Seminarios virtuales Miércoles del exportador

Registro ante FDA para exportar alimentos a Estados Unidos.

Lima, 07 de agosto de 2024

Lic. Química – Mag.
Viviana Scotto Z
CEO - VSNITC

vscotto@hotmail.com /
vscotto@vsnitc.com

REQUERIMIENTOS TÉCNICOS DE ACCESO AL MERCADO DE LOS EE.UU.

Son los requisitos establecidos por las instituciones correspondientes del gobierno de los EE.UU., aplicables a todos aquellos productos destinados al consumo humano que se importen a su mercado.


TERRORISMO
BIOTERRORISMO

USO DE MATERIALES BIOLOGICOS COMO ARMA TERRORISTA (BIOTERRORISMO)

Ley contra Bioterrorismo

El 12 de junio del 2002, los Estados Unidos firmó la Ley “Seguridad de la Salud Pública, Preparación y Respuesta contra el Bioterrorismo” o “Ley 107-188”. El Título III está diseñado para proteger al país contra amenazas de bioterrorismo a sus fuentes de alimentación, incluyendo alimentos foráneos. La ley deroga disposiciones a la U.S Food and Drugs Administration (FDA) para que se encargue de su ejecución.

La Ley contra el Bioterrorismo comenzó a regir en los EE.UU. a partir del 2003 y se encuentra destinada a proteger la producción, distribución y venta de alimentos de origen norteamericano e importado, en contra de posibles atentados terroristas. La ley deroga disposiciones a la FDA para que se encargue de su ejecución.

Ley contra Bioterrorismo

Otras previsiones de la Ley que podrán repercutir en el comercio de productos agroalimentarios son las siguientes:

- Autoriza a la FDA a detener cualquier envío de alimentos cuando exista "evidencia creíble" de que puede suponer un riesgo para personas o animales.

- Establece que aquellas personas o entidades que cometan infracciones graves o intenten importar productos que supongan un grave riesgo para la salud sean inhabilitadas para importar en los EEUU durante un plazo de cinco años.

- Requiere que todos los establecimientos, nacionales o extranjeros, que transformen, procesen, envasen o almacenen alimentos con destino a los EEUU estén registradas en la FDA. Pueden hacerlo a través de un sistema de registro vía Internet.

- Requiere que los importadores hagan una notificación previa de los envíos con una antelación mínima.

REGISTRO DE INSTALACIONES ALIMENTARIAS (SECCIÓN 305)

Las instalaciones alimentarias nacionales y extranjeras que fabrican, procesan, envasan, distribuyen, reciben o almacenan alimentos para consumo humano o animal en los Estados Unidos deberán registrarse en la FDA.

¿Quién tiene que registrarse?

- Fabricantes o
- Procesadores
- Empacadores
- Operaciones de almacenamiento

El requisito se aplica a todas las instalaciones, *no a firmas o compañías en Conjunto*

– Ejemplo: una compañía con 10 instalaciones debe registrar de forma individual a cada una de éstas

Ley contra Bioterrorismo

El procedimiento para la aplicación de la presente Ley considera cuatro secciones:

- Registro de instalaciones de Alimentos - Sección 305 (http://www.cfsan.fda.gov/~dms/fsbtact.html#pn)
- Notificación Previa para Embarques de Alimentos Importados – Sección 307
- Detección administrativa – Sección 303
- Mantenimiento e inspección de Registros de Alimentos – Sección 306

REGISTRO DE INSTALACIONES ALIMENTARIAS (SECCIÓN 305)

Se recomienda que el registro se haga a través de nuestra página Web (**http://www.access.fda.gov**)

- El Registro es gratis
- Se requiere contar con un agente en los EE. UU.
- Una vez que el establecimiento se registra, no se requiere un registro nuevo a menos que la firma se mude o cambie de dueño.
- Para un cambio de dueño, incluso para una fusión de empresas, o cambio de dirección, se necesita cancelar el registro y someter uno nuevo.

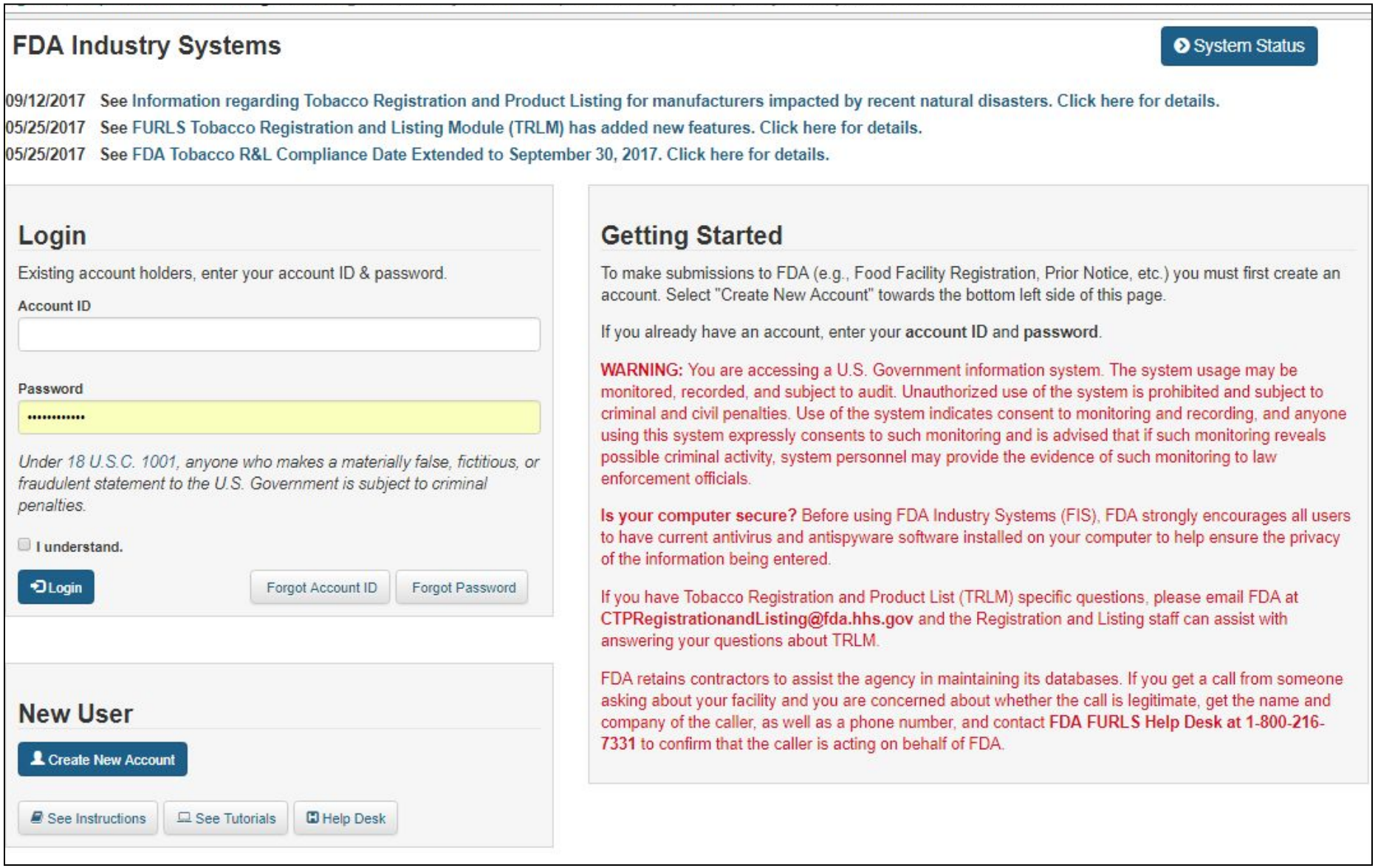
REGISTRO DE INSTALACIONES ALIMENTARIAS (SECCIÓN 305)

¿Como registrarse?

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

Registration of Food Facilities Step-by-Step Instructions
October 2003
Return to Online Registration[1]
Table of Contents

REGISTRO DE INSTALACIONES ALIMENTARIAS (SECCIÓN 305) – CREACION DE CUENTA


FDA Industry Systems
System Status
09/12/2017 See Information regarding Tobacco Registration and Product Listing for manufacturers impacted by recent natural disasters. Click here for details.
05/25/2017 See FURLS Tobacco Registration and Listing Module (TRLM) has added new features. Click here for details.
05/25/2017 See FDA Tobacco R&L Compliance Date Extended to September 30, 2017. Click here for details.
Login
Existing account holders, enter your account ID & password.
Account ID
Password
Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.
I understand.
Login
Forgot Account ID
Forgot Password
New User
Create New Account
See Instructions
See Tutorials
Help Desk
Getting Started
To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.
If you already have an account, enter your account ID and password.
WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.
Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.
If you have Tobacco Registration and Product List (TRLM) specific questions, please email FDA at CTPRegistrationandListing@fda.hhs.gov and the Registration and Listing staff can assist with answering your questions about TRLM.
FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact FDA FURLS Help Desk at 1-800-216-7331 to confirm that the caller is acting on behalf of FDA.

OAA | ADMINISTRATION (OAA)

Account Management

Account Management

- Edit Account Profile
- Change My Password
- Update System Access
- Create a Subaccount
- Deactivate a Subaccount
- Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as **ade58799** for **ADEX.**

You may choose an option on the left to manage your account or select an FDA system below.
To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

Registration and Listing Programs

Food

- [x] Food Facility Registration
- [x] Export Listing Module
- [x] Acidified/Low-Acid Canned Foods Registration and Process Filing
- [ ] Qualified Facility Attestation
- [ ] Shell Egg Producer Registration

Export Certification and Tracking

- [ ] Biologics Export Certification Application and Tracking System (BECATS)
- [ ] CDER Export Certification Application and Tracking System (CDER eCATS)
- [ ] CDRH Export Certification Application and Tracking System (CECATS)
- [x] CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
- [ ] CVM Export Certification Application and Tracking System (CVM eCATS)

FSMA Program(s)

- [ ] Accredited Third-Party Certification Program-- **Accreditation Body**
- [ ] Laboratory Accreditation for Analyses of Foods Program-- **Accreditation Body**
- [ ] Accredited Third-Party Certification Program--
- [ ] Laboratory Accreditation for Analyses of Foods Program--

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand.

Login | Forgot Account ID | Forgot Password

New User

Create New Account

See Instructions | See Tutorials | Help Desk

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government-authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
Contact FDA

OAA | ADMINISTRATION (OAA)

Create New Account

Create New Account

You must create a separate account to create your Medical Device Registration and Listing or Food Facility.

Step 1: Select Application(s) for Account Creation

Do you conduct work for a State Agency under Contract with the FDA?

If you are creating an account on behalf of a manufacturer, please select "No."

○ Yes ◉ No

Registration and Listing Programs

Food

- ☐ Acidified/Low-Acid Canned Foods Registration and Process Filing
- ☐ Food Facility Registration
- ☐ Qualified Facility Attestation
- ☐ Export Listing Module
- ☐ Shell Egg Producer Registration

Medical Devices

- ☐ Device Registration and Listing Module

Export Certification and Tracking

- ☐ Biologics Export Certification Application and Tracking System (BECATS)
- ☐ CDRH Export Certification Application and Tracking System (CECATS)
- ☐ CVM Export Certification Application and Tracking System (CVM eCATS)
- ☐ CDER Export Certification Application and Tracking System (CDER eCATS)
- ☐ CFSAN Export Certification Application and Tracking System (CFSAN eCATS)

Includes FDA-regulated food and cosmetics.

FSMA Program(s)

☐ Qualified Facility Attestation

Medical Devices

☐ Device Registration and Listing Module

Export Certification and Tracking

☐ Biologics Export Certification Application and Tracking System (BECATS)

☐ CDRH Export Certification Application and Tracking System (CECATS)

☐ CVM Export Certification Application and Tracking System (CVM eCATS)

☐ CDER Export Certification Application and Tracking System (CDER eCATS)

☐ CFSAN Export Certification Application and Tracking System (CFSAN eCATS)

Includes FDA-regulated food and cosmetics.

FSMA Program(s)

- ☐ Accredited Third-Party Certification Program-- Accreditation Body

Check this box if you are an AB and are submitting an application for FDA recognition.

- ☐ Accredited Third-Party Certification Program-- Certification Body

Check this box if you are a CB who needs to create an account. You must have a verification code to complete your account setup. FDA will send you the verification code via email after you have been accredited by a recognized AB.

- ☐ FSVP Importer Portal for FSVP Records Submission

Check this box if you are an FSVP importer who needs to use a secure portal to submit FSVP records requested by FDA.

- ☐ Laboratory Accreditation for Analyses of Foods Program-- Accreditation Body

Check this box if you are an AB and are submitting an application for FDA recognition.

- ☐ Laboratory Accreditation for Analyses of Foods Program-- Accredited Lab

Check this box if you are an accredited lab and are creating an account. You must have a verification code to complete your account setup. FDA will send you the verification code via email after you have been accredited by a recognized LAAF AB.

- ☐ Voluntary Qualified Importer Program

Other FDA Systems

- ☐ Prior Notice System Interface
- ☐ Import Trade Auxiliary Communication System (ITACS)
- ☐ CBER Biological Product Deviation Reporting (CBER eBPDR)

Cancel | Clear | Continue

Edit Account Profile

Review Account Information.

Account Information

First Name
ANA

Middle Initial

Last Name / Surname
xxxxxxxxxxxx

Title
MANAGER

Company Name
SAC

Web Address

Phone Number
051 1 111111111

FAX Number

E-mail Address
XXXXX@hotmail.com

Secret Question 1
What is your year of birth?

Secret Answer 1
January 18th

Secret Question 2
What was your high school mascot?

Secret Answer 2
PRADO

Physical Address (Business) of Account Holder

Address Line 1
xxxxxxxxxxxxxx

Address Line 2

City
LIMA

State / Province / Territory
Lima

Zip Code (Postal Code)
LIMA 27

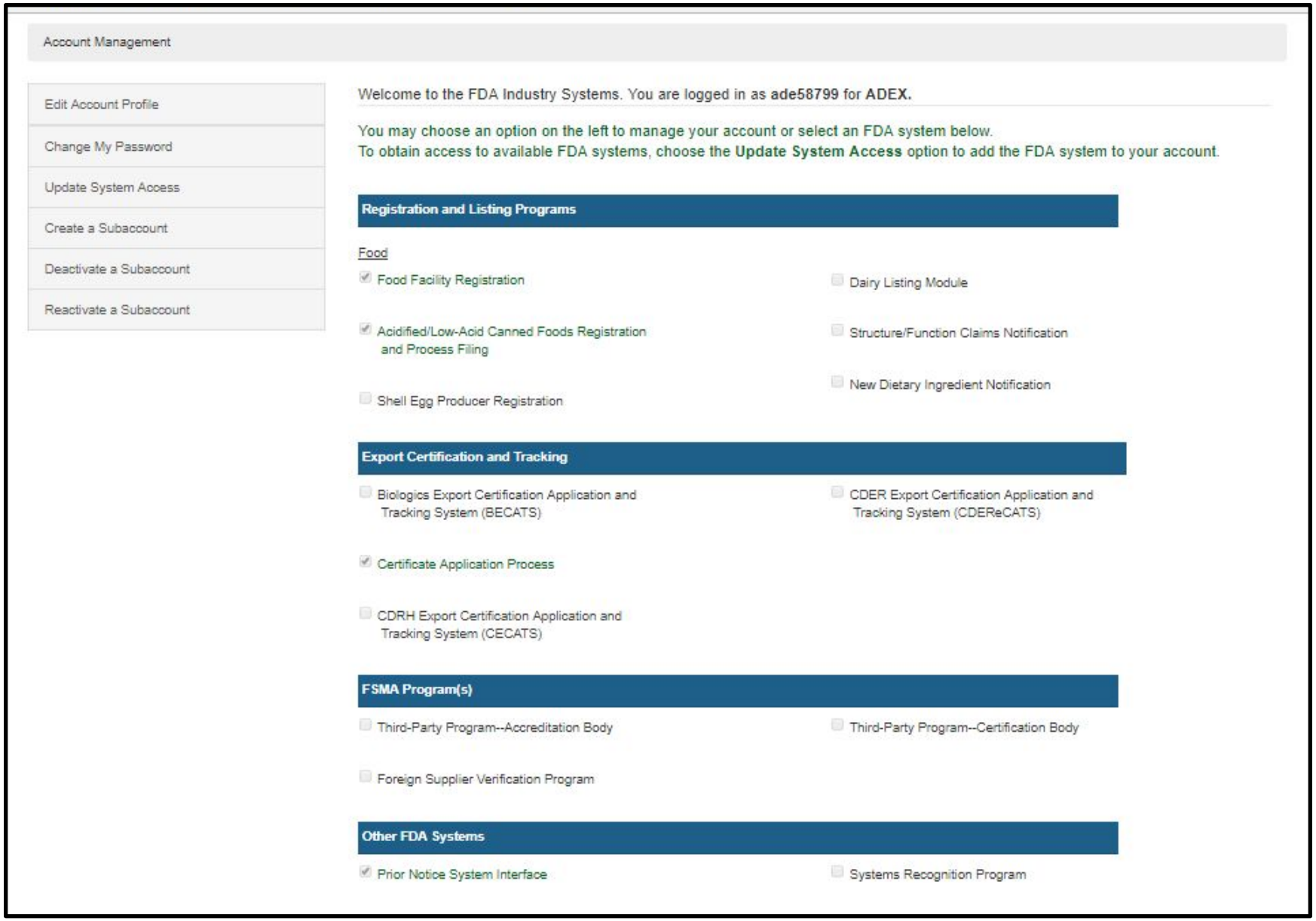
Country / Area
PERU

You have successfully created an account
Your account ID is **com16906**

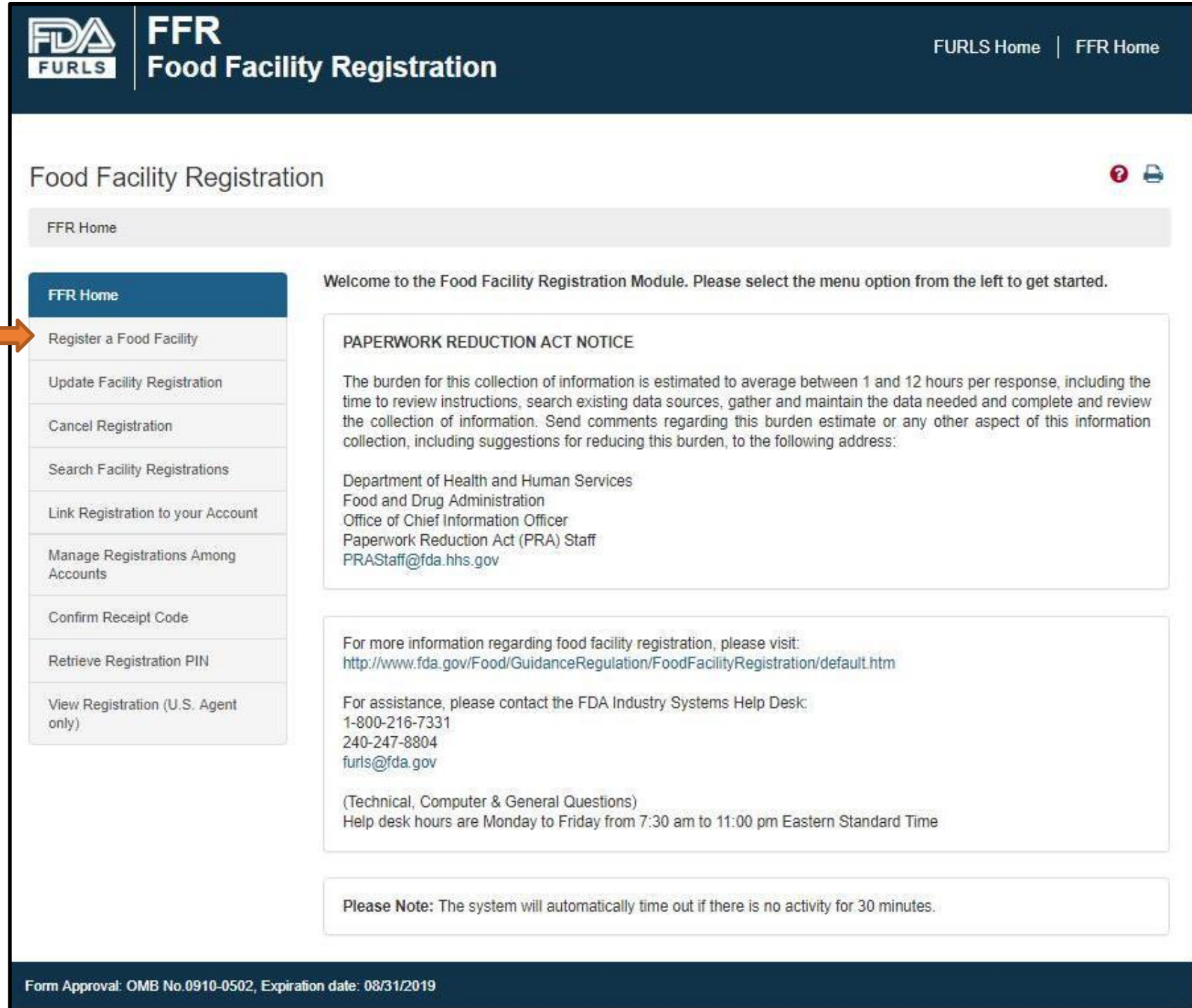
YOU WILL NEED TO REMEMBER YOUR ACCOUNT ID AND PASSWORD TO LOGIN TO THE SYSTEM IN THE FUTURE.

Login

REGISTRO DE INSTALACIONES ALIMENTARIAS (SECCIÓN 305) – CREACION DE CUENTA

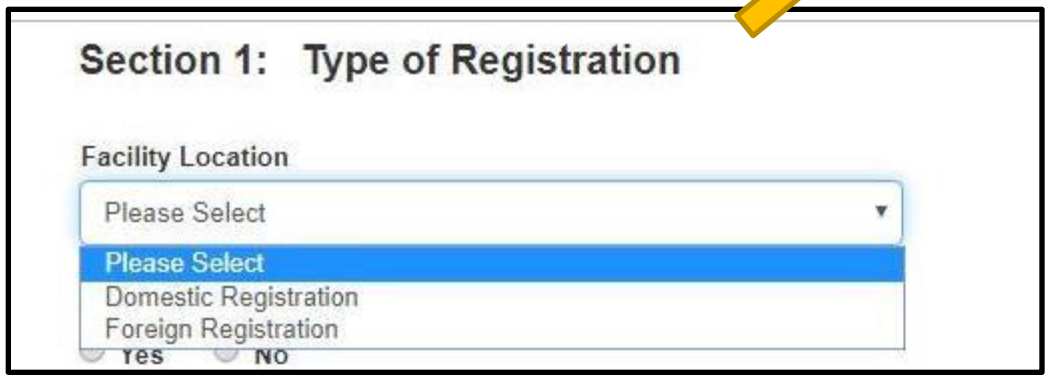


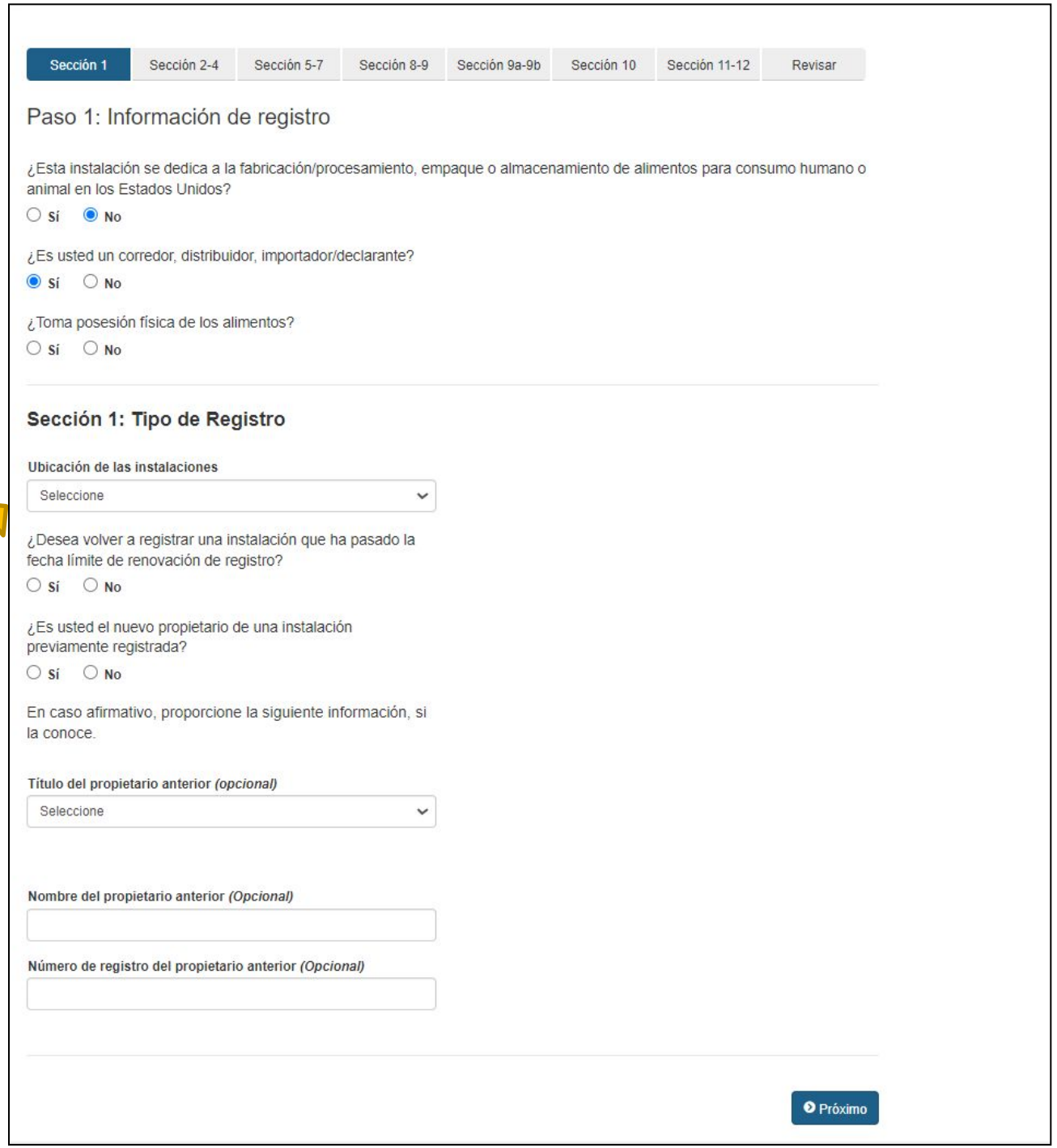
Sistema de Registro (FFRM – Food Facility Registration Module) seleccionar:



Sección 1:

1.Seleccione “foreign registration”
2. Si usted es el nuevo dueño de una facilidad previamente registrada, marque “Yes” y entre el número de registro anterior

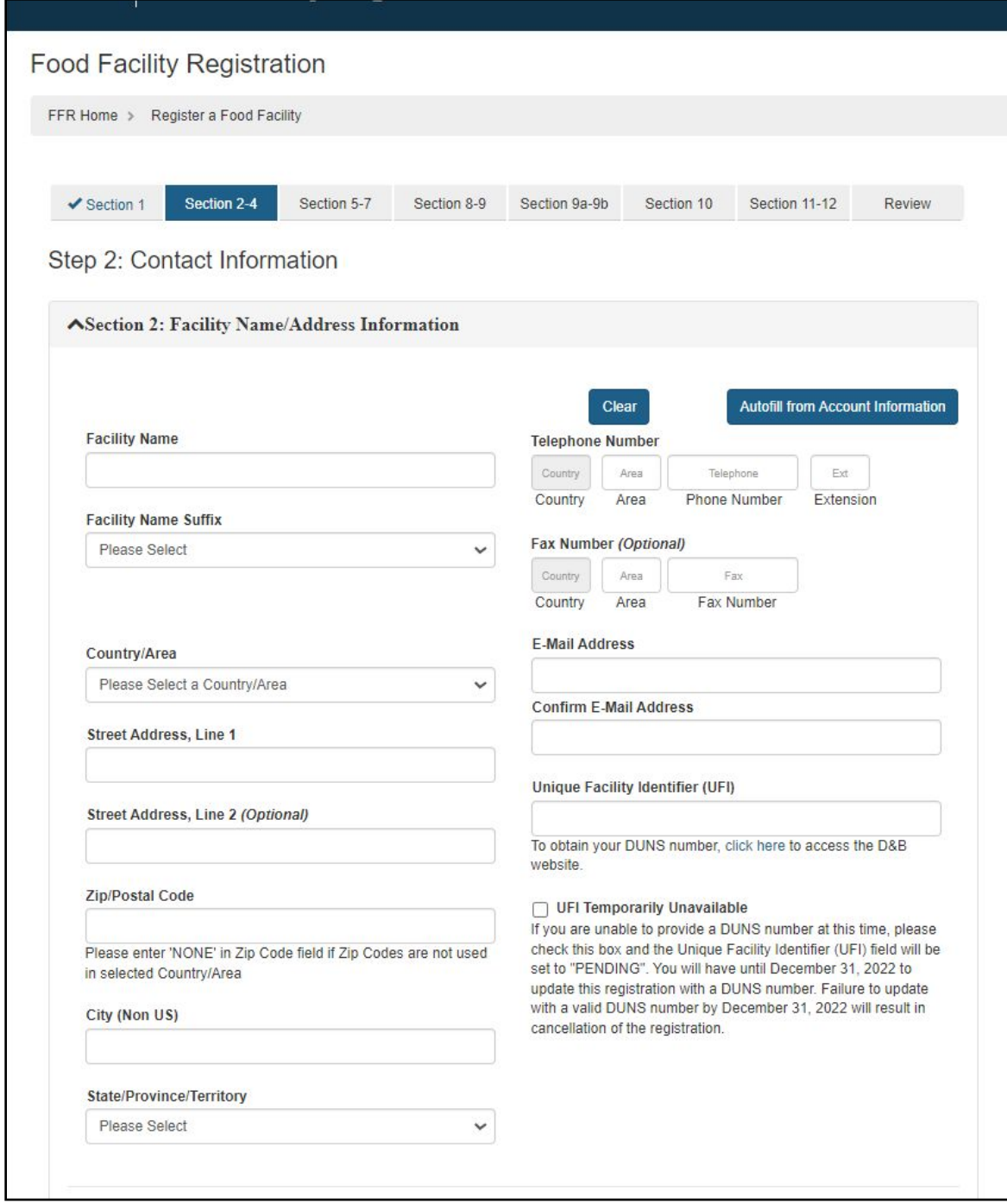




Sección 2:

Al entrar la información en esta sección:

Use el nombre legal
Use la dirección *física* del establecimiento que maneja producto (no la oficina)



Sección 7: Agente en los EE.UU.

- Es requisito para las instalaciones en el extranjero identificar a un Agente en los EE.UU.
- El Agente en los EE.UU. puede ser cualquier “persona” que resida o sostenga un domicilio de negocios en los EE.UU. y que esté presente físicamente en los EE.UU.
- Una “persona" se define como un individuo, sociedad, corporación o asociación

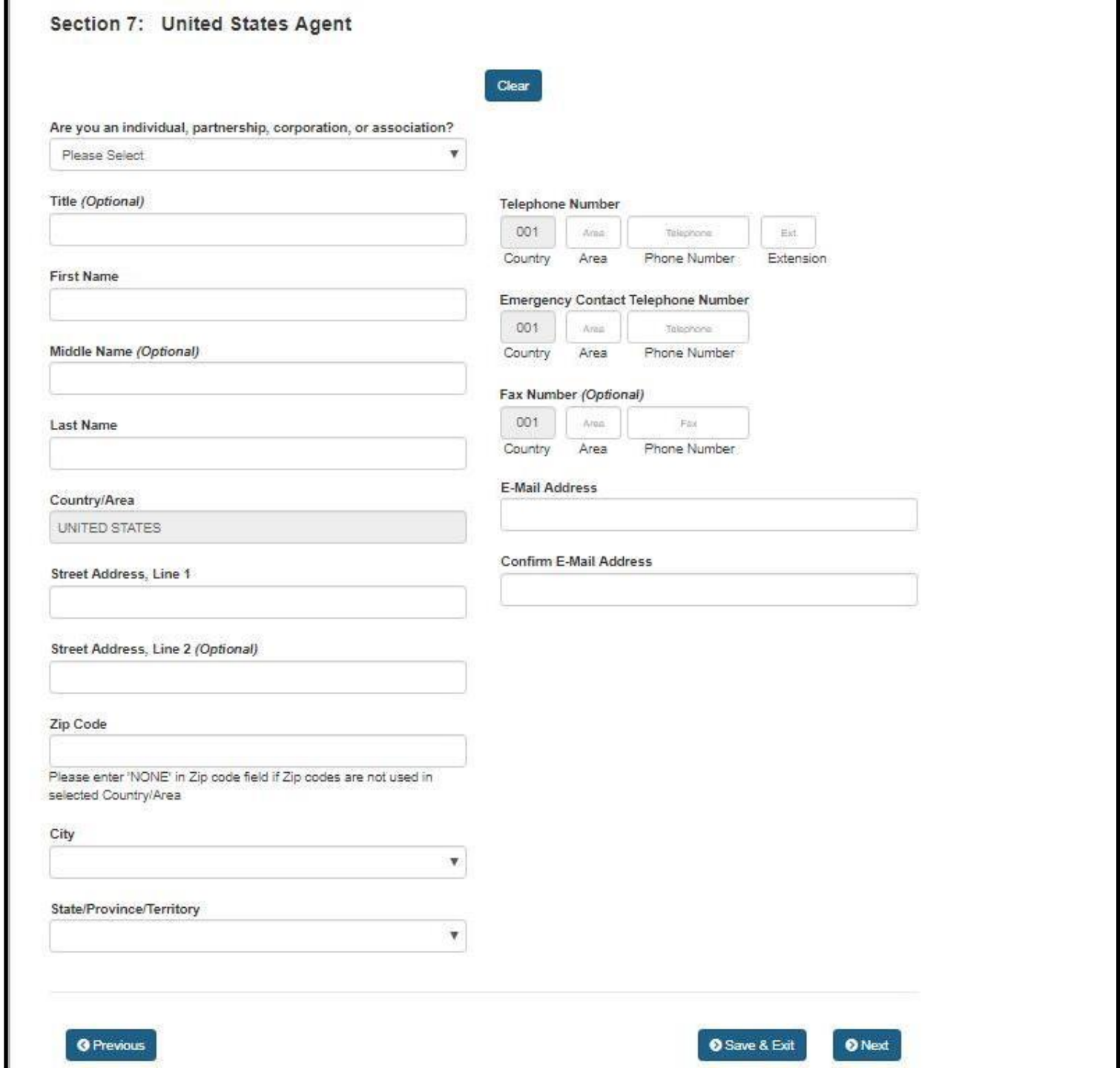
OBLIGACIONES DEL AGENTE

- Actuar como enlace en la comunicación entre el FDA y las instalaciones extranjeras.
- El FDA aceptará los registros presentados por el Agente en nombre de la instalación extranjera.
- El FDA considerará las representaciones presentadas por el Agente como si fuesen presentadas por la instalación extranjera y cualquier información presentada por el FDA será equivalente presentarla directamente a la instalación extranjera.

OBLIGACIONES DEL AGENTE

- El FDA recomienda que el Agente y la entidad extranjera firmen un contrato escrito especificando las responsabilidades del Agente.
- La instalación extranjera no deberá presentar al FDA una copia de este acuerdo como parte del registro de la instalación.
- Si un agente registra una instalación sin la previa autorización de esta instalación, el FDA considerará el registro como una declaración falsa, ficticia o fraudulenta al Gobierno de los EE.UU. bajo el Código 1001 de EE.UU.
- El FDA solamente permite un Agente por instalación extranjera.

Sección 7: Entre la información del agente en EE.UU.



Section 7: United States Agent

Clear

Are you an individual, partnership, corporation, or association?

Please Select

Title *(Optional)*

First Name

Middle Name *(Optional)*

Last Name

Country/Area

UNITED STATES

Street Address, Line 1

Street Address, Line 2 *(Optional)*

Zip Code

Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area

City

State/Province/Territory

Telephone Number

001 Country | Area | Phone Number | Ext Extension

Emergency Contact Telephone Number

001 Country | Area | Phone Number

Fax Number *(Optional)*

001 Country | Area | Phone Number

E-Mail Address

Confirm E-Mail Address

Previous | Save & Exit | Next

Draft Confirmation ✔

The food facility registration information you provided has been saved. This information will be available for you to edit and complete for seven days from the date you began your registration. If you do not complete your online registration within that time and submit it in FFRM, this registration information will be removed from FFRM.

You may edit, complete, and submit your online registration by logging in to FURLS and clicking the 'Complete Draft Registration' button located on the FFR Home. When you return to complete this registration, the reference code is *47256*.

NOTE: FDA will not issue your food facility registration number until your online registration form has been completed and submitted in FFRM.

Complete Draft Registration

Your account has access to the following draft registrations. Please click on a reference code to select a registration for update to complete the draft registration.

Show 25 entries

Reference Code	Facility Name	Facility Address
47256		

Showing 1 to 1 of 1 entries

Sección 9: Categorías de alimentos

Step 5: Product Categories

Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37 .

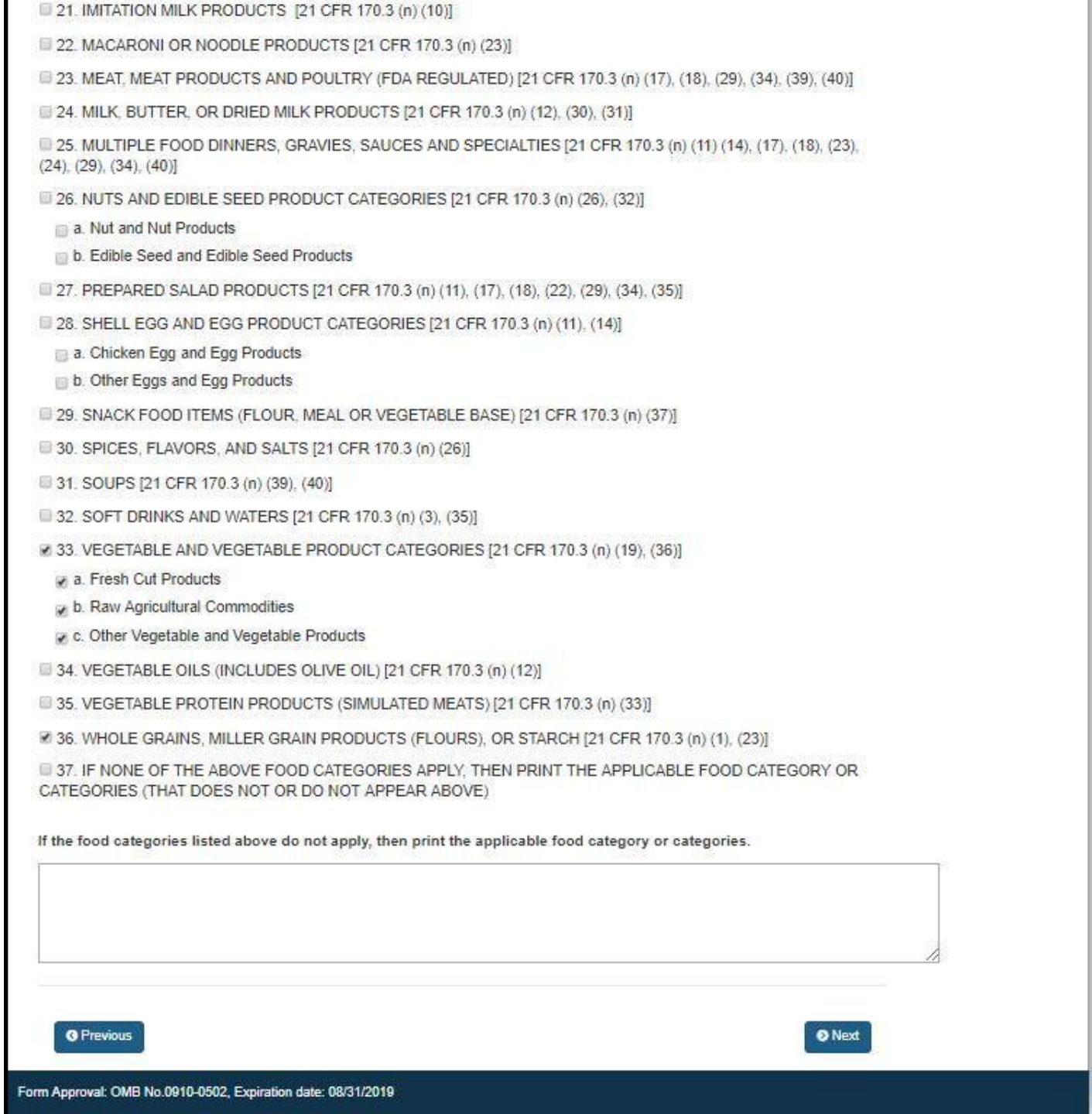
Select All | Unselect All

- [x] 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]
- [x] 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula
- [x] 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]
- [x] 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]
- [ ] 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]
- [x] 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING / INSTANT CEREALS [21 CFR 170.3 (n) (4)]
- [ ] 7. CHEESE AND CHEESE PRODUCT CATEGORIES [21 CFR 170.3 (n) (5)]
  - [ ] a. Soft, Ripened Cheese
  - [ ] b. Semi-Soft Cheese
  - [ ] c. Hard Cheese
  - [ ] d. Other Cheeses and Cheese Products
- [ ] 8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]
- [x] 9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]
- [ ] 10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]
- [ ] 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)]
- [x] 12. DIETARY SUPPLEMENT CATEGORIES
  - [x] a. Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3(o) (20)]
  - [x] b. Vitamins and Minerals
  - [ ] c. Animal By-Products and Extracts
  - [x] d. Herbals and Botanicals

Sección 9: Categorías de alimentos

- [ ] 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)]
- [x] 12. DIETARY SUPPLEMENT CATEGORIES
  - [x] a. Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3(o) (20)]
  - [x] b. Vitamins and Minerals
  - [ ] c. Animal By-Products and Extracts
  - [x] d. Herbals and Botanicals
- [ ] 13. DRESSING AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]
- [ ] 14. FISHERY / SEAFOOD PRODUCT CATEGORIES [21 CFR 170.3 (n) (13), (15), (39), (40)]
  - [ ] a. Fin Fish, Whole or Filet
  - [ ] b. Molluscan Shellfish
  - [ ] c. Other Shellfish
  - [ ] d. Ready to Eat (RTE) Fishery Products
  - [ ] e. Processed and Other Fishery Products
- [ ] 15. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)]
- [ ] 16. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9) (41), 21 CFR 170.3 (o) (21)]
- [ ] 17. FRUIT AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]
  - [ ] a. Fresh Cut Produce
  - [ ] b. Raw Agricultural Commodities
  - [ ] c. Other Fruit and Fruit Products
- [ ] 18. FRUIT OR VEGETABLE JUICE, PULP OR CONCENTRATE PRODUCTS [21 CFR 170.3 (n) (3), (16), (35)]
- [ ] 19. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]
- [ ] 20. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]
- [ ] 21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]
- [ ] 22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]
- [ ] 23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]
- [ ] 24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]
- [ ] 25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11) (14), (17), (18), (23), (24), (29), (34), (40)]

Sección 9: Categorías de alimentos



- [ ] 21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]
- [ ] 22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]
- [ ] 23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]
- [ ] 24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]
- [ ] 25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11) (14), (17), (18), (23), (24), (29), (34), (40)]
- [ ] 26. NUTS AND EDIBLE SEED PRODUCT CATEGORIES [21 CFR 170.3 (n) (26), (32)]
  - [ ] a. Nut and Nut Products
  - [ ] b. Edible Seed and Edible Seed Products
- [ ] 27. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)]
- [ ] 28. SHELL EGG AND EGG PRODUCT CATEGORIES [21 CFR 170.3 (n) (11), (14)]
  - [ ] a. Chicken Egg and Egg Products
  - [ ] b. Other Eggs and Egg Products
- [ ] 29. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]
- [ ] 30. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]
- [ ] 31. SOUPS [21 CFR 170.3 (n) (39), (40)]
- [ ] 32. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]
- [x] 33. VEGETABLE AND VEGETABLE PRODUCT CATEGORIES [21 CFR 170.3 (n) (19), (36)]
  - [x] a. Fresh Cut Products
  - [x] b. Raw Agricultural Commodities
  - [x] c. Other Vegetable and Vegetable Products
- [ ] 34. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]
- [ ] 35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]
- [x] 36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]
- [ ] 37. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE)

If the food categories listed above do not apply, then print the applicable food category or categories.

Previous

Next

Form Approval: OMB No.0910-0502, Expiration date: 08/31/2019

- Warehouse = almacén o bodega
- Acidified/Low Acid Canned
- Food = Productos herméticamente sellados que no requieren refrigeración
- Catering Point = Proveedores de agua y comida a aviones y embarcaciones
- Molluscan Shellfish = Procesador de Moluscos
- Commissary = comisariato
- Contract Sterilizer = Esterilizador bajo contrato

- Labeler/Relabeler = etiquetador/re-etiquetador
- Manufacturer o Processor = Fabricante o Procesador
- Packer/Repacker = Empacador
- Salvage Operator (reconditioner) = Rescate de alimentos/reacondicionador
- Animal Food = fabricante, Procesador o Almacén de alimentos para animales

Sección 9b: Selecciones <u>todas</u> las actividades que realiza la instalación – Consumo Animal

Section 9b: General Product Categories - Food for Animal Consumption; and Type of Activity Conducted at the Facility

To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 33 .

Select All | Unselect All

- ☐ 1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS)
- ☐ 2. OILSEED OR OILSEED PRODUCTS (I.E., COTTONSEED, SOYBEANS, OTHER OILSEEDS OR OILSEED PRODUCTS)
- ☐ 3. ALFALFA PRODUCTS OR LESPEDEZA PRODUCTS
- ☐ 4. AMINO ACIDS OR RELATED PRODUCTS
- ☐ 5. ANIMAL PROTEIN PRODUCTS
- ☐ 6. BOTANICALS AND HERBS
- ☐ 7. BREWER PRODUCTS
- ☐ 8. CHEMICAL PRESERVATIVES
- ☐ 9. CITRUS PRODUCTS
- ☐ 10. DIRECT FED MICROBIALS
- ☐ 11. DISTILLERY PRODUCTS
- ☐ 12. ENZYMES
- ☐ 13. FATS OR OILS
- ☐ 14. FERMENTATION PRODUCTS
- ☐ 15. FORAGE PRODUCTS
- ☐ 16. HUMAN FOOD BY-PRODUCTS NOT OTHERWISE LISTED
- ☐ 17. MARINE PRODUCTS
- ☐ 18. MILK PRODUCTS
- ☐ 19. MINERALS OR MINERAL PRODUCTS
- ☐ 20. MISCELLANEOUS OR SPECIAL PURPOSE PRODUCTS
- ☐ 21. MOLASSES OR MOLASSESS PRODUCTS
- ☐ 22. NON-PROTEIN NITROGEN PRODUCTS
- ☐ 23. PEANUT PRODUCTS

Sección 9b: Selecciones <u>todas</u> las actividades que realiza la instalación – Consumo Animal

- 14. FERMENTATION PRODUCTS
- 15. FORAGE PRODUCTS
- 16. HUMAN FOOD BY-PRODUCTS NOT OTHERWISE LISTED
- 17. MARINE PRODUCTS
- 18. MILK PRODUCTS
- 19. MINERALS OR MINERAL PRODUCTS
- 20. MISCELLANEOUS OR SPECIAL PURPOSE PRODUCTS
- 21. MOLASSES OR MOLASSESS PRODUCTS
- 22. NON-PROTEIN NITROGEN PRODUCTS
- 23. PEANUT PRODUCTS
- 24. PROCESSED ANIMAL WASTE PRODUCTS
- 25. SCREENINGS
- 26. TECHNICAL ADDITIVES
- 27. VITAMINS OR VITAMIN PRODUCTS
- 28. YEAST PRODUCTS
- 29. MIXED FEED (E.G., POULTRY, LIVESTOCK, EQUINE)
- 30. PET FOOD
- 31. PET TREATS OR PET CHEWS
- 32. PET NUTRITIONAL SUPPLEMENTS (E.G., VITAMINS, MINERALS)
- 33. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE)

If the food categories listed above do not apply, then print the applicable food category or categories.

Previous Next

Form Approval: OMB No.0910-0502, Expiration date: 08/31/2019

Sección 9a:

- Seleccione todas las categorías que le apliquen.
- Las categorías se basan en 21 CFR 170.3(n).
- También se relacionan a los primeros dos dígitos del código de producto (product code). Si no le aplica ninguno, entonces marque el 37.

Sección 9b:

Marque todas las que apliquen

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

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

Home > For Industry > Import Program > Product Code Builder

Product Code Builder

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

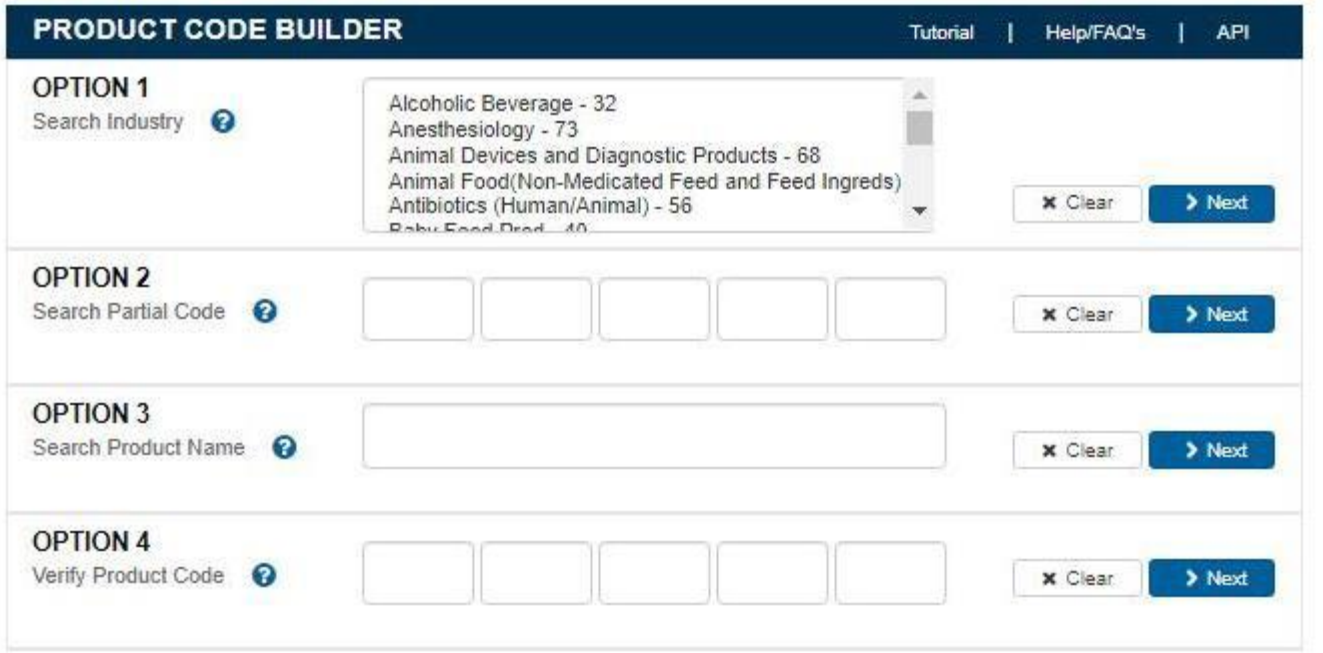
Product Code Builder Tool | Tutorial

The Product Code Builder online tool/application will guide you through an easy and user friendly selection
product code. By building upon the code portions you select, the application will provide valid choices for ea
(Industry, Class, Subclass, PIC, and Product).

To assist you in using the Product Code Builder application, we have provided several areas where you car

- **Helpful Tips** - These tips are located on the first screen of the application. They give an overview of th
building your product code.
- **FAQ/Help section** - This section contains a series of frequently asked questions and answers related t
- **Complete Tutorial Module** - The tutorial is designed to give you the information you need to successfu
tutorial in sequence, or jump right to a lesson that will meet an immediate need for information.

Page Last Updated: 12/08/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | França
| English



Sección 9 a/b:

Búsqueda de categorías de productos

PART 170 -- FOOD ADDITIVES
Subpart A--General Provisions

Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2011]
[CITE: 21CFR170.3]

TITLE 21--FOOD AND DRUGS

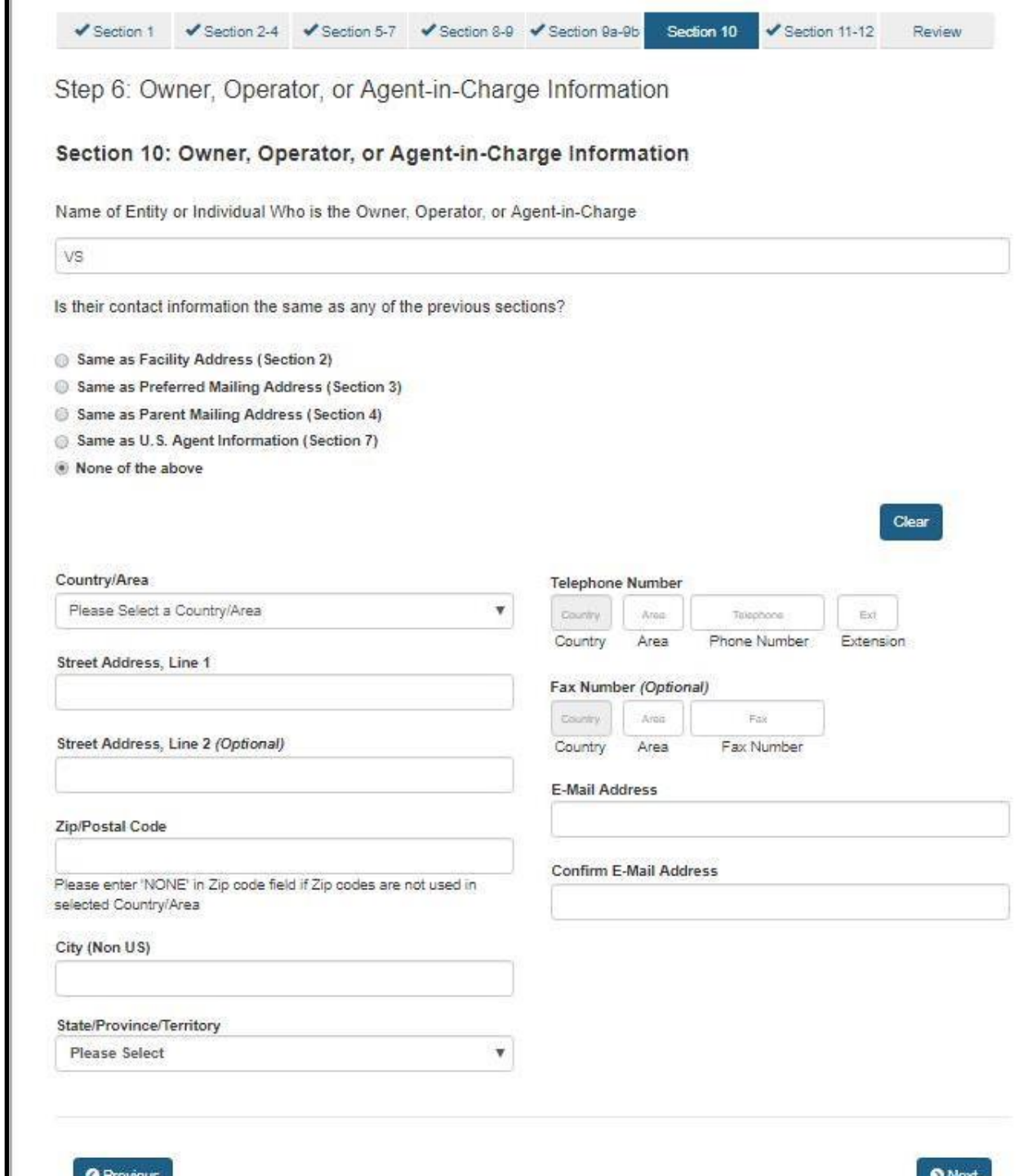
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)PART 170 -- FOOD ADDITIVES Subpart A--General Provisions

Sec. 170.3 Definitions.

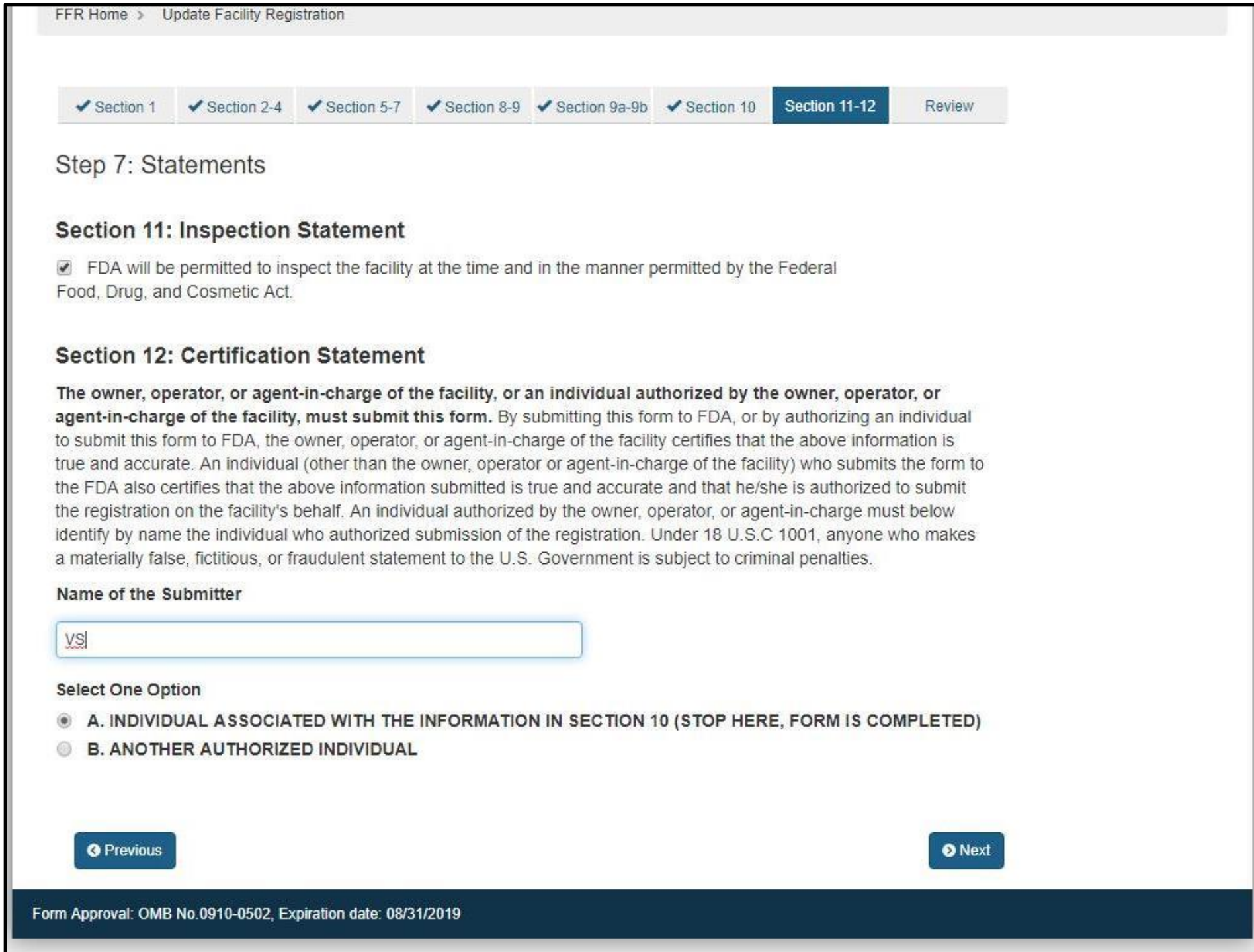
Sección 10:

- **Entre la información del dueño o persona con mayor responsabilidad del establecimiento.**
- **Si usted no es el dueño o la persona con mayor responsabilidad NO entre su nombre aquí.**



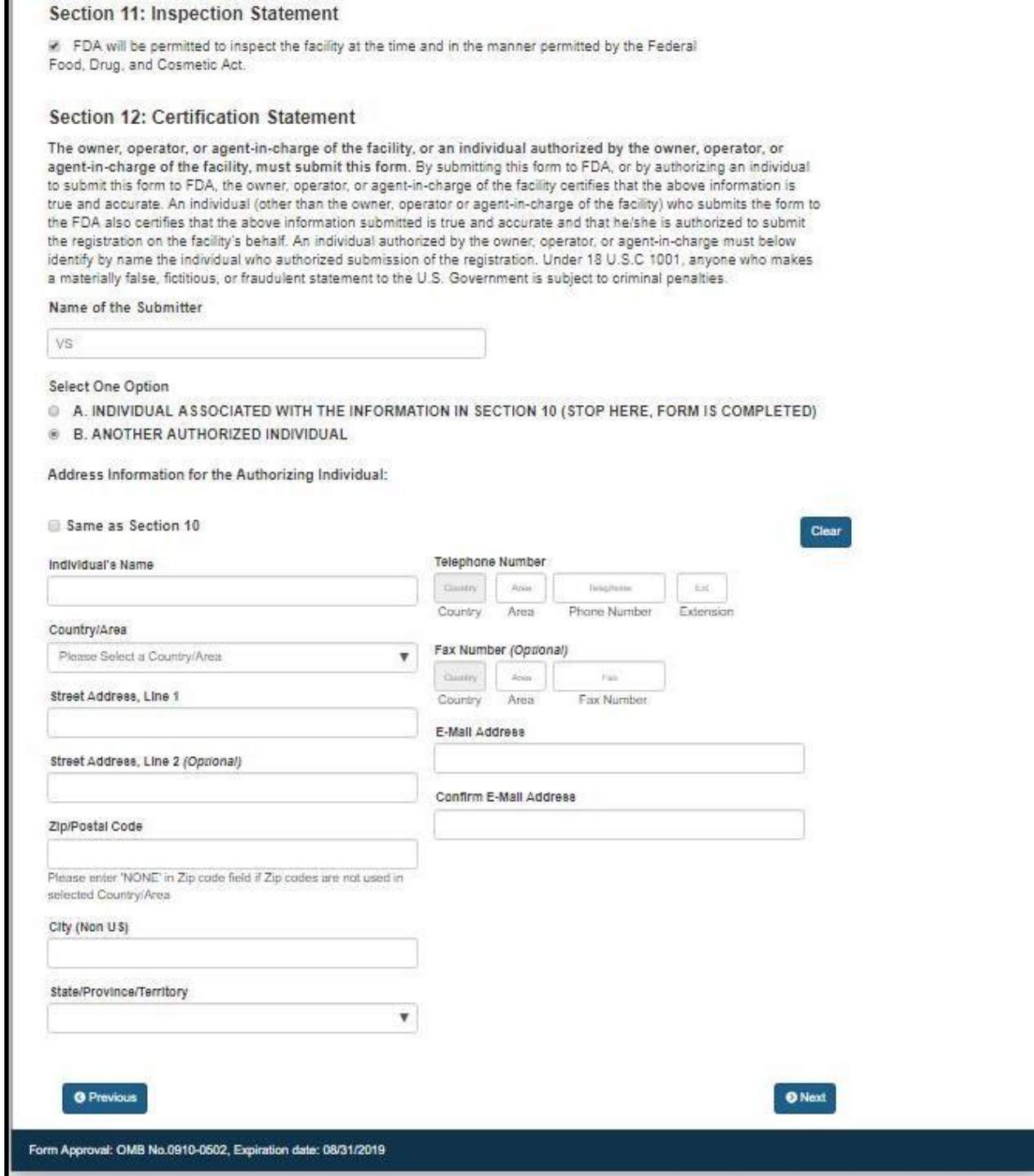
Sección 11 y 12:

Declaración de Inspección y de Responsabilidad



Sección 12:

- Escriba el nombre de la persona que está llenando este formulario (USTED)
- Si usted es el dueño o equivalente marque “A”
- Si usted esta llenando el registro a nombre del dueño o encargado, entonces marque “B”.
- Si marca “B” provea la información de la persona que le autorizó a llenar este formulario.



Section 11: Inspection Statement

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 12: Certification Statement

The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent-in-charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent-in-charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Name of the Submitter

VS

Select One Option

- A. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)
- B. ANOTHER AUTHORIZED INDIVIDUAL

Address Information for the Authorizing Individual:

Same as Section 10 — Clear

Individual's Name

Telephone Number — Country / Area / Phone Number / Extension

Country/Area — Please Select a Country/Area

Fax Number *(Optional)* — Country / Area / Fax Number

Street Address, Line 1

E-Mail Address

Street Address, Line 2 *(Optional)*

Confirm E-Mail Address

Zip/Postal Code

Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area

City (Non US)

State/Province/Territory

Previous — Next

Form Approval: OMB No.0910-0502, Expiration date: 08/31/2019

Section 1: Type of Registration

Edit

Facility Location : **Foreign Registration**

Are you the new owner of a previously registered facility?

Yes No

Previous Owner's Title:
Previous Owner's Name :
Previous Owner's Registration Number :

Section 8: Seasonal Facility Dates of Operation *(Optional)*

Edit

Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis *(Optional)*.

Harvest 1
Start Month: **January** — End Month: **June**

Harvest 2
Start Month: **August** — End Month: **December**

Section 9: General Product Categories - Human/Animal/Both

Edit

Food for Human Consumption — **Food for Animal Consumption**

Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility

Edit

Selected Product Name	Selected Activity Types
1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators); Labeler / Relabeler; Packer / Repacker;
3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators); Labeler / Relabeler; Packer / Repacker;
4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators); Acidified Food Processor; Low-Acid Food Processor; Labeler / Relabeler; Packer / Repacker;
6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING / INSTANT CEREALS [21 CFR 170.3 (n) (4)]	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators); Labeler / Relabeler; Packer / Repacker;
9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators); Labeler / Relabeler; Packer / Repacker;
12. DIETARY SUPPLEMENT CATEGORIES	

Section 12: Certification Statement

Edit

The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent-in-charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent-in-charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

NAME OF PERSON SUBMITTING THIS REGISTRATION FORM: VS

CHECK ONE BOX

A. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)
B. ANOTHER AUTHORIZED INDIVIDUAL

Address Information for the Authorizing Individual:

Individual's Name: -N/A-
Telephone Number: -N/A-
Address, Line 1: -N/A-
Fax Number: -N/A-
Address, Line 2: -N/A-
E-Mail Address: -N/A-
City: -N/A-
State/Province/Territory: -N/A-
Zip Code (Postal Code): -N/A-
Country/Area: -N/A-

Cancel Submit

Form Approval: OMB No.0910-0502, Expiration date: 08/31/2019

Food Facility Registration

FFR Home

- FFR Home
- Register a Food Facility
- Update Facility Registration
- Cancel Registration
- Search Facility Registrations
- Link Registration to your Account
- Manage Registrations Among Accounts
- Confirm Receipt Code
- Retrieve Registration PIN
- View Registration (U.S. Agent only)

Welcome to the Food Facility Registration Module. Please select the menu option from the left to get started.

You have the following Food Facility Registrations awaiting confirmation from the US Agent or Owner/Operator/Agent in Charge.

Show 10 entries Filter:

Facility Name	Address	Action
VS Company	AV. MOLL 4035, LIMA, Lima, 15458, PERU	

Showing 1 to 1 of 1 entries

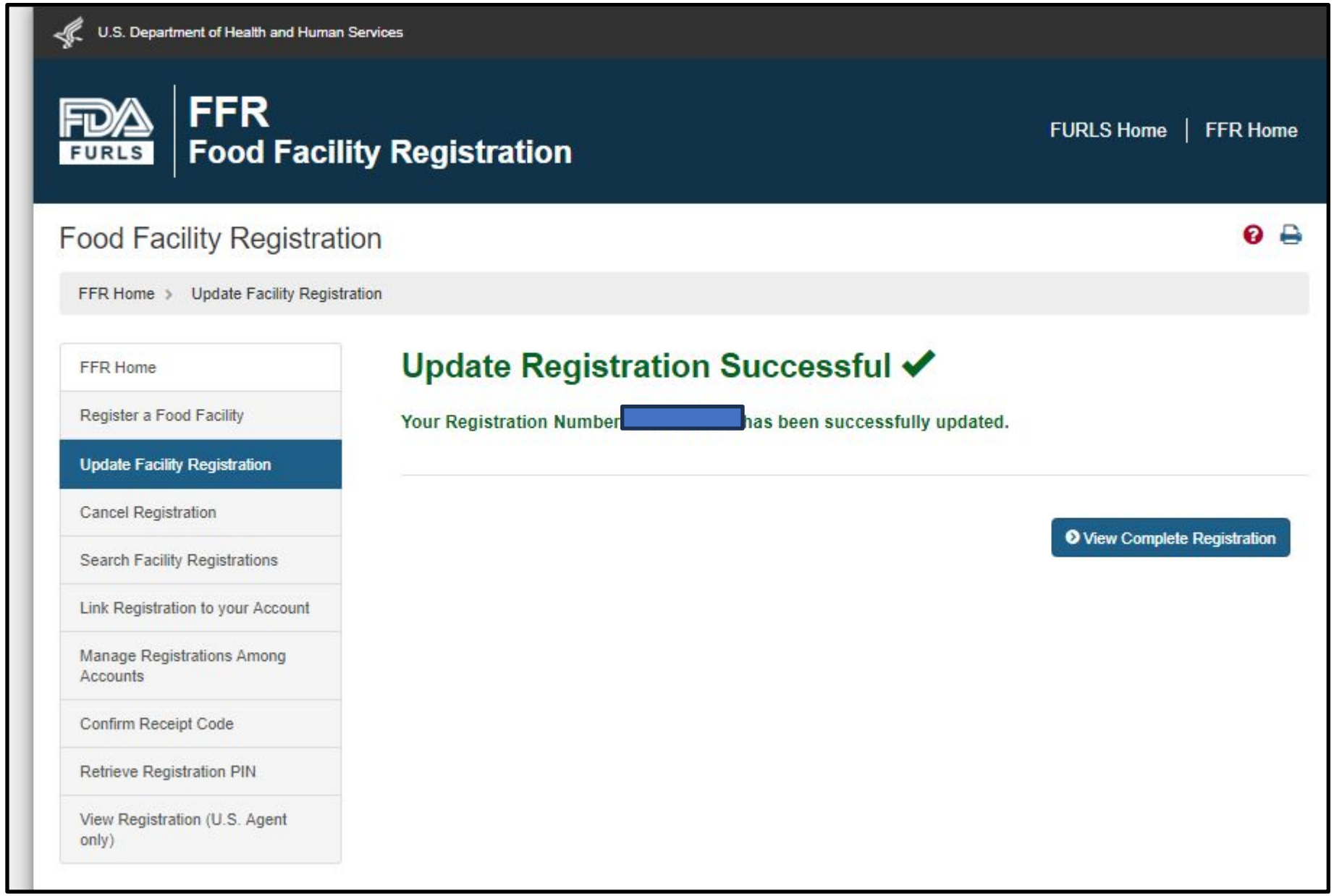
PAPERWORK REDUCTION ACT NOTICE

The burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

For more information regarding food facility registration, please visit:
http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm


U.S. Department of Health and Human Services
FDA FURLS
FFR
Food Facility Registration
FURLS Home | FFR Home
Food Facility Registration
FFR Home > Update Facility Registration
FFR Home
Register a Food Facility
Update Facility Registration
Cancel Registration
Search Facility Registrations
Link Registration to your Account
Manage Registrations Among Accounts
Confirm Receipt Code
Retrieve Registration PIN
View Registration (U.S. Agent only)
Update Facility Registration / Reference Code
Your account has access to the following registrations. Please click on a registration number to select a registration for update.
Show 25 entries
Registration Number
Facility Name
Facility Address
12345678911
vs
vvvvvvvvvvvvvvvv
Showing 1 to 1 of 1 entries


U.S. Department of Health and Human Services
FDA FURLS
FFR
Food Facility Registration
FURLS Home | FFR Home
Food Facility Registration
FFR Home > Update Facility Registration
FFR Home
Register a Food Facility
Update Facility Registration
Cancel Registration
Search Facility Registrations
Link Registration to your Account
Manage Registrations Among Accounts
Confirm Receipt Code
Retrieve Registration PIN
View Registration (U.S. Agent only)
Update Registration Successful
Your Registration Number [redacted] has been successfully updated.
View Complete Registration

NOTIFICACIÓN PREVIA PARA EMBARQUES DE ALIMENTOS IMPORTADOS – SECCIÓN 307

A partir del 12 de diciembre del 2003, la FDA deberá recibir notificación previa de todas y cada una de las partidas de alimentos que ingresen a los Estados Unidos.

La ley exige a los importadores que proporcionen a la FDA una notificación anticipada con no menos de 8 horas y no más de 5 días antes del envío, hasta que las normativas entren en vigor.

NOTIFICACIÓN PREVIA PARA EMBARQUES DE ALIMENTOS IMPORTADOS – SECCIÓN 307

Tiempo límite para presentar la notificación previa

La notificación previa debe ser recibida y confirmada electrónicamente por la FDA en un plazo no mayor de cinco días de anterioridad al arribo de cada partida de alimentos y, según lo especificado para cada medio de transporte a continuación, no menor de:

Productos que llegan por carretera:
Dos horas antes de arribar al puerto de llegada.

Productos que llegan por vía férrea:
Cuatro horas antes de arribar al puerto de llegada.

Productos que llegan por vía aérea:
Cuatro horas antes de arribar al puerto de llegada.

Productos que llegan por vía marítima:
Ocho horas antes de arribar al puerto de llegada.

La hora se calcula con base en la zona horaria del puerto de llegada, el cual es el lugar a donde llega el producto por primera vez a los Estados Unidos.

- En el caso de los alimentos enviados vía correo internacional postal la notificación previa deberá hacerse siempre **antes** de que el producto sea enviado a los Estados Unidos; porque el número de confirmación de la notificación previa debe aparecer en la declaración de aduanas que acompaña el envío.

- La FDA confirmará la recepción de la notificación previa a la parte que la está realizando por medio de un mensaje que contiene el número de confirmación de la notificación previa, momento a partir del cual comenzará a correr el plazo para la llegada de los productos a los Estados Unidos. La confirmación de la notificación se hará a través del mismo medio que se usó para la notificación inicial.

“Si se deben hacer cambios en la notificación previa, se debe cancelar esta notificación y presentar una nueva”.

Aviso Previo (Prior Notice)

Todas las entradas que incluyan alimentos o suplementos dietéticos, incluyendo muestras y entradas a la Zona Franca o en ruta a otro país necesitan Aviso Previo.

Para entradas por correo internacional, el Aviso se hace antes que se haga el envío. El recibo con la confirmación debe acompañar la entrada.

Entradas que no tienen Aviso Previo o presenten algún problema no pasan al sistema electrónico de OASIS. En este caso el único recurso es con Aduana y el PNC.

PRIOR NOTICE SYSTEM INTERFACE
UNITED STATES FOOD AND DRUG ADMINISTRATION

FDA

F19X14684155

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: F19X14684155
Entry Identifier: ###-2042914-5
Port of Arrival: Houston, TX (5301)
Entry Type: Consumption
Anticipated Arrival: 04/22/2019 02:05
Mode of Transportation: Water, Vessel Container
Number of Intended Prior Notices: 1

Submitter

V S
VS
AV. MOLL 567
LIMA, Lima 15048
PERU

Importer

INTERNATIONAL MSC SAC BROKERS
1102 KRESS
HOUSTON, Texas 77020
UNITED STATES

Carrier

MSC-MEDITERRANEAN SHIPPING COMPANY S A
Carrier Code (SCAC): MSCU

Vessel Name:
Voyage Number
Bill of Lading - Master:
Container Numbers: 1

PRIOR NOTICES

0001	CORN, WHOLE GRAIN	PE	04/20/2019 22:08:02	190292975574

PRIOR NOTICE SYSTEM INTERFACE
UNITED STATES FOOD AND DRUG ADMINISTRATION

FDA

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: F19X14685221
Entry Type: Baggage
Entry Identifier: +++-2043920-0
Anticipated Arrival: 04/22/2019 15:20
Port of Arrival: Miami Int'L Airport, FL (5206)
Mode of Transportation: Air, Passenger, Hand Carried
Number of Intended Prior Notices: 1

Submitter

V S
VS
AV. MOLL 284
LIMA, Lima 15046
PERU

Importer

MIAMI INTERNATIONAL EIRL
AV. MOLL 284
FLORIDA, Texas 33186
UNITED STATES

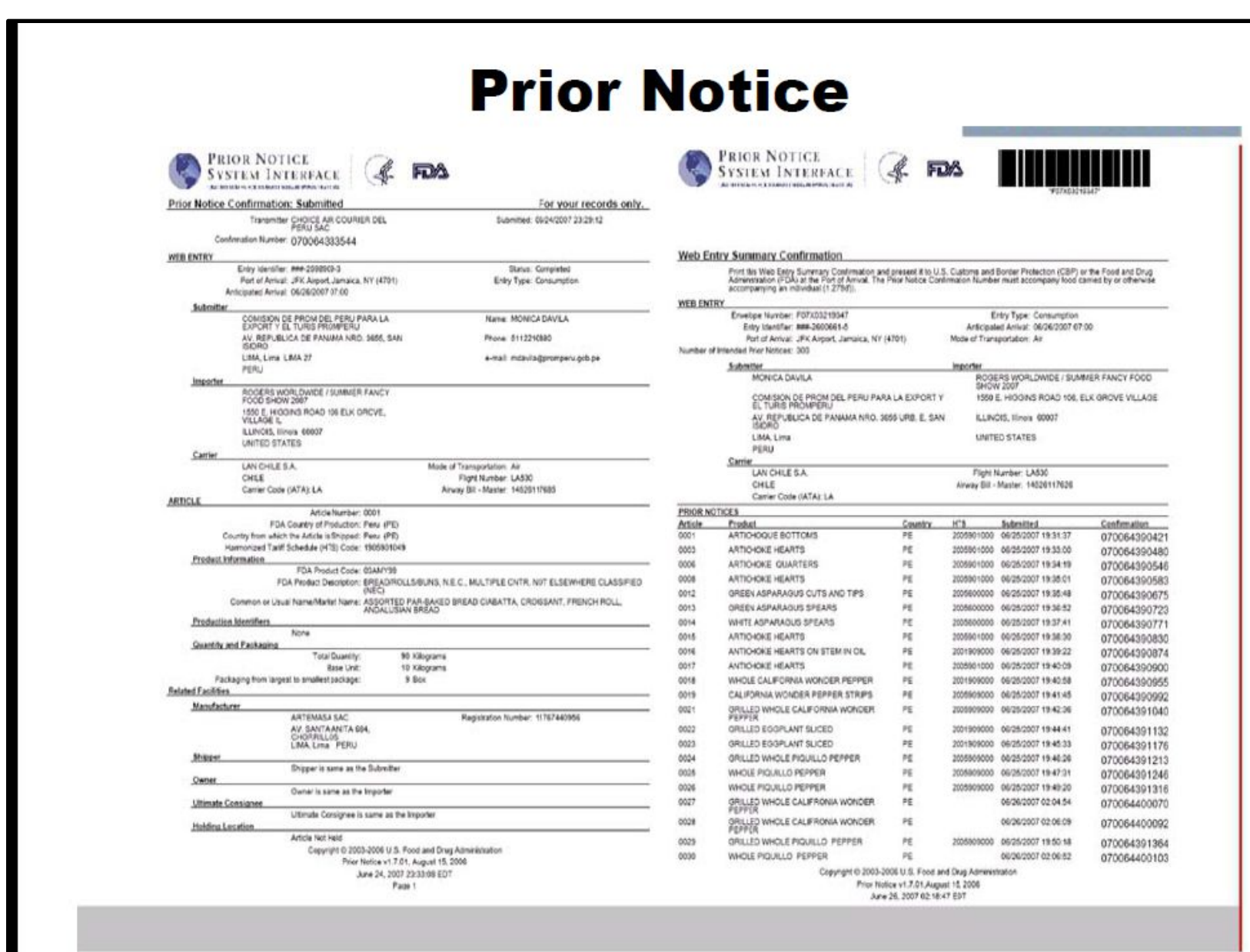
Carrier

AMERICAN AIRLINES INC.
Carrier Code (IATA): AA
Flight Number: 2467

PRIOR NOTICES

0001	CORN, WHOLE GRAIN	PE	04/21/2019 17:54:40	190292986505

Prior Notice



PRIOR NOTICE SYSTEM INTERFACE

FDA

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: ###-2008909-3 — 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 — Name: MONICA DAVILA

AV. REPUBLICA DE PANAMA NRO. 3655, SAN ISIDRO — Phone: 5112210880

LIMA, Lima LIMA 27 — e-mail: mdavila@promperu.gob.pe

PERU

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. — Mode of Transportation: Air

CHILE — Flight Number: LA530

Carrier Code (IATA): LA — Airway Bill - Master: 14529117685

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 — Registration Number: 11767440956

AV. SANTAANTA 694, CHORRILLOS

LIMA, Lima PERU

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

Prior Notice v1.7.01, August 15, 2006

June 24, 2007 23:33:08 EDT

Page 1

PRIOR NOTICE SYSTEM INTERFACE

FDA

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 (1.276(f)).

WEB ENTRY

Envelope Number: FDFX03219347 — 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: 303

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. — Flight Number: LA530

CHILE — Airway Bill - Master: 14529117626

Carrier Code (IATA): LA

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 19:36:48	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 19:42:26	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

Prior Notice v1.7.01,August 15, 2006

June 26, 2007 02:18:47 EDT

¿Qué ocurre al no enviar una notificación previa antes de que llegue el embarque a los Estados Unidos?

Si no se presenta la notificación previa o esta es inexacta o es presentada fuera del tiempo estipulado, la entrada del producto estará sujeta a rechazo.

Una vez que se ha negado la entrada del producto, la FDA ordenará que estos sean trasladados a una instalación segura. Los costos de transporte y almacenaje correrán a cargo del propietario, comprador, importador o destinatario, quien no podrá disponer de los productos hasta que la FDA así lo determine.

Según el caso, se admitirá que se presente una nueva notificación previa para que el producto pueda ser admitido y la FDA confirmará esta notificación de acuerdo con los plazos establecidos.

¿Puede ser corregida una notificación previa incompleta?

Si la transmisión de la notificación previa no es validada, el remitente tendrá una oportunidad de hacer las correcciones pertinentes.

La Interfaz del Sistema PN de la FDA tiene funciones de ayuda y retroalimentación interactiva para auxiliar al remitente y minimizar errores u omisiones de escritura. Adicionalmente, la Oficina de Ayuda en Línea estará disponible para ayudar a los usuarios a partir del 12 de diciembre del 2003.

Razones por las cuales aduanas podrá rechazar un producto alimenticio:

- El nombre de marca se encuentra registrado y protegido en los EUA.
- El producto podría ser dañino al consumidor.
- Factura comercial no se presentó o es incorrecta.
- Hay problemas con la etiqueta como falta del nombre del país de origen en inglés, el nombre del producto, el peso neto en onzas, la lista de ingredientes, el contenido nutritivo, o el nombre y localización de la empresa que lo produce, exporta o importa.

Razones por los cuales USDA podrá rechazar un producto alimenticio:

- Contiene bacteria u otros organismos dañinos en la carne.
- Contiene plagas para las plantas (“plant pests”) definido como insectos, enfermedades u otras organismos que podrían ser perjudiciales para la agricultura de los Estados Unidos
- Contiene residuos de plaguicidas en exceso de lo permitido (varía por producto y por plaguicida).
- No cumple con las normas establecidas de tamaño, calidad, condición o madurez (algunos productos)

Razones por las cuales FDA podrá rechazar un producto alimenticio Adulterado:

- Contiene androstendiona, cloranfenicol, clorofluorcarbones, cumarinas, ciclamato, dioxinas, dulcina, ginseng, histamina, anís estrellado japonés, listeria, micotoxina, patulina, radionúclidos, shigella, hepatitis A, salmonela, sacarina o sulfitos.
- Contiene bacteria perjudicial a la salud
- Contiene más del 0.5% de alcohol (confite).
- Contiene residuos peligrosos de plaguicidas (productos frescos)
- Contiene suciedad o sustancias en descomposición
- Contiene un colorante que no está aprobado
- Contiene un suplemento dietético no apto para uso en alimentos
- Contiene una sustancia añadida para aumentar el volumen o peso
- El envase parece estar hecho de una sustancia dañina
- El envase parece estar hinchado o no ser impermeable
- El producto (de dulce) contiene sustancias no nutritivas
- El producto tiene un olor que no debe tener
- En envase no es sujeto a manipulación
- Es de una planta que no sigue buenas prácticas de manufactura (GMP)

Razones por las cuales FDA podrá rechazar un producto alimenticio Adulterado:

- La empresa no ha cumplido con el proceso de registro con FDA
- La empresa no ha registrado su proceso con FDA
- La empresa productora no está registrada como productor de alimentos enlatados acidificados o de baja acidez
- No contiene suficiente ácido
- Parece haber sido empacado en condiciones no sanitarias
- Parece que se ha dejado afuera un ingrediente importante
- Parece que se ha sustituido una sustancia por un ingrediente
- Parece ser de un animal que estaba enfermo
- Parece ser un producto inferior, disfrazado

Adulterado y Error de Nomenclatura porque:

Contiene el colorante FD/C Amarillo No. 5 sin mencionarlo en la etiqueta [Aparte del nombre en Inglés, proporcionar el equivalente en español]

Error de nomenclatura por lo que: [También cambiar los nombres en Inglés por los correspondientes en español]

- Contiene sacarina sin que se mencione con un aviso en la etiqueta, (error de nomenclatura).
- Contiene sulfitos sin declararlo en la etiqueta
- Contiene colorante no especificado en la etiqueta
- Contiene un preservante químico sin declarar en la etiqueta su nombre y su función en el producto
- Contiene un saborizante artificial sin declararlo en la etiqueta
- Información requerida en la etiqueta es muy difícil de leer o de entender
- La calidad del producto es inferior a lo requerido (algunos productos)
- Parece no cumplir con la definición de ese tipo de producto (“Standards of Identity”).

Otras Razones:

El envase fue llenado menos de lo permitido (para algunos productos)
El nombre en la etiqueta no identifica correctamente el contenido
La etiqueta contiene información que parece falsa o engañosa
La etiqueta dice contener “Ginseng”, sin ser cierto
La etiqueta está en violación de la Ley de Empaquetado y Etiquetado Justo (Fair Packaging and Labelling Act)
La etiqueta no da el nombre común de cada ingrediente y hay dos o más ingredientes, la etiqueta no indica la cantidad del contenido, la etiqueta no incluye el nombre y ubicación del fabricante, empacador o distribuidor
La etiqueta no contiene el contenido nutritivo, la etiqueta no contiene información en inglés, La etiqueta promete beneficios no comprobados para la salud,
Parece una imitación de otro producto sin que se indique en la etiqueta
El producto (alimento para niños) no cumple con la ley (falta de documentación).
El producto (leche o crema) requiere un permiso especial (permiso).
El producto (te) es muy inferior en pureza o en calidad (té prohibido).
La etiqueta (jugo de frutas o vegetales) no especifica el porcentaje de jugo de la fruta o vegetal nombrado).
Su venta es prohibida en el país de producción o de exportación.

Recomendaciones generales para atender un proceso de inspección de instalaciones de la US.FDA

Actividades previas a una inspección

1. Responder la factory profile en los 5 días posteriores a su recepción.
2. Coordine fecha de visita.
3. Realice una evaluación interna.
4. Subsanar las fallas y deficiencias identificadas durante la evaluación interna.
5. Mantener vigente el plan de inocuidad, documentación y registros.
6. Crear el equipo de inocuidad, con sus responsabilidades.

Factory Profile

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
12420 Parklawn Dr., Room 2042
Rockville, MD 20857

FACTORY PROFILE

Please provide the following information by email to: USFDAForeignFoodInspectionPlanning@fda.hhs.gov
to assist the U.S.FDA in planning and scheduling an inspection at your Facility.

Facility Information

1. Facility Name:

2. Address of the Main Office or Headquarters (if different than the manufacturing address):

3. Manufacturing Address (English) include City, State/Province/Area, Country, Country Code or Zip Code:

4. Manufacturing Address (Native/Local Language) include City, State/Province/Area, Country, Country Code or Zip Code:

5. Using https://www.mapcoordinates.net/en , what is your Firms Manufacturing location:
   Latitude: Longitude:

6. Does the Firm conduct business under any other name?
   ☐ Yes (Please List) ☐ No

7. Is the Firm associated with a parent company, holding company, group organization, or have a subsidiary or affiliate firms?
   ☐ Yes (Please List) ☐ No

8. Does the Firm, including all associated companies and subsidiaries, average over $10,000,000 in annual sales for each of the previous 3 years?
   ☐ Yes ☐ No

9. Does the Firm have additional manufacturing locations (i.e. farm or additional packing site)?
   ☐ Yes (Please List, and submit a separate Factory Profile for each location) ☐ No

10. The manufacturing location is near what major city?

11. Facility Contact Information:
    i. Telephone number (include country code):
    ii. Email Address:
    iii. Website(s):

12. What are the DAYS and HOURS of production? (Example: M - F 0800 - 1700)

13. Is your facility in production the entire year?
    ☐ Yes ☐ No
    i. If "No", when is the growing season or seasonality? Specify months of peak operation:

CALIFICACIÓN DE DESEMPEÑO

Certificado de entrenamiento de la FSPCA

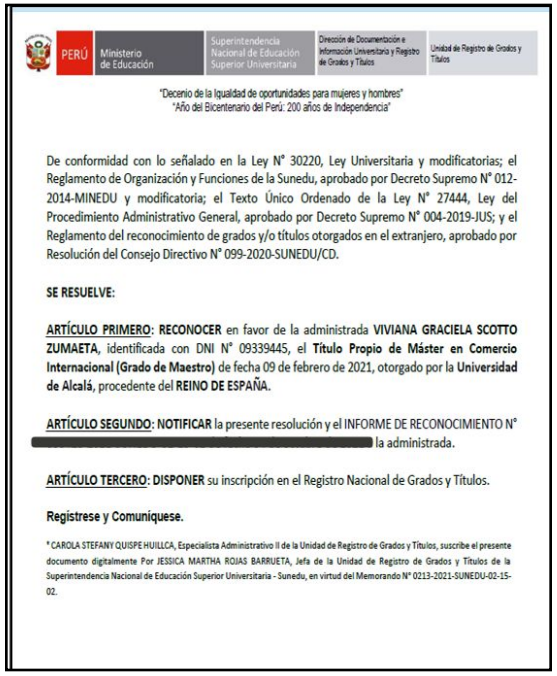
Individuo Calificado en Controles Preventivos", por sus siglas en inglés PCQI (Preventive Control Qualified Individual).


FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
CERTIFICATE OF TRAINING
is awarded to
VIVIANA GRACIELA SCOTTO ZUMAETA
in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
FSPCA Preventive Controls for Human Food
delivered by Lead Instructor
[redacted]
completed on
05/19/2017
Robert Brackett, VP and Director
Institute for Food Safety and Health
Gerald Wottais, Executive Director
International Food Protection Training Institute
Joseph Corby, Executive Director
Association of Food and Drug Officials
IFSH
ifpti
Certificate [redacted]

Constancias de capacitación emitida por la empresa.


BRCGS Food Safety
Certificate of Achievement
This is to certify
VIVIANA GRACIELA SCOTTO ZUMAETA
Has completed and passed
Global Standard for Food Safety Issue 9: Sites Training
Certificate date
05-nov-2022
Michelle Tindale
Director of Performance Enhancement
John Kukoly
BRCGS Director

Constancias de trabajo, títulos universitario


PERÚ Ministerio de Educación | Superintendencia Nacional de Educación Superior Universitaria | Dirección de Documentación e Información Universitaria y Registro de Grados y Títulos | Unidad de Registro de Grados y Títulos
"Decenio de la Igualdad de oportunidades para mujeres y hombres"
"Año del Bicentenario del Perú: 200 años de Independencia"

De conformidad con lo señalado en la Ley N° 30220, Ley Universitaria y modificatorias; el Reglamento de Organización y Funciones de la Sunedu, aprobado por Decreto Supremo N° 012-2014-MINEDU y modificatoria; el Texto Único Ordenado de la Ley N° 27444, Ley del Procedimiento Administrativo General, aprobado por Decreto Supremo N° 004-2019-JUS; y el Reglamento del reconocimiento de grados y/o títulos otorgados en el extranjero, aprobado por Resolución del Consejo Directivo N° 099-2020-SUNEDU/CD.

SE RESUELVE:

ARTÍCULO PRIMERO: RECONOCER en favor de la administrada **VIVIANA GRACIELA SCOTTO ZUMAETA**, identificada con DNI N° 09339445, el **Título Propio de Máster en Comercio Internacional (Grado de Maestro)** de fecha 09 de febrero de 2021, otorgado por la **Universidad de Alcalá**, procedente del **REINO DE ESPAÑA**.

ARTÍCULO SEGUNDO: NOTIFICAR la presente resolución y el INFORME DE RECONOCIMIENTO N° [redacted] la administrada.

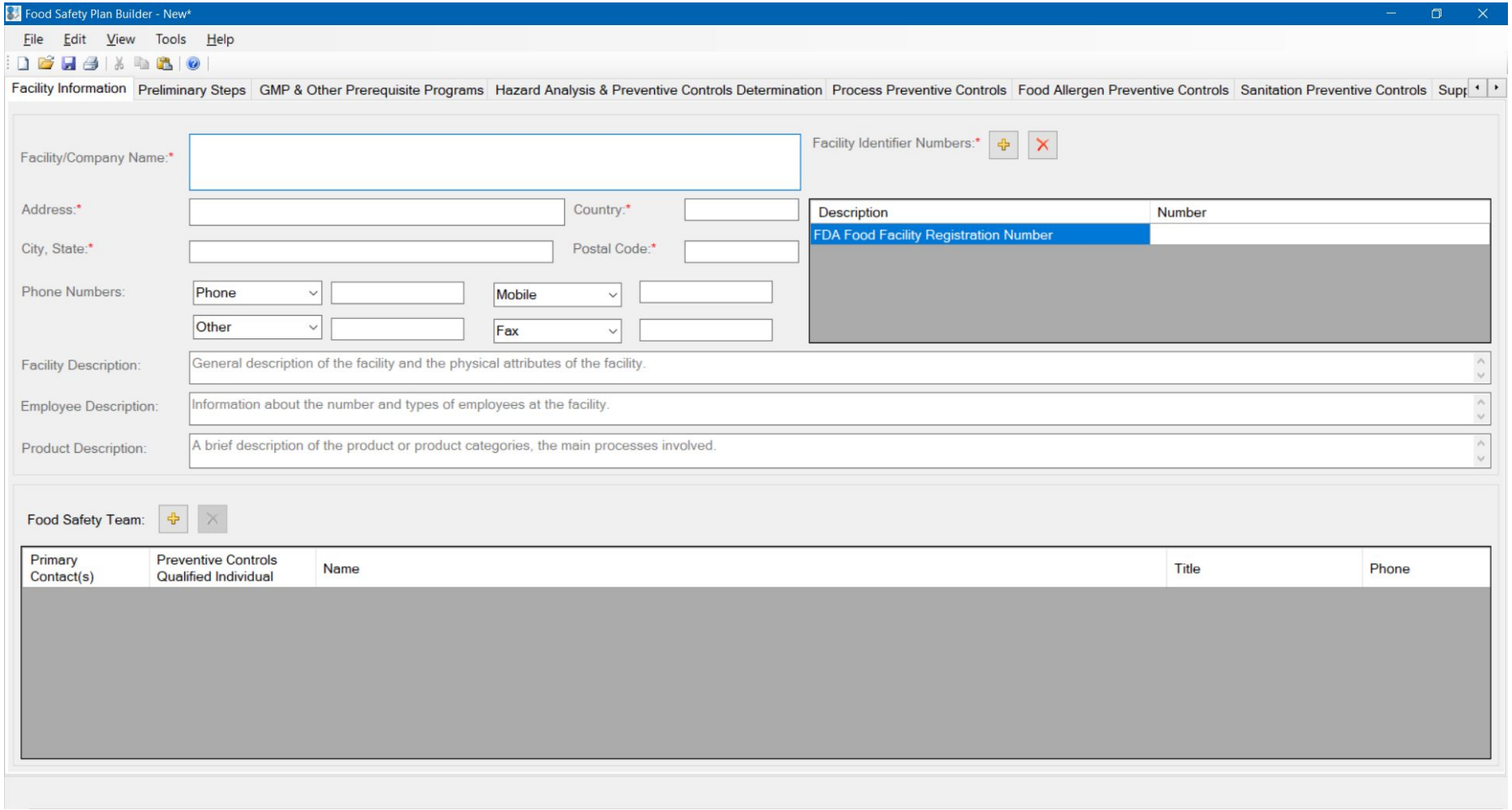
ARTÍCULO TERCERO: DISPONER su inscripción en el Registro Nacional de Grados y Títulos.

Regístrese y Comuníquese.

* CAROLA STEFANY QUISPE HUILLCA, Especialista Administrativo II de la Unidad de Registro de Grados y Títulos, suscribe el presente documento digitalmente Por JESSICA MARTHA ROJAS BARRUETA, Jefa de la Unidad de Registro de Grados y Títulos de la Superintendencia Nacional de Educación Superior Universitaria - Sunedu, en virtud del Memorando N° 0213-2021-SUNEDU-02-15-02.

Esta información debe estar integrada en el archivo laboral de cada trabajador.

Desarrollar el plan de inocuidad de acuerdo a la competencia de la empresa



Evidenciar todo lo solicitado en el plan de inocuidad que pide FDA (cumplimiento FSMA)

PROCESO DE INSPECCIÓN

1. Trabaje con el equipo de trabajo (La dirección general, Responsables de inocuidad, Gerente de producción, Gerencia de empaque, Supervisores y trabajadores que desempeñan una actividad.
2. Participar en la reunión de la sesión de apertura.
3. Documentar y evidenciar las observaciones identificadas por el oficial de la FDA
4. Alcanzar toda la información que le sea requerida (demostrarlo con los registros).
5. Revise con detalle las observaciones establecidas en la 483 Form o 4056 Form.
6. Comuníquese con el oficial de la FDA para poder coordinar donde enviará las observaciones y no conformidades levantadas.

SIEMPRE OBTENGA UNA COPIA DEL ACTA DE CIERRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FDA

PRODUCE FARM INSPECTION OBSERVATIONS

Name of State and Department (if acting under commission with FDA)

DISTRICT OFFICE ADDRESS

DISTRICT OFFICE PHONE NUMBER | DATE(S) OF INSPECTION | FEI NUMBER

LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
(Most responsible individual present) TO:

FARM NAME (include Business name, if different)

OWNER/OPERATOR

FARM MAILING ADDRESS

FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS (e.g., location identifiers such as GPS coordinates)

TYPE OF INSPECTION:
☐ Initial ☐ Routine ☐ Follow-up ☐ For-cause
☐ Other (please specify)

CROPS OBSERVED DURING INSPECTION

This form lists factual observations made by the FDA representative(s) during the inspection of the farm's operation.

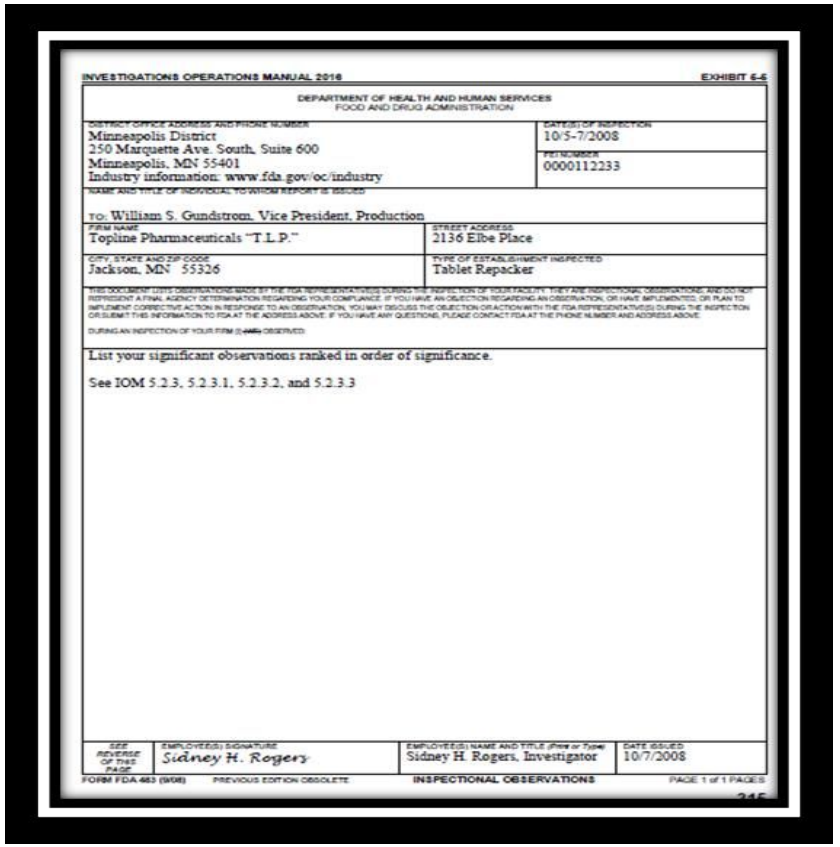
This is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule (21 CFR Part 112) or any other legal requirement.

Representatives of the regulatory agency should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. Representatives of the regulatory agency should record observations in the topic area listed below that, in the representatives' judgment, is the most appropriate topic. Not all topic areas may be applicable in every situation. In addition, representatives of the regulatory agency may not examine every aspect of the farm's operation during an inspection, so a topic area left blank should not be interpreted to mean the farm is in compliance, or not in compliance, with requirements related to that topic area.

Representatives of the regulatory agency should discuss all observations with the management of the farm or their representative as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when this form is issued. Discussion should include those observations which may be written on the form and those that will only be discussed with management during the closeout meeting. This form should be issued during the exit conference of all produce inspections, including when no observations have been recorded.

The farm may use this opportunity to ask questions about the observations or to request clarification. If the farm has implemented, or plans to implement, corrective action in response to an observation, this may be discussed with the representatives of the regulatory agency during the inspection. Representatives of the regulatory agency should annotate the form, as applicable, with any completed or promised corrections discussed during the inspection. FDA representatives are encouraged to verify the farm's completed corrective actions during the inspection as long as the verification does not unreasonably extend the duration of the inspection. Inclusion of annotations regarding corrective actions does not signify any conclusion by the regulatory agency regarding the sufficiency of the actions.

FORM FDA 4034 (01/10) Page 1 of 3



INVESTIGATIONS OPERATIONS MANUAL 2016 EXHIBIT 6-6

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
Minneapolis District
250 Marquette Ave. South, Suite 600
Minneapolis, MN 55401
Industry information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION
10/5-7/2008

FEI NUMBER
0000112233

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: William S. Gundstrom, Vice President, Production

FIRM NAME
Topline Pharmaceuticals "T.L.P."

STREET ADDRESS
2136 Elbe Place

CITY, STATE AND ZIP CODE
Jackson, MN 55326

TYPE OF ESTABLISHMENT INSPECTED
Tablet Repacker

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (1 [illegible] OBSERVED:

List your significant observations ranked in order of significance.

See IOM 5.2.3, 5.2.3.1, 5.2.3.2, and 5.2.3.3

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sidney H. Rogers

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Sidney H. Rogers, Investigator

DATE ISSUED
10/7/2008

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 1 PAGES

Ud puede proporcionar evidencias de que un falla o deficiencia identificada durante la inspección ha quedado corregido.

Posterior al proceso de inspección

a) Alcanzar la información evidenciando que atendió las observaciones.

b) Esperar el resultado de la visita de inspección

c) Otras acciones derivadas del proceso de inspección

MUCHAS GRACIAS …….

Mag. Viviana Scotto Z.
Individuo Calificado en Controles Preventivos (PCQI)
Certificate # d10699ee
FSPCA Preventive Controls for Human Food
Especialista en: Global Standard for Food Safety Issue 9: Sites Training
email: vscotto@vsnitc.com / vscotto@hotmail.com
Web: www.vsnitc.com/
Phone: +51 999798885

VS NITC
National & International Trade Consulting

Seminarios virtuales Miércoles del exportador

Preguntas y respuestas

Lic. Química – Mag.
Viviana Scotto Z
CEO - VSNITC
vscotto@hotmail.com /
vscotto@vsnitc.com