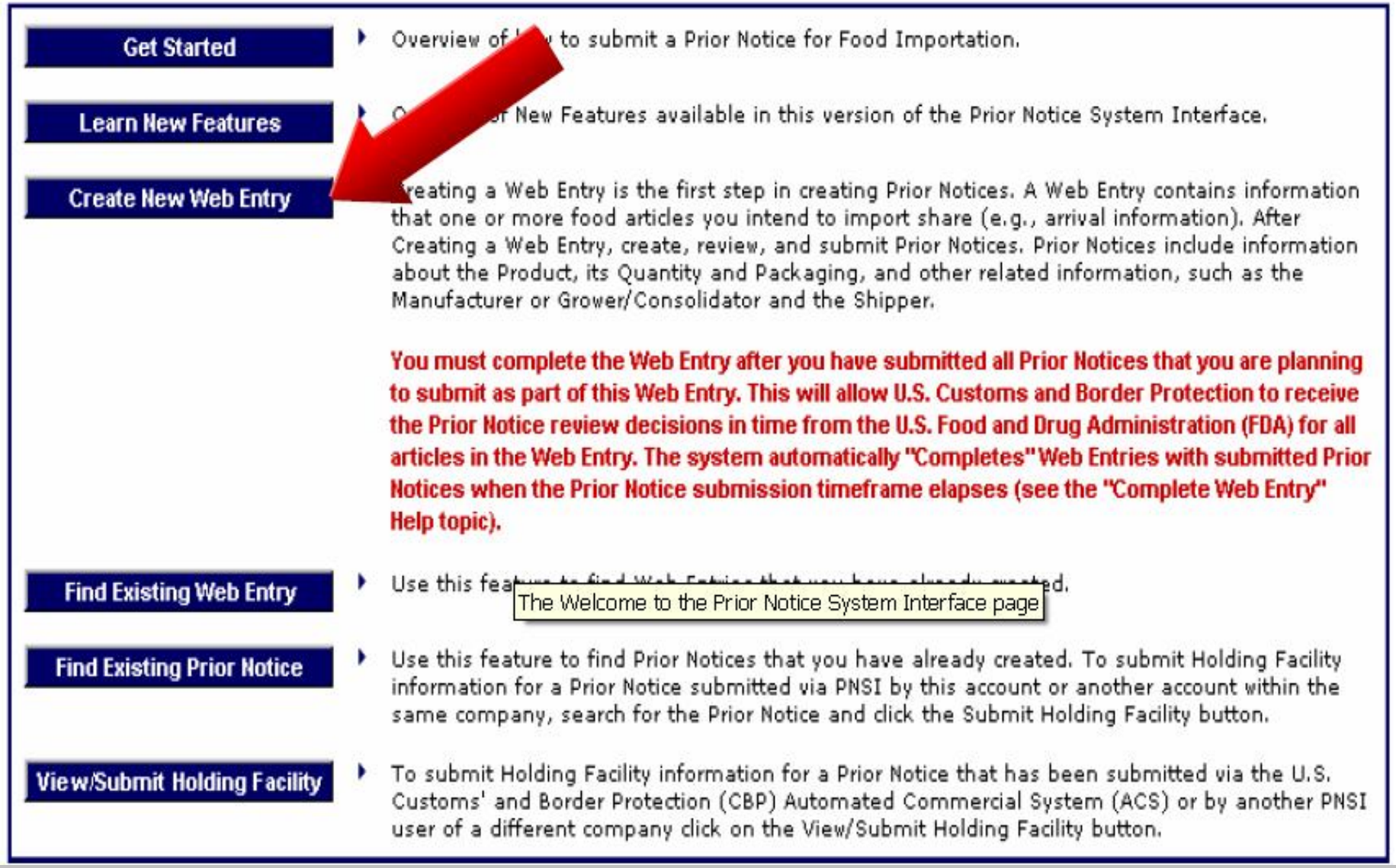
Personas con legitimidad para realizar el lanzamiento de los prior notices:

•Cualquiera de las partes que tenga conocimiento de la información requerida por la FDA (Puede ser el exportador, el importador, el transportista, el agente o inclusive un tercero designado por las partes)

• Es responsabilidad del exportador asegurarse que este trámite se realice.

Prior Notice – Login

Prior Notice



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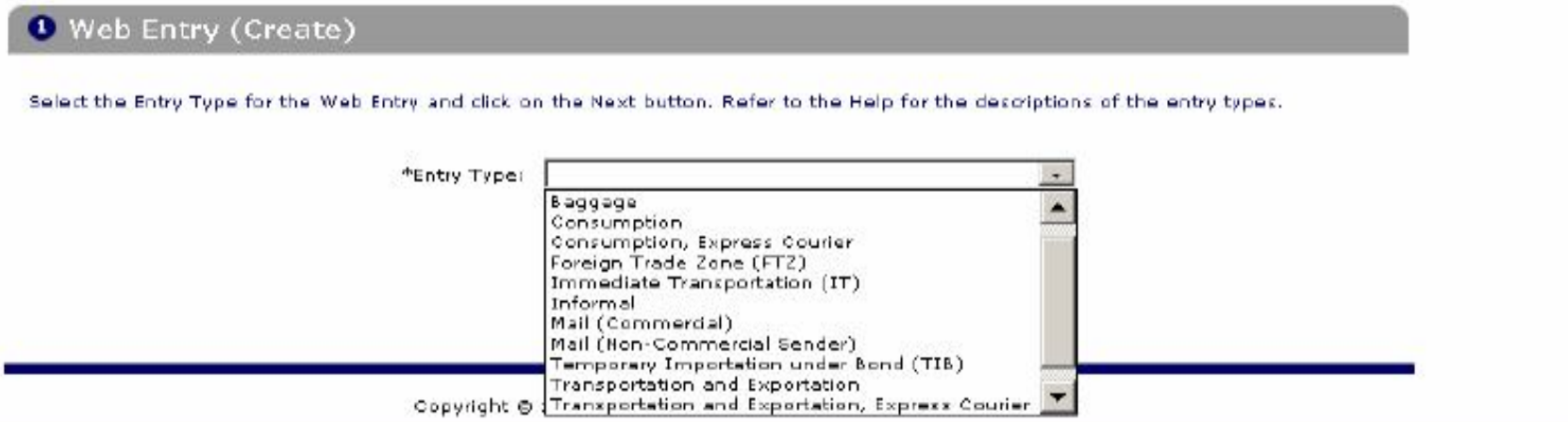

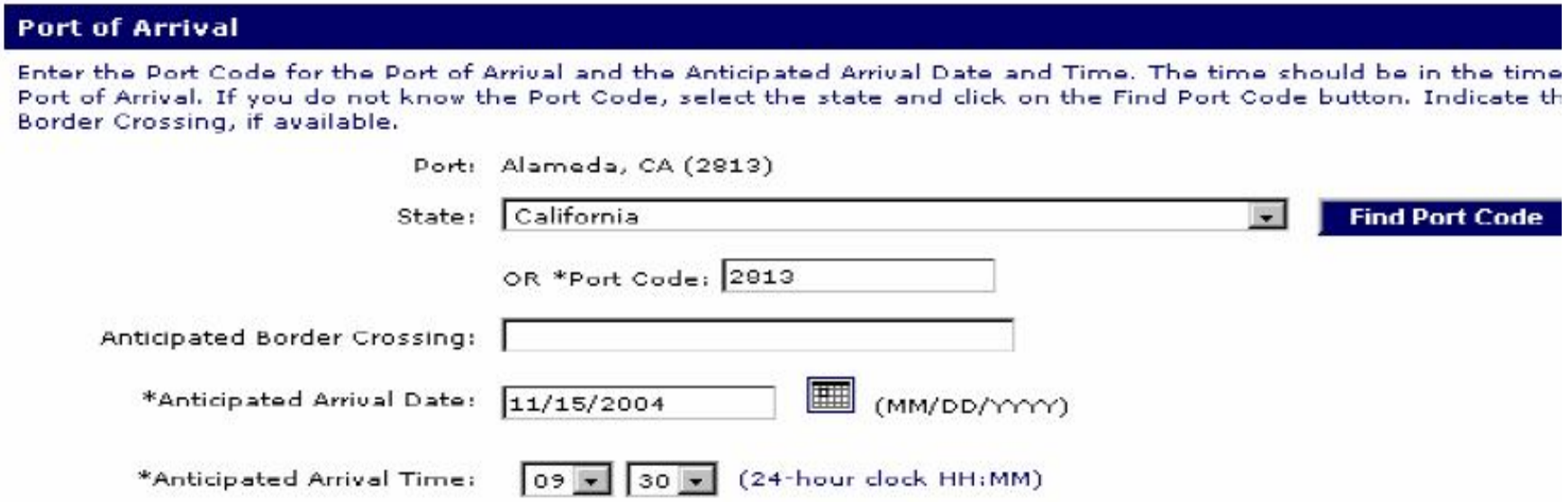

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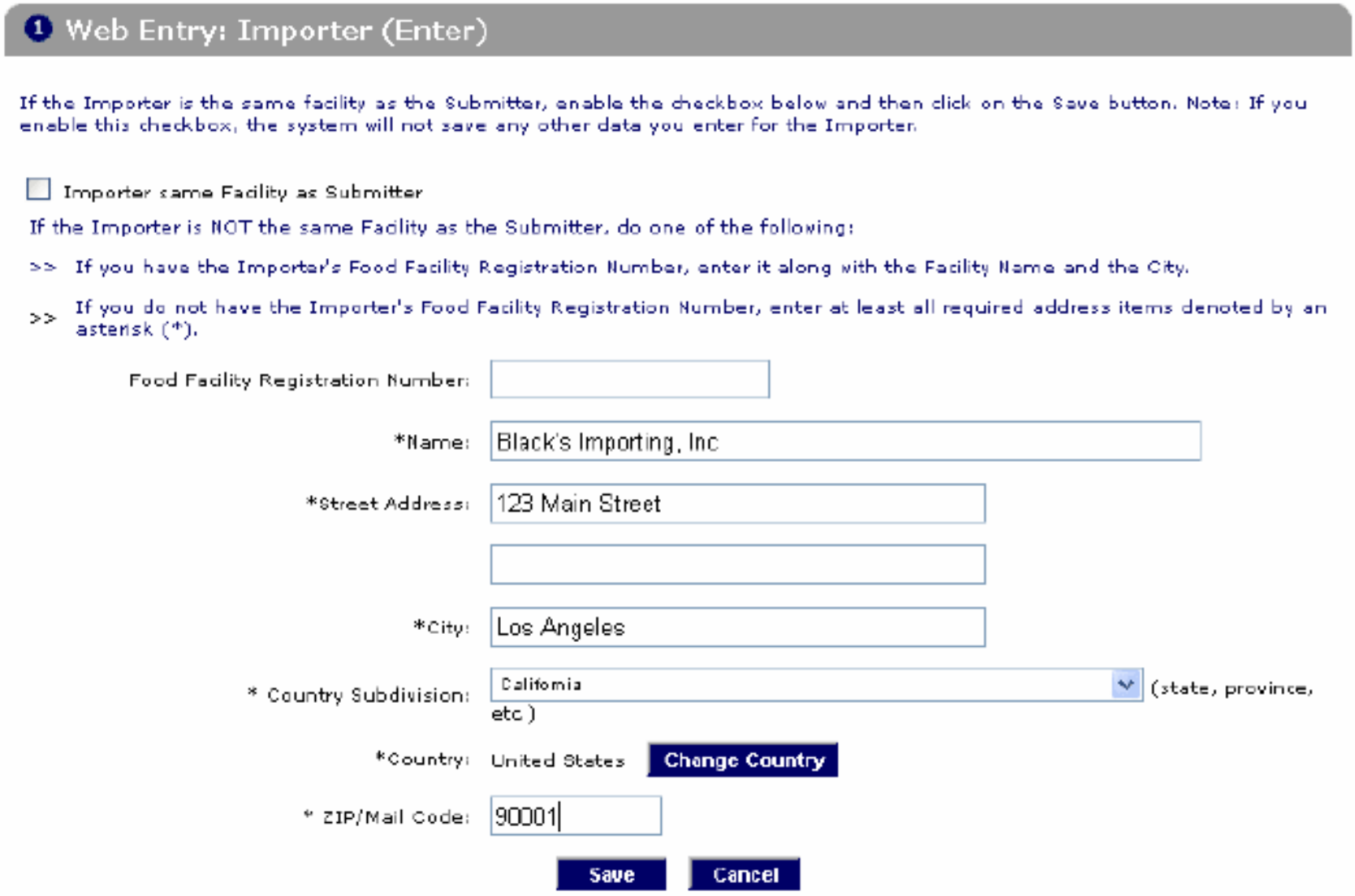

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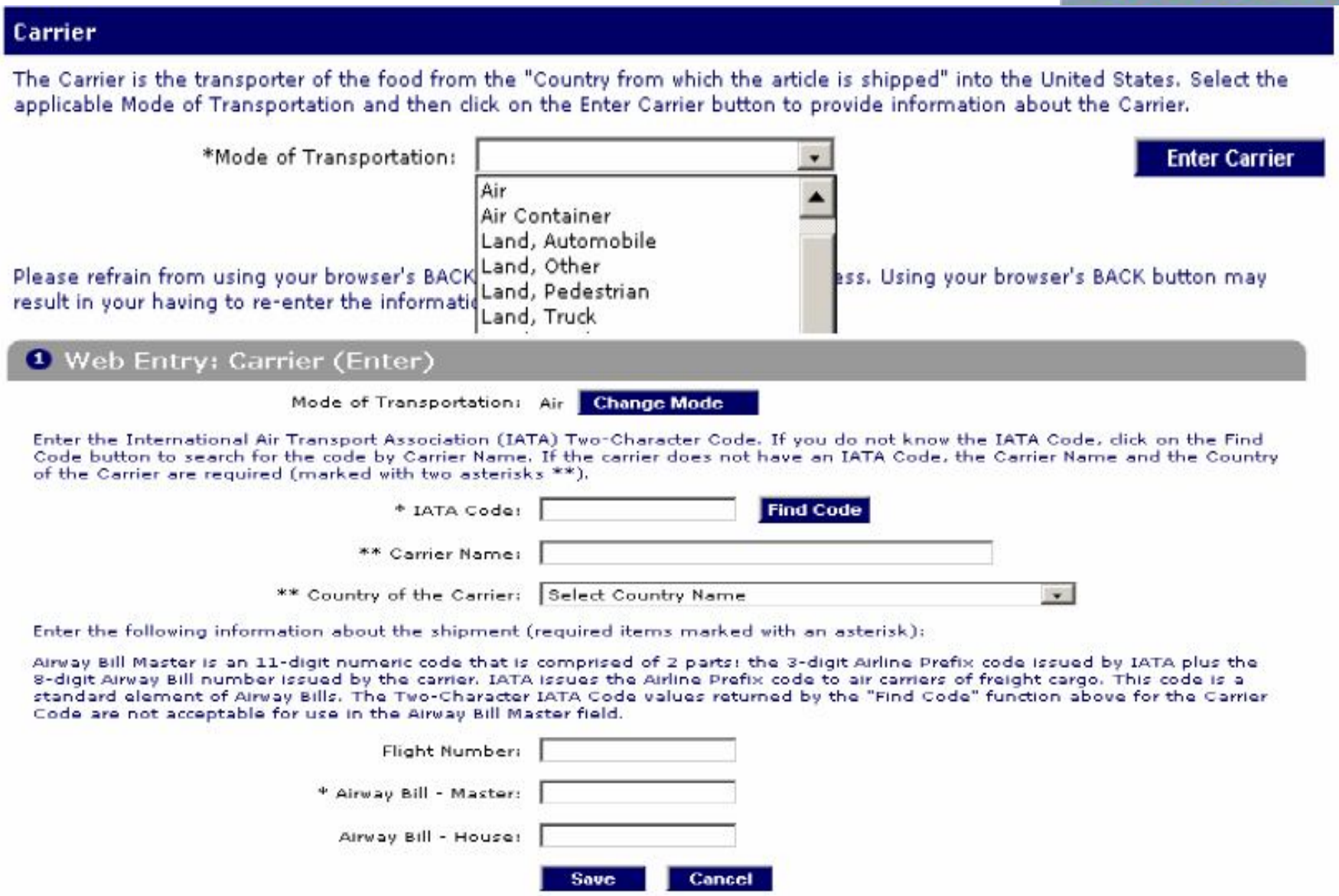
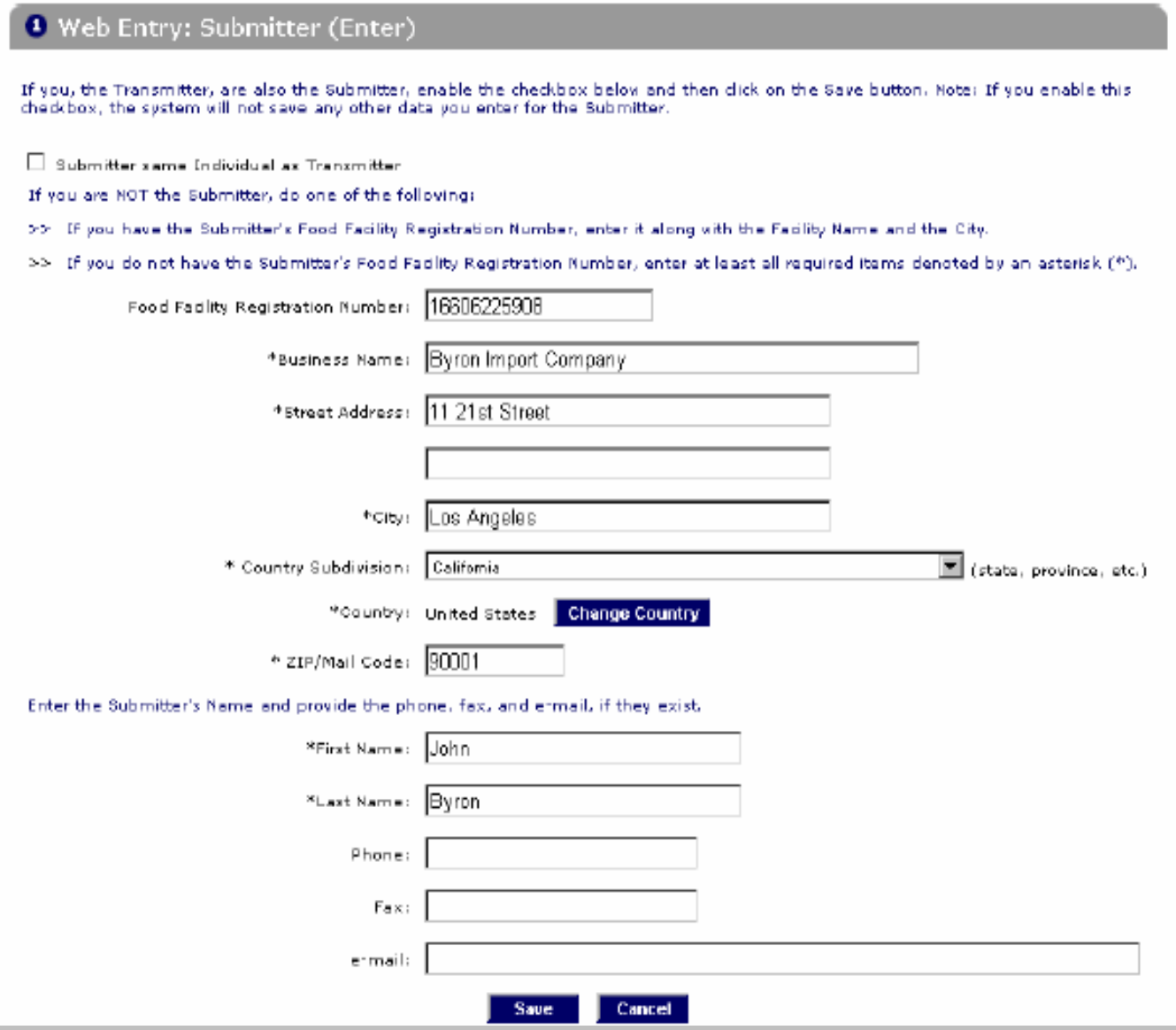


Prior Notice



Web Entry: Submitter (Enter)

If you, the Transmitter, are also the Submitter, enable the checkbox below and then click on the Save button. Note: If you enable this checkbox, the system will not save any other data you enter for the Submitter.

☐ Submitter same Individual as Transmitter

If you are NOT the Submitter, do one of the following:

>> If you have the Submitter's Food Facility Registration Number, enter it along with the Facility Name and the City.

>> If you do not have the Submitter's Food Facility Registration Number, enter at least all required items denoted by an asterisk (*).

Food Facility Registration Number: 16606225908

*Business Name: Byron Import Company

*Street Address: 11 21st Street

*City: Los Angeles

* Country Subdivision: California (state, province, etc.)

*Country: United States Change Country

* ZIP/Mail Code: 90001

Enter the Submitter's Name and provide the phone, fax, and e-mail, if they exist.

*First Name: John

*Last Name: Byron

Phone:

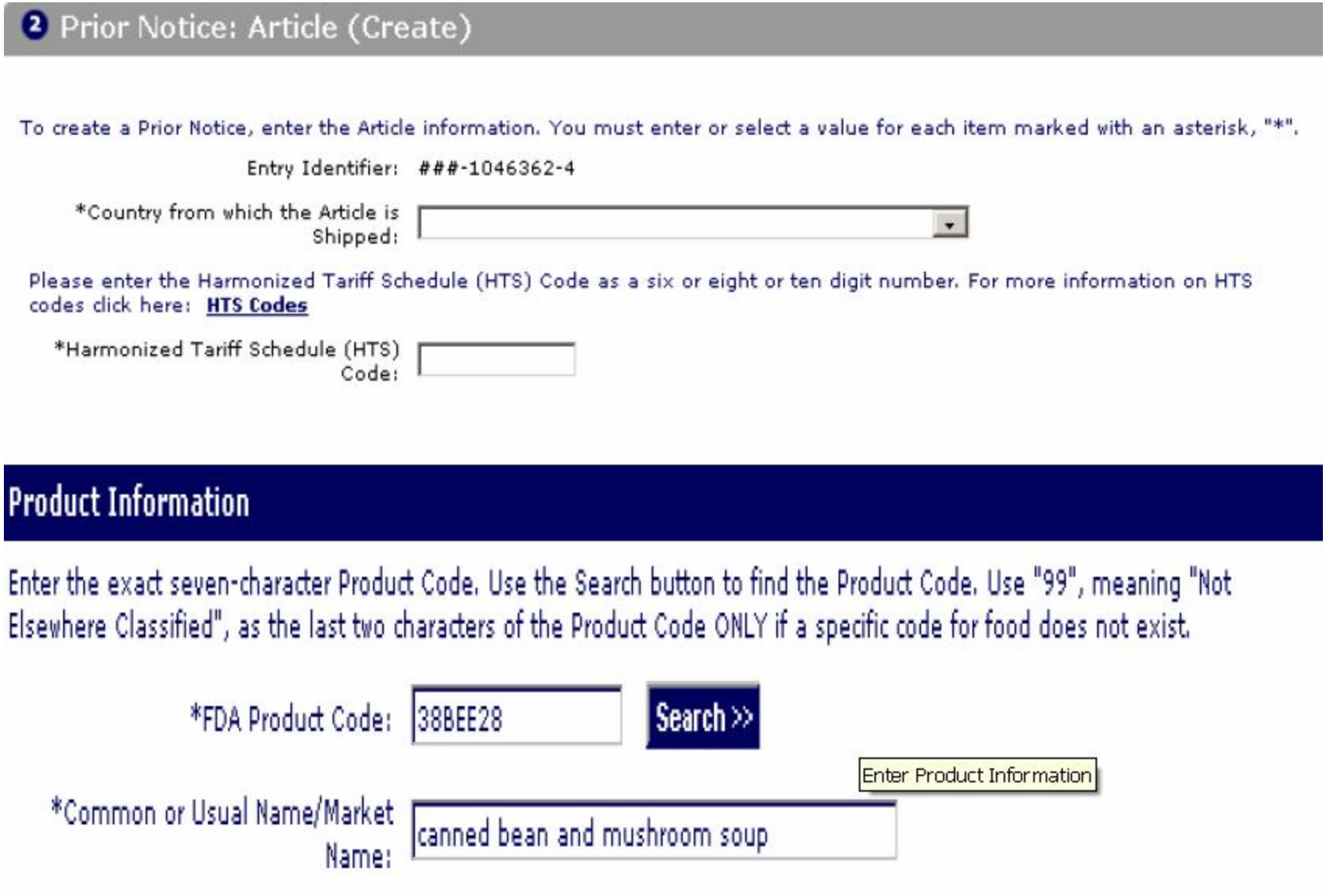
Fax:

e-mail:

Save Cancel

Prior Notice

Prior Notice



Prior Notice

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): 16 Ounces, weight (avdp) ☐ 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	100	Case	Total Quantity: 64,000 Ounces, weight (avdp)
	40	Can, Cylindrical	Calculate

Save Cancel

Prior Notice

Prior Notice

If the Owner is the same Facility as another that you have already entered for this Prior Notice, select the Facility and click on the Save button. (If you do this, the system will ignore any other data you enter for the Owner.)

Owner same Facility as:

Otherwise, do one of the following:

>> If you have the Owner's Food Facility Registration Number, enter it along with the Facility Name and the City.

>> If you do not have the Owner's Food Facility Registration Number, enter at least all required address items denoted by an asterisk (*).

Food Facility Registration Number:

*Name:

*Street Address:

*City:

* Country Subdivision:
(state, province, etc.)

Country: United States (US) Change Country

* ZIP/Mail Code:

Should this Facility be the default Owner for new Prior Notices for this Web Entry? No

Save Cancel

Prior Notice

2 Prior Notice: Shipper (Enter)

If the Shipper is the same Facility as another that you have already entered for this Prior Notice, select the Facility and click on the Save button. Note: If you do this, the system will ignore any other data you enter for the Shipper.

Shipper same Facility as:

Otherwise, do one of the following:

>> If you have the Shipper's Food Facility Registration Number, enter it along with the Facility Name and the City.

>> If you do not have the Shipper's Food Facility Registration Number, enter at least all required address items denoted by an asterisk (*).

Food Facility Registration Number:

*Name:

*Street Address:

*City:

Country Subdivision: (state, province, etc.)

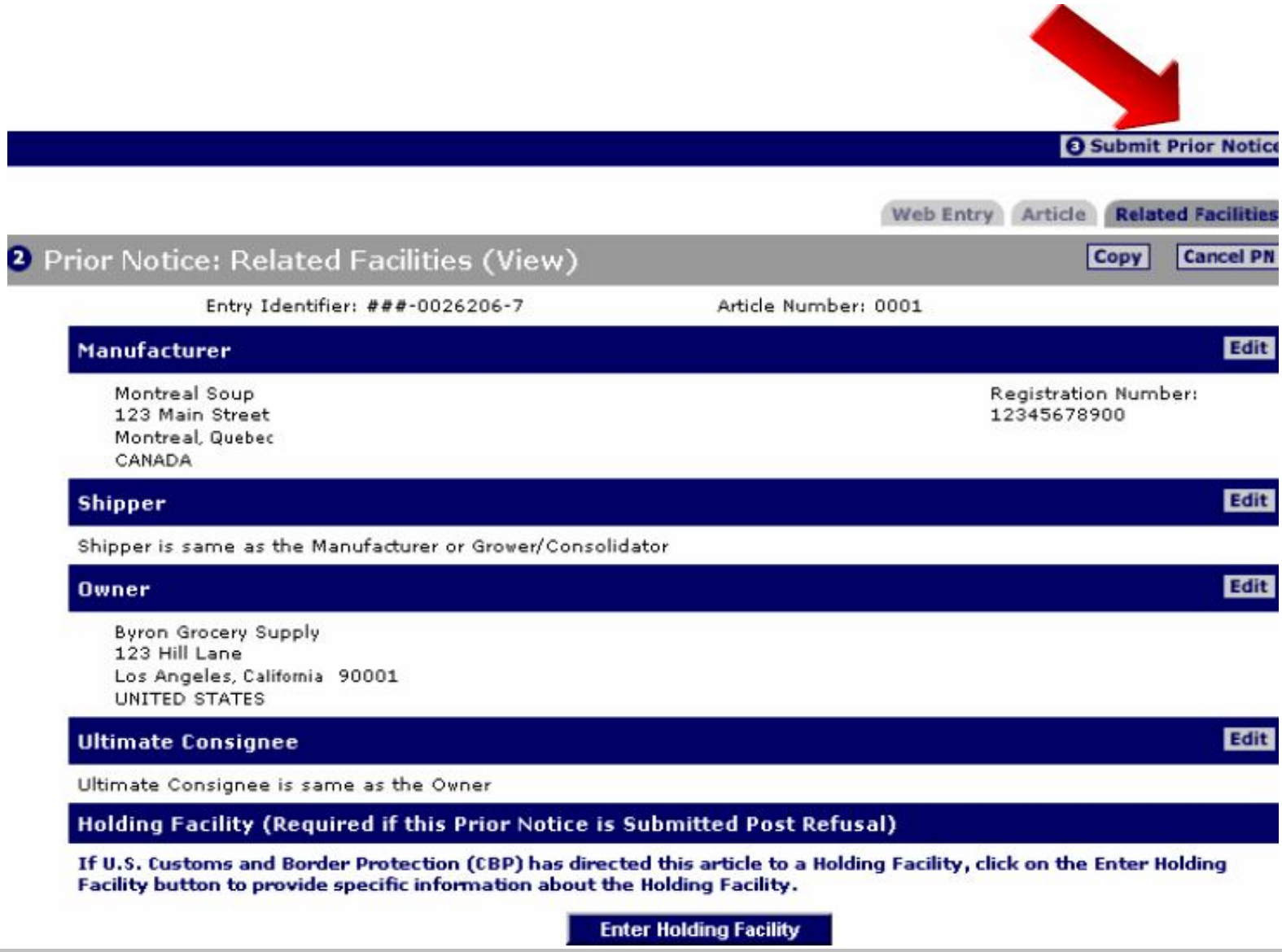
*Country: Canada Change Country

ZIP/Mail Code:

Should this Facility be the default Shipper for new Prior Notices for this Web Entry? No

Save Cancel

Prior Notice



Prior Notice

1 Create Web Entry | 2 Create Prior Notice | 4 Complete Web Entry

You must complete the Web Entry after you have submitted all PriorNotices that you are planning to submit as part of this Web Entry. This will allow U.S. Customs and Border Protection (CBP) 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. Completing the Web Entry indicates that you do not need to submit further Prior Notices for this Web Entry.

The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.[illegible](f)). After you submit all Prior Notices and Complete the Web Entry, it is recommended that you provide a copy of the Web Entry S[illegible] Confirmatio to the Carrier for presentation to U.S. Customs and Border Protection (CBP) or the Food and Drug Administration (FDA) [illegible]Port of Arrival.

Prior Notice: Submitted

View Web Entry | Copy | Cancel PN | Print/Save

Transmitter: CFSAN Tester

Submitted: 11/01/2004 17:35:39

Confirmation Number: 040004979825

Web Entry

Entry Identifier: ###-0026210-1

Status: Open

Port of Arrival: Alameda, CA (2813)

Anticipated Border Crossing:

Anticipated Arrival Date and Time: 11/05/2004 09:30

Entry Type: Consumption

Submitter

Byron Import Company
11 21st Street
Los Angeles, California 90001
UNITED STATES

Registration Number: 16606225908
Name: John Byran
Phone:
Fax:
e-mail:

Importer

Prior Notice

PRIOR NOTICE SYSTEM INTERFACE

Prior Notice Confirmation: Submitted

For your records only.

Transmitter: CHOICE AIR COURIER DEL PERU SAC
Submitted: 06/24/2007 23:29:12
Confirmation Number: 070064333544

WEB ENTRY

Entry Identifier: ###-2598909-3
Status: Completed
Port of Arrival: JFK Airport, Jamaica, NY (4701)
Entry Type: Consumption
Anticipated Arrival: 06/26/2007 07:00

Submitter

COMISION DE PROM DEL PERU PARA LA EXPORT Y EL TURIS PROMPERU
AV. REPUBLICA DE PANAMA NRO. 3655, SAN ISIDRO
LIMA, Lima LIMA 27
PERU

Name: MONICA DAVILA
Phone: 5112210880
e-mail: mdavila@promperu.gob.pe

Importer

ROGERS WORLDWIDE / SUMMER FANCY FOOD SHOW 2007
1550 E. HIGGINS ROAD 106 ELK GRCVE, VILLAGE IL
ILLINOIS, Illinois 60007
UNITED STATES

Carrier

LAN CHILE S.A.
CHILE
Carrier Code (IATA): LA

Mode of Transportation: Air
Flight Number: LA530
Airway Bill - Master: 14526117685

ARTICLE

Article Number: 0001
FDA Country of Production: Peru (PE)
Country from which the Article is Shipped: Peru (PE)
Harmonized Tariff Schedule (HTS) Code: 1905901049

Product Information

FDA Product Code: 03AMY99
FDA Product Description: BREAD/ROLLS/BUNS, N.E.C., MULTIPLE CNTR, NOT ELSEWHERE CLASSIFIED (NEC)
Common or Usual Name/Market Name: ASSORTED PAR-BAKED BREAD CIABATTA, CROISSANT, FRENCH ROLL, ANDALUSIAN BREAD

Production Identifiers

None

Quantity and Packaging

Total Quantity: 90 Kilograms
Base Unit: 10 Kilograms
Packaging from largest to smallest package: 9 Box

Related Facilities

Manufacturer

ARTEMASA SAC
AV. SANTA ANITA 684, CHORRILLOS
LIMA, Lima PERU

Registration Number: 11767440956

Shipper

Shipper is same as the Submitter

Owner

Owner is same as the Importer

Ultimate Consignee

Ultimate Consignee is same as the Importer

Holding Location

Article Not Held

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PRIOR NOTICE SYSTEM INTERFACE

F07X03219347

Web Entry Summary Confirmation

Print this Web Entry Summary Confirmation and present it to U.S. Customs and Border Protection (CBP) or the Food and Drug Administration (FDA) at the Port of Arrival. The Prior Notice Confirmation Number must accompany food carried by or otherwise accompanying an individual (1.279(f)).

WEB ENTRY

Envelope Number: F07X03219347
Entry Type: Consumption
Entry Identifier: ###-2600661-5
Anticipated Arrival: 06/26/2007 07:00
Port of Arrival: JFK Airport, Jamaica, NY (4701)
Mode of Transportation: Air
Number of Intended Prior Notices: 300

Submitter

MONICA DAVILA
COMISION DE PROM DEL PERU PARA LA EXPORT Y EL TURIS PROMPERU
AV. REPUBLICA DE PANAMA NRO. 3655 URB. E, SAN ISIDRO
LIMA, Lima
PERU

Importer

ROGERS WORLDWIDE / SUMMER FANCY FOOD SHOW 2007
1550 E. HIGGINS ROAD 106, ELK GROVE VILLAGE
ILLINOIS, Illinois 60007
UNITED STATES

Carrier

LAN CHILE S.A.
CHILE
Carrier Code (IATA): LA

Flight Number: LA530
Airway Bill - Master: 14526117626

PRIOR NOTICES

Article	Product	Country	HTS	Submitted	Confirmation
0001	ARTICHOQUE BOTTOMS	PE	2005901000	06/25/2007 19:31:37	070064390421
0003	ARTICHOKE HEARTS	PE	2005901000	06/25/2007 19:33:00	070064390480
0006	ARTICHOKE QUARTERS	PE	2005901000	06/25/2007 19:34:19	070064390546
0008	ARTICHOKE HEARTS	PE	2005901000	06/25/2007 19:35:01	070064390583
0012	GREEN ASPARAGUS CUTS AND TIPS	PE	2005600000	06/25/2007 19:35:48	070064390675
0013	GREEN ASPARAGUS SPEARS	PE	2005600000	06/25/2007 19:36:52	070064390723
0014	WHITE ASPARAGUS SPEARS	PE	2005600000	06/25/2007 19:37:41	070064390771
0015	ARTICHOKE HEARTS	PE	2005901000	06/25/2007 19:38:30	070064390830
0016	ANTICHOKE HEARTS ON STEM IN OIL	PE	2001909000	06/25/2007 19:39:22	070064390874
0017	ANTICHOKE HEARTS	PE	2005901000	06/25/2007 19:40:09	070064390900
0018	WHOLE CALIFORNIA WONDER PEPPER	PE	2001909000	06/25/2007 19:40:58	070064390955
0019	CALIFORNIA WONDER PEPPER STRIPS	PE	2005909000	06/25/2007 19:41:45	070064390992
0021	GRILLED WHOLE CALIFORNIA WONDER PEPPER	PE	2005909000	06/25/2007 19:42:36	070064391040
0022	GRILLED EGGPLANT SLICED	PE	2001909000	06/25/2007 19:44:41	070064391132
0023	GRILLED EGGPLANT SLICED	PE	2001909000	06/25/2007 19:45:33	070064391176
0024	GRILLED WHOLE PIQUILLO PEPPER	PE	2005909000	06/25/2007 19:46:26	070064391213
0025	WHOLE PIQUILLO PEPPER	PE	2005909000	06/25/2007 19:47:31	070064391246
0026	WHOLE PIQUILLO PEPPER	PE	2005909000	06/25/2007 19:49:20	070064391316
0027	GRILLED WHOLE CALIFRONIA WONDER PEPPER	PE		06/26/2007 02:04:54	070064400070
0028	GRILLED WHOLE CALIFRONIA WONDER PEPPER	PE		06/26/2007 02:06:09	070064400092
0029	GRILLED WHOLE PIQUILLO PEPPER	PE	2005909000	06/25/2007 19:50:18	070064391364
0030	WHOLE PIQUILLO PEPPER	PE		06/26/2007 02:06:52	070064400103

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FCE

Food Canning Establishment

FCE

Un alimento enlatado low-acid tiene las siguientes características:

1. Equilibrio en el pH de manera que este sea mayor a 4.6 y la actividad de agua mayor que 0.85.
2. Se encuentre sellado dentro de un contenedor hermético (es decir, seguro contra la entrada de microorganismos).
3. Recibe un tratamiento de calor que lo esterilice de manera adecuada para su comercialización.
4. Pueda ser almacenado y distribuido bajo condiciones normales no refrigeradas.

FCE

Deben registrarse con FCE:

Todos las procesadoras de conservas alimenticias localizadas en los Estados Unidos y todas las procesadoras localizadas en el exterior de los EEUU con fines de exportación a USA.

Los importadores, mayoristas, distribuidores, agentes de bolsa, etc. son excluidos de la exigencia del registro. Sin embargo, se deben asegurar que las firmas que ellos representan cumplen con todas las regulaciones aplicables.

FCE

¿CÓMO HACE UNA CASA MATRIZ QUE POSEE UNO O VARIOS PLANTAS PROCESADORAS DE COMIDA?

Un formato de Registro de FCE (FDA format 2541) tendrá que ser presentado para **cada** planta procesadora.

Para cada una le será adjudicado un número distinto de FCE.

FCE

Todas las plantas procesadoras de ácido bajo y acidificados **deben registar sus instalaciones ante la FDA** y recibir un número FCE (Food Canning Establishment).

Información sobre los puntos de obligatorio cumplimiento en el link:
http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods

El formulario para el registro del FCE (FDA Forms 2541a - Registro de Establecimiento de Enlatado) está disponible en el link: www.cfsan.fda.gov/~comm/lacf-toc.html

FCE

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index | Search | go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Food

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Home > Food > Food Safety > Product-Specific Information

- Food Safety
  - Product-Specific Information
    - Acidified & Low-Acid Canned Foods
      - Establishment Registration & Thermal Process Filing
      - Instructions
      - Electronic Submissions

Establishment Registration & Thermal Process Filing

All commercial processors of low-acid and acidified foods located in the United States and all processors in other countries who export low-acid canned food or acidified food products into the United States must register their processing plants with FDA. Wholesalers, importers, distributors, brokers, etc. are not required to register and file processes. **However, they must ensure that processing firms they represent** comply with all registration and process filing requirements.

- Instructions for Establishment Registration and Filing Forms

Forms

- Food Canning Registration (PDF - 378KB)
  Form FDA 2541 (Food Canning Establishment Registration)
- Food Process Filing For All Methods Except Low-Acid Aseptic (PDF - 518KB)
  Form FDA 2541a
- Food Process Filing For Low-Acid Aseptic Systems (PDF)
  Form FDA 2541c

Food Canning Establishment Registration

Public reporting burden for this collection of information is estimated to average .17 hours per response, 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 any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer (HFA-710), 5600 Fishers Lane, Rockville, MD 20857.

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 OMB control number.

FORM APPROVED: OMB No. 0910-0037
EXPIRATION DATE: 8-31-2011

TYPE OF SUBMISSION

- ☐ Initial Registration
- ☐ Relocation *(new registration required)*
- ☐ Change of Registration Information

Specify Type of Change _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FOOD CANNING ESTABLISHMENT REGISTRATION

Enter Current FCE: *(if applicable)* _____

FOR FDA USE ONLY	
FCE No.	Date Received by FDA
OOB Code / Date	District
Reference	

FOOD PROCESSING PLANT LOCATION

Establishment Name _____

Number and Street _____

City and State or Province (or other Subdivision) _____

Zip (or other Postal Code) _____ Country (if other than U.S.) _____

Telephone No. _____ Telefax No. _____

PREFERRED MAILING ADDRESS ☐ Same as Plant Location

Establishment Name _____

Number and Street _____

City and State or Province (or other Subdivision) _____

Zip (or other Postal Code) _____ Country (if other than U.S.) _____

Telephone No. _____ Telefax No. _____

LOW ACID AND/OR ACIDIFIED FOODS PROCESSED AT THIS LOCATION

Food Product name, form or Style, and packing Medium

(Do not list meat and poultry foods under the jurisdiction of the Food Safety and Inspection Service of the U.S. Department of Agriculture)

	(Check One) Low-Acid	Acidified
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

PLEASE NOTE THE FOLLOWING:

- The form 2541 is only accepted through the postal system. Please do not e-mail or fax this form.
- After successfully registering the Food Canning Establishment with this form and the address validation is completed you will be mailed instructions on how to file your processes using our online system.
- Forms, instructions, regulations, and information can also be secured online at http://www.cfsan.fda.gov/~comm/lacf-toc
- For more information contact the LACF Registration Coordinator at (301) 436-2047 or by e-mail at lacf@fda.hhs.gov

See "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods" for guidance in completing this form. Forward completed form to:

Food and Drug Administration
LACF Registration Coordinator (HFS-303)
Center for Food Safety & Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

FACILITY CONTACT PERSON (must be located at a plant location)

Name, Business Address and Position Held at Plant Location: _____

Phone Number: _____ Email Address: _____ Signature: _____ Date: _____

NOTE: No commercial processor shall engage in the processing of low-acid or acidified foods unless completed Forms FDA 2541 and FDA 2541a or FDA 2541c have been filed with the Food and Drug Administration, 21 CFR 108.25(c)(1) and (2) and 108.35(c)(1) and (2).

FORM FDA 2541 (10/08) PREVIOUS EDITION IS OBSOLETE

Food Process Filing for All Methods Except Low – Acid Aceptic

SOLUZIONI

DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ PUBLIC HEALTH SERVICE ■ FOOD AND DRUG ADMINISTRATION

FOOD PROCESS FILING FOR ALL METHODS EXCEPT LOW-ACID ASEPTIC

(Use "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods" accompanying Form FDA 2541a.)

FORM APPROVED: OMB NO. 0910-0037
EXPIRATION DATE: 8/31/2011
See Burden Statement on page 3.

FCE	SID
_ _ _ _ _	2 0 _ _ _ _ / _ _ _ (Y Y Y Y M M D D S S S)

A. PRODUCT

Name, Form or Style, and Packing Medium: ______________________

pH: ___ . __ (Before Acidification) ______________________

Governing Regulation:
- ☐ low-acid (21 CFR 108.35/113)
- ☐ acidified (21 CFR 108.25/114)

Type of Submission:
- ☐ new
- ☐ replaces __ __ – __ __ __ – __ __ __ / __ __ __
- ☐ cancels __ __ – __ __ __ – __ __ __ / __ __ __

Process Use:
- ☐ scheduled
- ☐ alternate for __ __ – __ __ __ – __ __ __ / __ __ __
- ☐ emergency for __ __ – __ __ __ – __ __ __ / __ __ __

B. PROCESSING METHOD

NAME OF STERILIZER (MFR. & TYPE) ______________________

HEATING MEDIUM (e.g., Steam, water, immersion or spray, steam-air) ______________________

1. ☐ Still
   - a. ☐ Horizontal b. ☐ Vertical
   - Divider Plates (complete for a. or b.)
     - ☐ None ☐ Perforated
   - c. ☐ Crateless
   - Bottom Surface (complete for c.)
     - ☐ Solid ☐ Perforated
2. ☐ Agitating
   - a. ☐ End over End
   - ☐ Axial
   - b. ☐ Continuous
   - ☐ Batch
3. ☐ Hydrostatic
   - ☐ Inner Chain only
   - ☐ Outer Chain only
   - ☐ Both Inner and Outer Chain
   - ☐ Single Chain
   - ☐ Multiple Chain
4. ☐ Flame
5. ☐ Other (explain)
6. ☐ Acidified
   - Maximum Equilibrium pH: __ . __
   - Method of Acidification: ______________________
   - Acidifying Agent: ______________________
   - Pasteurization Method: ______________________
   - Preservative Used: ______________________
   - Concentration: __ . __, __ . __, __ . __

CONTAINER TYPE:

1. ☐ Tinplate/Steel Can
2. ☐ Aluminum Can
   - ☐ 2-piece ☐ 3-piece
   - ☐ Welded ☐ Cemented
3. ☐ Glass or Ceramic
4. ☐ Flexible Pouch (specify material):
5. ☐ Semirigid (specify material): Lid ______ Body ______
   - Seal Method ______________________
6. ☐ Other (specify): ______________________

PROCESS ESTABLISHMENT SOURCE *(Limit entry to 30 characters)* ______________________

DATE LAST ESTABLISHED Y Y Y Y M M

PROCESS RECOMMENDATIONS ATTACHED? ☐ YES ☐ NO

C. CRITICAL FACTORS: AS DELINEATED BY PROCESS AUTHORITY TO ASSURE COMMERCIAL STERILITY *(Check or Describe)*

Factor	Code	Entry
None of the following	NO ☐	
Maximum Water Activity (a_w)	MW ☐	(. __ __)
Consistency / Viscosity	CV	
Value		(__ __ __ __ __ . __ __ __)
Units		______
Method Name		______
Temperature		(__ __ __ . __)
Container Position in Retort	CP ☐	______
Nesting of Containers	NC ☐	______
Fill Method (check applicable method)	FM	
Hand or Volumetric	☐	
Vibrating or Tumble	☐	
Other (specify)	☐	______
% Solids	SO ☐	(__ __ . __)
Solid to Liquid Ratio (wt. to wt.)	SL ☐	(__ __ . __)
Drained wt./Net wt. Ratio	DW ☐	(__ . __ __)

Factor	Code	Entry
Arrangements of Pieces in Container	AP ☐	______
Formulation Changes	FC ☐	
Preparation Method	PM ☐	
Product Quality	PQ ☐	
Matting Tendency	MT ☐	
Layer Pack	LP ☐	
Max. Flexible Pouch/Semirigid Container Thickness in Retort	MP ☐	(__ . __ __)
Max. Residual Air (Flexible Pouch/Semirigid Container)	MR ☐	(__ __ . __) c.c.
Particle Size	PS ☐	______
Syrup Strength	SS ☐	(__ __ . __)
Starch Added	SA ☐	
Max. %		(__ __ . __)
Type		______
Other Binder	OB ☐	______
Min. % Moisture of Dry Ingredients	MM ☐	(__ __ . __)
Other (specify)	OT ☐	______

FORM FDA 2541a (10/08) Page 1 PREVIOUS EDITION IS OBSOLETE

NOTE: No commercial processor shall engage in the processing of low-acid or acidified foods unless completed Forms FDA 2541 and FDA 2541a have been filed with the Food and Drug Administration, 21 CFR 108.25(c)(1) and (2) and 108.35(c)(1) and (2).

PSC Graphics: (301) 443-1090 EF

Food Process Filing for Low – Acid Aceptic Systems

DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Food and Drug Administration

FOOD PROCESS FILING FOR LOW-ACID ASEPTIC SYSTEMS

(USE FDA BOOKLET TITLED "ASEPTIC PACKAGING SYSTEM SUPPLEMENT")

(TYPE OR PRINT ALL INFORMATION REQUESTED. IF AN ITEM DOES NOT APPLY ENTER "NA". FILE ACIDIFIED ASEPTIC (pH 4.6 or BELOW) ON FORM 2541a)

NOTE: No commercial processor shall engage in the processing of low-acid foods unless completed Forms FDA 2541 and FDA 2541c have been filed with the Food and Drug Administration, 21 CFR 108.35 (c)(1) and (2).

FORM APPROVED: OMB No. 0910-0037
EXPIRATION DATE: 8/31/2011

FDA USE ONLY

DATE RECEIVED BY FDA

1. FCE _ _ _ _ _

2. ESTABLISHMENT NAME

ADDRESS *(No. and Street)*

CITY | STATE

ZIP (OR OTHER POSTAL CODE) | COUNTRY

3. SID 2 0 _ _ - _ _ - _ _ / _ _ _
(YYYY MM DD SSS)

4. ☐ NEW ☐ CANCELS ☐ REPLACES _ _ _ _ - _ _ - _ _ / _ _ _ (YYYY MM DD SSS)

5. ☐ SCHEDULED ☐ ALTERNATE FOR _ _ _ _ - _ _ - _ _ / _ _ _ (YYYY MM DD SSS)

6. SUP SID 2 0 _ _ - _ _ - _ _ / _ _ _ (YYYY MM DD SSS)

7. PRODUCT NAME, FORM OR STYLE, AND PACKING MEDIUM

8. NAMES OF STERILIZING SYSTEMS

a. Product[1]

b. Packaging

9. PROCESS ORIGIN

No.	Source for 8.a. and 8.b.	Date *(mm/yyyy)*
a.		
b.		

10. CONTAINER TYPE *(Check one)*

a. ☐ Tinplate or Steel Can b. ☐ Aluminum Can c. ☐ Glass

d. ☐ Other *(Specify below and in item 22 if necessary)* _____

11. MAXIMUM WATER ACTIVITY[2]	12. pH		13. MAXIMUM CONSISTENCY OR VISCOSITY IN CENTIPOISES OR APPROPRIATE UNITS					14. SPECIFIC GRAVITY AT 77 ± 2°F	15. INSIDE DIAMETER OF HOLDING TUBE *(inches)*	16. HOLDING TUBE LENGTH *(inches)*
	Normal	Max.[3]	Value at 77±2°F	Value at Other Temp	Other Temp (°F)	Units	Method Name			
0.	.	.	.	.				.	. .	

17. OTHER CRITICAL CONTROL FACTORS *(Check all that apply)*

- 61 ☐ Percent Solids
- 62 ☐ Ratio of Solids to Liquids
- 63 ☐ Syrup Strength
- 66 ☐ Method of Preparation
- 70 ☐ Formulation
- 71 ☐ Rehydration *(specify method in 22)*
- 72 ☐ Particulates *(specify maximum size in 22)*
- 73 ☐ Other *(specify in 22)*

18. CONTAINER DIMENSIONS (Inches and Sixteenths)				19. SCHEDULED PROCESS					20. MAXIMUM FOOD FLOW RATE (gal / min)	21. THRUPUT (containers / minute)
No.	Diameter or Length	Height or Width	Height	Minimum Initial[4] Temp (°F)	Time (sec)	Temp (°F)	Least Sterilizing Value (F_o)[5]	Flow Correction Factor		
1					.		.	.		
2					.		.	.		
3					.		.	.		
4					.		.	.		
5					.		.	.		
6					.		.	.		

FOOTNOTES

1 For steam injection, enter volume increase and thermal expansion factors in 22.

2 If reduced water activity is used as an adjunct to the process, specify the maximum water activity.

3 Where acidification is followed for normally low-acid fruits, vegetables or vegetable products for the purpose of thermal processing, specify the maximum finished product equilibrium pH.

4 If a critical factor is in the process.

5 Or equivalent scientific basis of process adequacy.

22. COMMENTS

AUTHORIZED COMPANY REPRESENTATIVE

NAME *(Type or Print)*	TITLE	
SIGNATURE	DATE	PHONE NO.

FORM FDA 2541c (10/08) PREVIOUS EDITION IS OBSOLETE.

FCE

Una vez concluido el llenado de los formatos, debemos enviar los mismos a:

LACF Registration Coordinator (HFS-618)
Center for Food Safety and Applied Nutrition (FDA)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Into the Trash It Goes

A federal study found that 96.4 billion pounds of edible food was wasted by U.S. retailers, food service businesses and consumers in 1995 — about **1 pound of waste per day** for every adult and child in the nation at that time. That doesn't count food lost on farms and by processors and wholesalers.

For a family of four people, that amounted to about **122 pounds of food thrown out each month** in grocery stores, restaurants, cafeterias and homes. Here is a depiction of that family's monthly share, the sum of waste in eight different food groups as detailed in the study.

Source: United States Department of Agriculture; Census Bureau

BILL MURRIN AND JOAN MURRELL/THE NEW YORK TIMES. PHOTOGRAPH BY TONY CENICOLA/THE NEW YORK TIMES

Muchas Gracias.

isanguineti@soluzioniinternational.com

i_sanguineti@hotmail.com