

# Registration of Food Facilities with the FDA

US Food and Drug Administration **(FDA)**

International Office for Latin America

[US-FDA-LAO@fda.hhs.gov](mailto:US-FDA-LAO@fda.hhs.gov) po

# Agenda

- FDA in Brief
- General information about the Export of Food to the USA.
- Registration of Food Facilities

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# What is the FDA?

US federal public health agency, regulatory issues, belongs to the Department of Health and Human Services.



- **Drugs for human use**
  - Prescription, over-the-counter (OTC), generic
- **Biological products such as vaccines, blood supply, blood products.**
- **Medical devices**
  - From simple items like tongue depressors to complex technologies like pacemakers
- **Products that emit radiation –** Microwave ovens, tanning beds, laser pointers
- **Food**
  - Food safety
  - Food additives (including radiation used to treat food)
  - Baby formula
  - Dietary supplements
  - Food utensils
  - Containers-packaging
- **Cosmetics**
- **Veterinary Products**
  - Livestock and pet food
  - Animal drugs
- **Tobacco Products**
- **Color additives (food, medicine, cosmetics).**

# Important Aspects of the US Food Safety System



- FDA is responsible for the safety of 80% of all food consumed in the US, both domestically produced and imported.

## – Exceptions

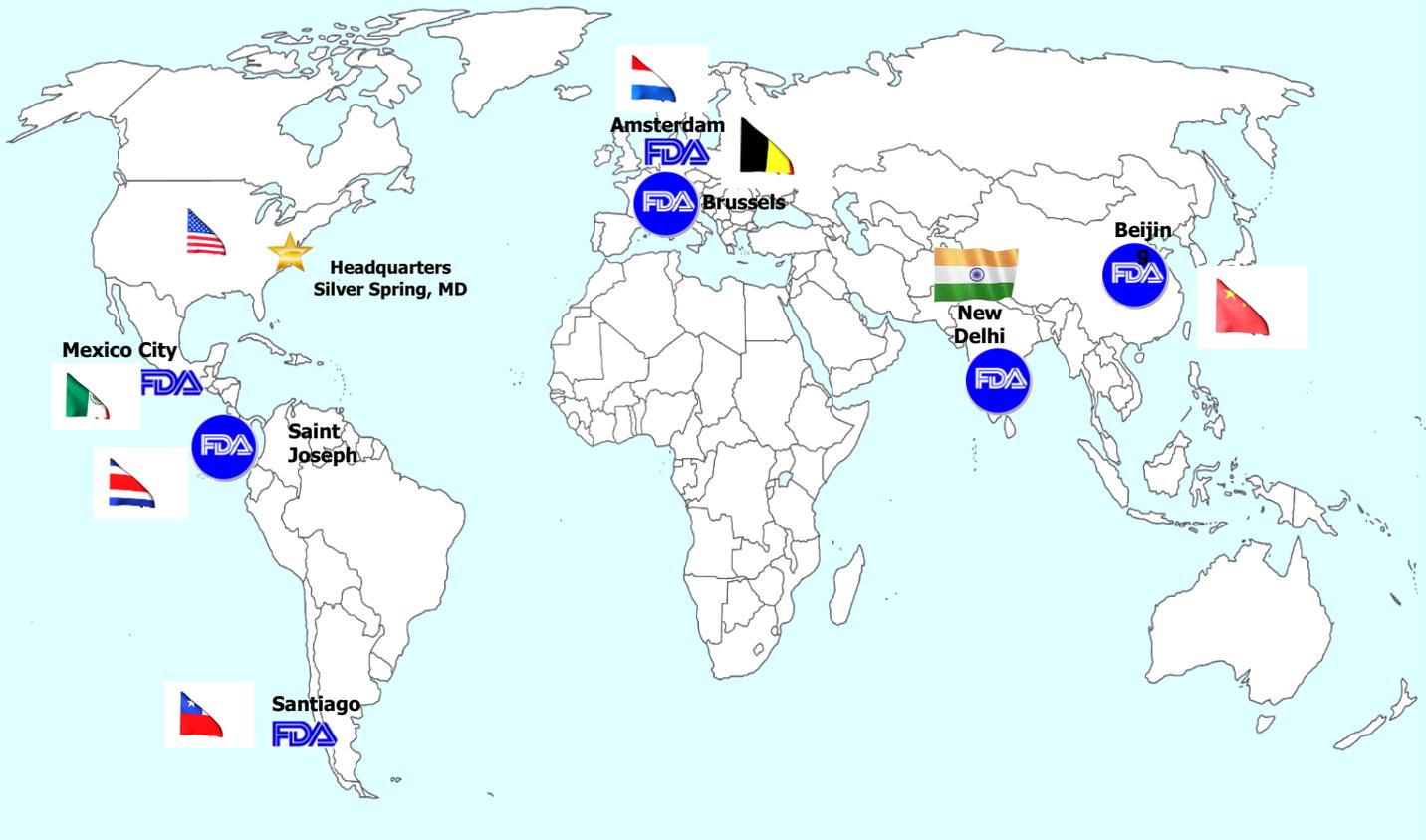
- Meats and meat products
- Poultry and poultry products
- Catfish
- Frozen and processed eggs  
(liquid, dehydrated)
- Animal and Plant Health

***USDA  
Regulated***

- Alcoholic beverages  
with more than 7% alcohol

**Regulated by TTB:  
Alcohol and Tobacco  
Tax and Trade Bureau**

# FDA International Offices





# **General information about the Export of Food to the USA**



All food intended for import into the United States of America must meet the same requirements as domestic products, including:

- Food safety
- Good Manufacturing Practices, Good Agricultural Practices or others, as appropriate.
- **Registration of Facilities**
- Labelling
- Specific requirements for certain products (acidified products, low-acid products stable at room temperature, milk, fish and shellfish, juices and fruit pulps).
- Compliance with the Food Safety Modernization Act (FSMA).

In addition, you must comply with the Prior Notice system.

You must also be available to receive FDA inspections.



# Registration of Food Facilities

- **Why should food facilities be registered?**
- This is a necessary process to be in compliance with US law.

You can find the law in the US Code of Federal Regulations: Title 21, Chapter I, Subchapter A, Part 1, Subpart H.

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-1/subpart-H?toc=1>



# Registration of Food Facilities

- **Why should food facilities be registered?**

The information supplied allows the FDA to learn about food traders in the US, and also helps determine the possible location and source of foodborne disease outbreaks or potential bioterrorism incidents.



# Registration of Food Facilities

- Who must register?
  - Manufacturers or processors
  - Packers
  - Storage operations
- The requirement applies to any and all facilities, *not to firms or joint ventures*.
  - Company with 10 facilities in different locations.
  - Export logistics company.
  - Company with independent headquarters.



# About the Registration of Facilities

- It is recommended that registration be done through the FDA website ( <http://www.access.fda.gov> )
- Registration is free



# About the Registration of Facilities

- Mandatory requirement to select a US Agent
- The system will verify that the selected US agent agrees to be an agent of the company in question.
- After verification, the system will send the registrant an email with the Registration Number and Personal Identification Number (PIN).



## About the Registration of Facilities (cont.)

- The registration must be updated within 60 days of any change made to the facility's registration information.
- If the registered facility changes its address or ownership, or if there is a merger of companies, said registration must be canceled and a new registration made with the updated information.



## About the Registration of Facilities (cont.)

Help in the registration process:

The District offices in the United States and the FDA Regional Office for Latin America do not have the resources to provide technical support for the registration process.

There is a dedicated support office for the food facility registration process, which works Monday through Friday, from 9:00 am to 6:00 pm ET time.

Phone: 1-800-216-7331 or 1-240-247-8804

Email: [furls@fda.gov](mailto:furls@fda.gov)

# Resources to facilitate the registration process for food facilities

- [Account Management](#)
- [Registration of Food Facilities Step-by-Step Instructions](#)
- [Update Facility Registration](#)
- [Biennial Registration Renewal](#)
- [Retrieve Registration PIN](#)
- [Additional Capabilities in FFRM](#)



# Unique Facility Identifier (UFI)

- 21 CFR 1.232(a)(2) requires that as of October 1, 2020, domestic and foreign facilities provide a UFI recognized as acceptable by the FDA.
- The FDA currently recognizes the Data Universal Numbering System (DUNS) number as an acceptable UFI. DUNS numbers are assigned and administered by Dun & Bradstreet
- For information on how to apply for a DUNS number, please use the following link:

<https://www.fda.gov/media/143997/download>



# Recommendations related to the Unique Facility Identifier (UFI)

- Use your own physical address. Do not use agent or shipper information.
- Do not use the location of your headquarters. Every facility must have a DUNS number.
- The legal name and address of the facility on the FDA registration application must match the DUNS information.
- The DUNS number is free, with up to four changes in 90 days.



# DUNS Contact Information

- D&B Phone: 1-866-705-5711
- Email: [ImportSafetySupport@DNB.com](mailto:ImportSafetySupport@DNB.com)
- D&B website: <https://importregistration.dnb.com/>



# Registration Cancellations

- The FDA will not confirm your registration or provide you with a registration number until it verifies the accuracy of your facility's UFI and ensures that the facility's specific address associated with the UFI is the same address associated with your registration.
- The FDA verifies the submitted UFI.
  - (21 CFR 1.231(a)(3) and (b)(5)).D&B). Per 21 CFR 1.231(a)(3) and (b)(5)



# Registration Cancellations

- Starting March 10, 2023, FDA Food Facility Registrations (FFR) without an accurate Unique Facility Identifier (UFI) are being cancelled. Firms that are impacted by FFR cancelled can have their registration reinstated once they provide the required UFI information.



# FDA Food Facility Registration Reinstatement

## **Step 1** : Obtain the DUNS number

Register with D&B, using the same name and physical address of the facility that you have listed on your FDA Food Facility Registration. There can be no differences.

- a. Please visit the [\*\*D&B Import Safety Lookup Portal\*\*](#) to either search your existing records and submit update requests, or to obtain new DUNS numbers. Please refer to the user guide for more information – [\*\*Import Safety Lookup Portal User Guide to obtain a D-U-N-S Number.\*\*](#)



# FDA Food Facility Registration Reinstatement

- b. D&B registration requests returned incomplete (e.g. unable to obtain a DUNS number or update existing registrations) can be forwarded to [importsafetyregistrations@dnb.com](mailto:importsafetyregistrations@dnb.com) for a second review, with an explanation to support your initial request. For example, location of the new branch (headquarters location DUNS 123456789); Address Update: Relocated Facility; Trade name update.
  
- i. Note – D&B may contact you to request legal business documents to support the registration application(s). D&B phone calls may be made on a recorded line.



# FDA Food Facility Registration Reinstatement

- **Step 2** :

Once you have received a specific DUNS number for the facility's address, request your FFR and UFI verification by emailing [cfsanfoodfacilityregistration@fda.hhs.gov](mailto:cfsanfoodfacilityregistration@fda.hhs.gov) using the format described below:

# FDA Food Facility Registration Reinstatement

Subject: UFI accuracy verification

Email body:

- Food Facility Registration Number
- DUNS number
- Food Facility Registration (FFR) Section 2 – Facility Name
- Food Facility Registration (FFR) Section 2 - address, city, state/province, mailing/zip code.

Note:

Section 2 of the FFR is for the legal business name and physical address; Section 6 is for trade names and alternate trade names; Section 3 is for the mailing address; Section 4 is for the parent company. In the body of the email, only include relevant information from section 2 of the FFR.



# FDA Food Facility Registration Reinstatement

Please follow the steps above to submit an accurate UFI and to have the FDA verify the accuracy of your UFI. Upon UFI accuracy verification, the facility may use the same registration number.

# FDA Food Facility Registration Reinstatement



- Will the facility receive a new FFR number?
  - No, after the facility provides an accurate UFI (DUNS number) they will be able to utilize the same number
  
- How can the industry stay up to date with the FFR requirements?
  - The FURLS team has sent several emails and conducted a webinar. You can stay up to date by signing up for FDA emails using the following link: [US Food and Drug Administration \(govdelivery.com\)](https://www.fda.gov/delivery)

# FDA Food Facility Registration Reinstatement

## **Food and Nutrition**

Bacteriological Analytical Manual

CFSAN Constituent Update: Food, Cosmetics, Colors

CFSAN News for Educators

FDA Foodborne Illness Outbreak Investigation

FDA/CFSAN Color Additive News

Dietary Supplements Ingredient Advisory List

Food Importer News from the U.S. FDA

Food Safety Modernization Act (FSMA)

Interstate Certified Shellfish Shippers

Interstate Milk Shippers

Retail Food Protection

Seafood Safety Updates

U.S. Food Exporter News from FDA

Smarter Food Safety

Food Facility Registration and Renewal 



# FDA Food Facility Registration Reinstatement

- Who can I contact for help?

Please contact FURSL by phone at 1-800-216-7331 or by email [at FURLS@fda.gov](mailto:FURLS@fda.gov) .



## How to carry out the Facility Registration?

Enter the following link:

<https://www.access.fda.gov/>



# Opening an account in the system (Food Facility (FFR) system)

Click on:  
**Login**



U.S. Department of Health and Human Services

**FDA**  
FIS

**U.S. FOOD AND DRUG ADMINISTRATION**  
INDUSTRY SYSTEMS

FDA Home | FIS Home

### FDA Industry Systems

[Check System Status](#)

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

[Log-In](#) [Create Account](#)

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

### Systems Index

<p><b>FURLS Acidified/Low Acid Canned Foods (LACF)</b> Form <a href="#">2541/2541d/2541e/2541f/2541g</a> OMB Approval Number <b>0910-0037</b> OMB Expiration Date <b>09/30/2017</b> See <a href="#">OMB Burden Statement</a></p> <p><a href="#">Info</a> <a href="#">Help</a></p>	<p><b>FURLS Biologics Export Certification Application &amp; Tracking System (BECATS)</b> FDA <b>3613</b> OMB Approval Number <b>0910-0498</b> OMB Expiration Date <b>03/31/2018</b> See <a href="#">OMB Burden</a></p> <p><a href="#">Info</a> <a href="#">Help</a></p>	<p><b>FURLS Dairy Listing Module (DLM)</b> FDA <b>3972</b> OMB Approval Number <b>0910-0509</b> OMB Expiration Date <b>09/30/2017</b> See <a href="#">OMB Burden</a></p> <p><a href="#">Info</a> <a href="#">Help</a></p>
<p><b>FURLS CDER Export Certification Application &amp; Tracking System (CDEReCATS)</b> FDA <b>3613</b> OMB Approval Number <b>0910-0498</b> OMB Expiration Date <b>03/31/2018</b> See <a href="#">OMB Burden</a></p> <p><a href="#">Info</a> <a href="#">Help</a></p>	<p><b>FURLS CDRH Export Certification Application &amp; Tracking System (CECATS)</b> FDA <b>3613</b> OMB Approval Number <b>0910-0498</b> OMB Expiration Date <b>03/31/2018</b> See <a href="#">OMB Burden</a></p> <p><a href="#">Info</a> <a href="#">Help</a></p>	<p><b>FURLS CFSAN Certificate Application Process (CAP)</b> FDA <b>3613d/3613e</b> OMB Approval Number <b>0910-0793</b> OMB Expiration Date <b>05/31/2018</b> See <a href="#">OMB Burden</a></p> <p><a href="#">Info</a> <a href="#">Help</a></p>



## FDA Industry Systems

[System Status](#)

08/31/2016 See [The 2016 Food Facility Registration Biennial Renewal period begins at 12:00 AM on October 1st 2016.](#)

08/04/2016 See [CDERECATS is not accepting applications or issuing export certificates for the Foreign Exported CPP.](#)

### Login

Existing account holders, enter your account ID & password.

Account ID

Password

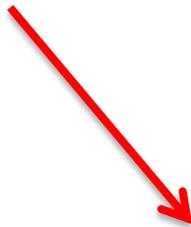
*Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*

I understand.

Login

[Forgot your password](#)

Click on :  
Create New  
Account



### 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 contact **AskCTP at 1-877-287-1373 or AskCTP@fda.hhs.gov** and the AskCTP 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.

### Create New Account

Create New Account

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

#### Step 1: Select Application(s) for Account Creation

##### Registration and Listing Programs

###### Food

Acidified/Low-Acid Canned Foods Registration and Process Filing

Dairy Listing Module

Food Facility Registration

New Dietary Ingredient Notification

Shell Egg Producer Registration

Structure/Function Claims Notification

Do you work for a State agency under contract with the FDA?

Yes  No

###### Medical Devices

Device Registration and Listing Module

###### Tobacco Products

Tobacco Registration and Listing System

##### Export Certification and Tracking

Biologicals Export Certification Application and Tracking System (BECATS)

CDER Export Certification Application and Tracking System (CDEReCATS)

Certificate Application Process  
*Includes Landfood, Seafood, Cosmetics, Food Additive, Food Contact Substances, Dietary Supplements, Infant Formula, Medical Foods, and Foods for Special Dietary Use.*

CDRH Export Certification Application and Tracking System (CECATS)

##### Other FDA Systems

Prior Notice System Interface

Cancel

Clear

Continue

1. Check:  
Food facility Registration

2. And answer the question which will appear:  
Do you work for a State agency under contract with the FDA?

3. If you are going to use the Prior Notice system, select Prior Notice system interface

4. Click on :  
continue

Step 2: Enter Your Account Information

2A: Point of Contact Information

First Name

Middle Initial (Optional)

Last Name / Surname

Job Title

Company Name

Web Address (Optional)

(Example: <http://www.name.domain> or <http://name.domain>)

Phone Number

Country	Area	Telephone	Ext
---------	------	-----------	-----

Country Area Phone Number Extension

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

FAX Number (Optional)

Country	Area	Fax Number
---------	------	------------

Country Area Fax Number

E-mail Address

Confirm E-mail Address

2C: Physical Address (Business) of Account Holder

Country / Area

Address Line 1

Address Line 2 (Optional)

City

State / Province / Territory

Zip Code (Postal Code)

Do you have preferred mailing address other than the physical address mentioned above?

Yes  No



5. Fill in the information requested

6a. Answer the question :  
Do you have preferred mailing address other than the physical address mentioned above?

Step 2: Enter Your Account Information

2A: Point of Contact Information

First Name

Middle Initial (Optional)

Last Name / Surname

Job Title

Company Name

Web Address (Optional)  
  
(Example: http://www.name.domain or https://name.domain)

Phone Number  
 Country  Area  Telephone  Ext   
Country Area Phone Number Extension

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

FAX Number (Optional)  
 Country  Area  Fax Number

E-mail Address

Confirm E-mail Address

2B: Account information

Password

Passwords must be at least 8 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., %,\$). You will need to remember your password to login in the future.

2C: Physical Address (Business) of Account Holder

Country / Area  
 Please Select Country

Address Line 1

Address Line 2 (Optional)  
 Optional

City

State / Province / Territory  
 Please Select

Zip Code (Postal Code)

Do you have preferred mailing address other than the physical address mentioned above?  
 Yes  No

2D: Preferred mailing Address

Country / Area  
 Please Select Country

Address Line 1

Address Line 2 (Optional)  
 Optional

City

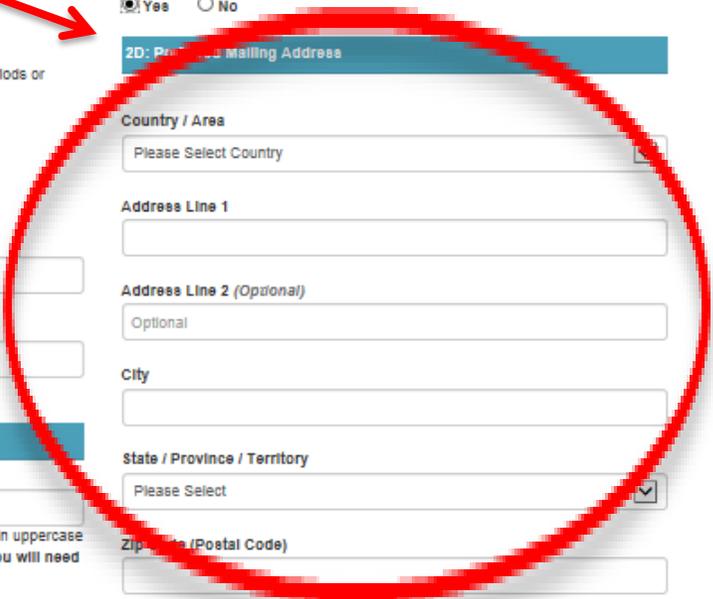
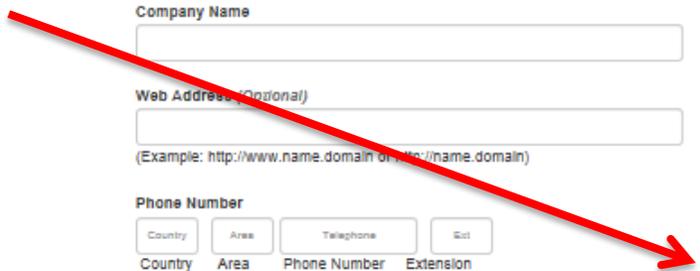
State / Province / Territory  
 Please Select

Zip Code (Postal Code)

6. If you answered "YES" to the question :

Do you have preferred mailing Address other than the physical address mentioned above??

- Then enter the requested information



## 2B: Account Information

Password

.....

Passwords must be at least 8 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., %, \$). You will need to remember your password to login in the future.

Confirm Password

.....

Secret Question 1

What was your high school mascot?

Secret Answer 1

vietnamitas

Secret Question 2

What was your childhood nickname?

Secret Answer 2

chiquis

Secret Question 3

What color was your first car?

Secret Answer 3

blue

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.

Previous

Clear

Continue

7. Fill in the information required

DO NOT FORGET your password

DO NOT FORGET your questions

DO NOT FORGET your secret answers

8. Check the box:  
I understand

9. Click on :  
continue

## 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 **del12345** for **Mexican delights**.

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.

**CFSAN - Center for Food Safety and Applied Nutrition**

Click to launch the Application(s)

Food Facility Registration

Certificate Application Process

Acidified/Low-Acid Canned Foods Registration and Process Filing

Structure/Function Claims Notification

Shell Egg Producer Registration

New Dietary Ingredient Notification

**Other FDA Systems**

Prior Notice System Interface

Systems Recognition Program

The system will assign you a "User ID"

Company name

Indicate which system you will use:  
**Food Facility Registration**

Now you have an account in the system. You may proceed to the registration.



# Food Facility Registration

Choose the option: **Register a Food facility**

- FFR Home
- Register a Food Facility**
- Biennial Registration Renewal - 2018
- Cancel Registration
- Search Facility Registrations
- Link Registration to your Account
- Manage Registrations Among Accounts
- Confirm Notification Receipt
- 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.

## 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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

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

For assistance, please contact the FDA Industry Systems Help Desk:  
1-800-216-7331  
301-575-0156  
[furfs@fda.gov](mailto:furfs@fda.gov)

(Technical, Computer & General Questions)  
Help desk hours are Monday to Friday from 7:30 am to 11:00 pm Eastern Standard Time

If you are registering for the first time, the following questions will appear before Section 1 appears.

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?

Yes  No

Are you a broker, distributor, importer/filer?

Yes  No

Do you take physical possession of the food?

Yes  No

In accordance with Section 415 of the Federal Food, Drug, and Cosmetic Act, you are not required to register. As defined in 21 CFR 1.225, domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. must register with the FDA. Please be advised that if you choose to proceed with registering, you must comply with all registration requirements and other statutory requirements of the FD&C Act that may apply.

Regardless of the answers you choose, you can continue to register your food facility

# Section 1. Type of Registration



Food Facility Registration

FFR Home > Register a Food Facility

Section 1 | Section 2-4 | Section 5-7 | Section 8-9 | Section 9a-9b | Section 10 | Section 11-12 | Review

## Section 1: Type of Registration

### Facility Location

Choose option: **Foreign Registration**

Are you the new owner of a previously registered facility?

Yes  No

Select:

**YES**, if you are trying to register as owner of a previously registered facility

If "Yes", provide the following information, if known.

**NO**, if the facility you are trying to register has never been registered

### Previous Owner's Title (Optional)

Indicate previous owner title, Mr., Mrs., Ms., Dr., Other

### Previous Owner's Name (Optional)

Please provide name of previous owner, if known

### Previous Owner's Registration Number (Optional)

Indicate the previous owner's registration number

## Section 2. Name and Address of Facility



### ^Section 2: Facility Name/Address Information

**Facility Name**

**Facility Name Suffix**

**Country/Area**

**Street Address, Line 1**

**Street Address, Line 2**

**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**

**Telephone Number**  
     
Country Area Phone Number Extension

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

**E-Mail Address**

Enter the requested information

Make sure the address is the actual location of the facility (not the tax address, or of its offices, unless they are the same).



## Section 3. Preferred Mailing Address Information– Optional

Section 3: Preferred Mailing Address Information

Is the preferred mailing address the same as the facility address (Section 2)?  
 Yes  No

**Name**

**Country/Area**

**Street Address, Line 1**

**Street Address, Line 2**

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

**City**

**State/Province/Territory**

**Telephone Number (Optional)**  
     
Country Area Phone Number Extension

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

**E-Mail Address (Optional)**

Enter the information requested

Make sure the address is the location where you prefer to receive regular mail by post. This may be your office address.



## Section 4. Parent Company Name/Address - Optional

### ^Section 4: Parent Company Name/Address Information

Is the parent company address the same as the facility address or preferred mailing address (Sections 2 and 3)?

- Same as Facility Address (Section 2) ← **Check here, If the information is the same as in section 2 or**
- Same as Preferred Mailing Address (Section 3) ← **Check here, If the information is the same as in section 3 or**
- None of the above ← **Check here if it is none of the above and answer the requested information**

Clear

Autofill from Account Information

Company Name

Company Name Suffix

Country/Area

Street Address, Line 1

Street Address, Line 2

Zip/Postal Code

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

City

State/Province/Territory

Telephone Number

Country	Area	Telephone	Ext
Country	Area	Phone Number	Extension

Fax Number (Optional)

Country	Area	Fax
Country	Area	Fax Number

E-Mail Address (Optional)

## Section 5. Facility Emergency Contact Information

### Section 5: Facility Emergency Contact Information

For foreign facilities, FDA will use your U.S. agent as your emergency contact unless you choose to designate a different contact here.

If information is the same as another section, check which section:

Same as Facility Address (Section 2)

None of the above

Clear

Autofill from Account Information

Title *(Optional)*

Please Select



Please enter 001 as country code for Anguilla, Antigua and Barbuda, Bahamas, Barbados, Bermuda, British Virgin Islands, Cayman Islands, Dominica, Dominican Republic, Grenada, Jamaica, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Trinidad and Tobago, Turks and Caicos Islands.

Telephone Number

Country

Area

Telephone

Country

Area

Phone Number

First Name *(Optional)*

Middle Name *(Optional)*

Last Name *(Optional)*

E-Mail Address

Job Title *(Optional)*

For foreign facilities, FDA will use the US Agent as your emergency contact unless you designate a different contact in this section.

Enter the requested information

## Section 6. Trade Names



### Section 6: Trade Names

(If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as"))

Are there alternate trade names used by your facility in addition to the name provided in **Section 2: Facility Name/Address Information**?

Yes    No

Alternate Trade Name #1

Alternate Trade Name #2

Alternate Trade Name #3

Alternate Trade Name #4

If this facility is known by other names, indicate them here

### Section 7: United States Agent

Note: If you modify this address, please review the address in Section(s) 11 to verify that those addresses are still correct.

(To be completed by facilities located outside any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico)

If you are assigning a new US agent please select Yes. If you are simply changing the name or address of your current US agent please select No.

(Note: Registration number and PIN will be mailed to your new U.S Agent if you select Yes.)

Yes  No

Clear

Autofill from Account Information

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

Zip Code

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

City

Please Select

State/Province/Territory

Please Select

Telephone Number

Country Area Phone Number Extension

Emergency Contact Telephone Number

Country Area Phone Number

Fax Number (Optional)

Country Area Phone Number

E-Mail Address

Enter the requested information about the US Agent

**Section 8.** Seasonal Facility Dates of Operation

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

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

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

Dates of Operation

**Harvest 1**

Start Month

End Month

**Harvest 2**

Start Month

End Month



## Section 9. General Product Category– Human/Animals/Both

**Based on the activities of your facility, you can choose food for human or animal consumption; or both**

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

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

**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

- 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]
- 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula
- 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]
- 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)]
- 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING / INSTANT CEREALS [21 CFR 170.3 (n) (4)]

**Categories or types of Products**

If your facility does not manufacture, process, pack, or hold food for human consumption, select box 37: “...NONE OF THE ABOVE FOOD CATEGORIES APPLY”. You can enter your own description in the box provided.



**Section 9a – General Product Categories –  
Food for human consumption; and  
Type of Activity Conducted at the facility (continuation)**

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

TYPE OF ACTIVITY CONDUCTED AT THE FACILITY. Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.

Selected Product Name	Select Activity Types
12. DIETARY SUPPLEMENT CATEGORIES	
b. Vitamins and Minerals	None selected ▼

**Other Activity Conducted**

Select the type of **activities conducted at the facility** . You may check all types of operations that are performed at this facility regarding the **manufacturing and processing, packing, or holding of food**. For example, if you select the product category “alcoholic beverages, number 1” and you work as a “manufacturer / processor”, you must select that option on line 2 of column 8.

**Section 9b – General Product Categories –**  
Food for animal consumption; and  
Type of Activity conducted at the facility (continued)



**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.**

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

Of the 32 **categories**, select as many as apply. If none of the required categories apply, select box 33: “...NONE OF THE ABOVE FOOD CATEGORIES APPLY”. You can then enter your own description in the box provided.

**Section 9b – General Product Categories –  
Food for animal consumption; and  
Type of Activity conducted at the facility (continued)**



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

TYPE OF ACTIVITY CONDUCTED AT THE FACILITY. Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.

Selected Product Name	Select Activity Types
1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS)	<input type="text" value="None selected"/>

**Other Activity Conducted**

**Activities.**

The “Select all” and “Deselect All” options are also available, which allow users to select or deselect all available options at the same time.

## Section 10. Owner, Operator, or Agent-in-Charge Information



**Section 10: Owner, Operator, or Agent-in-Charge Information**

Name of Entity or Individual Who is the Owner, Operator, or Agent-in-Charge

Is their contact information the same as any of the previous sections?

Same as Facility Address (Section 2)  
 Same as Preferred Mailing Address (Section 3)  
 Same as Parent Mailing Address (Section 4)  
 Same as U.S. Agent Information (Section 7)  
 None of the above

Country/Area  
Please Select a Country/Area

Street Address, Line 1

Street Address, Line 2

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

Telephone Number  
     
Country Area Phone Number Extension

Fax Number (Optional)  
    
Country Area Fax Number

E-Mail Address

If the contact details of the owner, operator or agent-in-charge are the same as in any other section of the form, select the circle corresponding to that section; if not, enter the requested information.



## **Section 11.** Inspection Statement

The FDA may inspect the facility as permitted by the Federal Food, Drug, and Cosmetic Act.

## Section 12. Certification Statement

### 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**

**Select One Option**

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

Enter your name as the submitter of this registration.

Indicate the person who authorized the registration application.

# Registration Information Review



✓Section 1   ✓Section 2-4   ✓Section 5-7   ✓Section 8-9   ✓Section 9a-9b   ✓Section 10   ✓Section 11-12   **Review**

**Please review your registration. If all information is correct, click the Submit button below. To make changes to a section, click the Edit button for that section.**

Date \_\_\_\_\_ Created by \_\_\_\_\_

Created Date \_\_\_\_\_

Registration Status \_\_\_\_\_

Registration Status Reason \_\_\_\_\_

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?  
 Yes    No

**Section 1: Type of Registration**

Facility Location: Domestic 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:

if you want to change click " Edit "

**Section 2: Facility Name/Address Information**



**NOTE:** The address of the facility indicated in Section 1: Type of Registration (where you indicated whether this was a domestic or foreign facility) cannot be changed at this point. If you wish to change the facility's location, you must cancel this registration and start a new one.

Click on the “Submit ” button and you will see the following message

The FDA logo consists of the letters "FDA" in a white, bold, sans-serif font, centered within a solid blue square.

## Registration Submitted - Verification Pending

*In accordance with 21 CFR 1.231(a)(5) and (b)(7), FDA will not confirm a registration or provide a registration number until the person identified as the U.S. agent for a foreign facility confirms that person has agreed to serve as the U.S. agent. The U.S. agent that you have listed has been contacted and should respond to our confirmation request by 10/16/2016. Upon successful confirmation, the registration number and pin will be issued.*

*Once received, please keep the registration number and PIN for your records.*



## US Agent Verification

### This must be done by the US Agent

- Once all 12 registration sections are filled out and submitted, the system will send an email to the US Agent.
- The US Agent must follow the instructions included in the email and respond whether or not they agree to become the agent of the facility in question. This must be done within 30 calendar days after receiving the mail.

**NOTE:** The agents are advised to check their "spam" or "junk" folders if they have not received the notification in their inbox, since the email may have gone to one of these folders.

# US Agent Verification

From: <[CFSANFoodFacilityRegistration@fda.hhs.gov](mailto:CFSANFoodFacilityRegistration@fda.hhs.gov)>  
Date: Nov 14, 2016 11:24 PM  
Subject: Initial Agent Assignment Notification  
To: **US Agent Email** .  
Cc:



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
5001 Campus Drive, HFS-681  
College Park, MD 20740

The US agent will receive an email like this

**Date:** November 15, 2016

Dear Sir/Madam,

The U.S. Food and Drug Administration (FDA) is hereby notifying you that FDA received a food facility registration listing you as the U.S. Agent for the foreign food facility identified below. The registration was submitted to FDA as required by section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350d] and FDA's food facility registration regulation at Title 21, Code of Federal Regulations (CFR) Part 1, Subpart H. Under section 415 of the FD&C Act and 21 CFR Part 1, Subpart H, a foreign food facility engaged in manufacturing/processing, packing, or holding of food for consumption in the United States must be registered with FDA and such registration must include, among other things, the name and contact information of the U.S. Agent for the facility.

**Food Facility Name:** Facility name

**Food Facility Address:** Installation address

**Receipt Code:** AbC#d #

**Name of U.S. Agent:** This is where the contact information will be

**Title of U.S. Agent:**

**Street Address Line 1:** US Agent

**Street Address Line 2:** Name

**City:** Address

**ZIP Code:** Country

**Country/Area:**

## US Agent Verification

**In accordance with 21 CFR 1.231(a)(5) and (b)(7), FDA will not confirm a registration or provide a registration number until the person identified as the U.S. agent for a foreign facility confirms that person has agreed to serve as the U.S. Agent. We are requesting your action within 30 calendar days of receipt of this notification. If you take no action within 30 calendar days, the registration information will be removed from our database and the facility will be required to submit another registration submission.**

To confirm or decline this listing, please click on the following link and provide the above listed receipt code when prompted: <https://www.access.fda.gov/>.

**Click on the link  
and enter the code  
sent to you by the  
system**

If you confirm this listing, you will assume the responsibilities of the U.S Agent and the registrant will receive their registration number. Please note that you will need to save the above listed receipt code to maintain access to this registration in the future.

If you decline this listing, the registrant will be notified that you have not agreed to serve as the U.S. Agent for the facility. We will then request that the facility amend its registration to designate another U.S. Agent who has affirmatively agreed to serve.

If you confirm this listing as the U.S. Agent for the foreign food facility listed above, but your contact information is incorrect, 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 update this information within 60 calendar days of any change to the previously submitted contact information using Form FDA 3537. The authorized individual may be, but is not required to be, the U.S. Agent for the facility. When using Form FDA 3537, the owner, operator, or agent in charge, or the individual authorized by one of them, must check the items being updated in Section 1 of the form. If the facility has an existing electronic account (established when the facility is registered electronically) that is linked to this registration, the registration may be updated electronically via <https://www.access.fda.gov/>.

Alternatively, the owner, operator, or agent in charge of the facility, or an individual authorized by one of them, may submit an update by mail or fax to:

U.S. Food and Drug Administration  
5001 Campus Drive, HFS-681  
College Park, MD USA 20740  
Fax: [301-436-2804](tel:301-436-2804)

Section 743 of the FD&C Act [21 U.S.C. 379j-31] authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees [21 U.S.C. 379j-31].



The US Agent must:

1. Click on "Create an Account"
2. Choose "Food Facility Registration"
3. Enter the information needed to create an account.
4. Once the account is created in the system, your US Agent will have a user ID (provided by the system) and a password (created by the US agent).
5. You must log into the system with your user ID and password
6. You will see a menu on the left side. Select the option "Confirm Notification Receipt"
7. Enter the "Receipt Code" that should have arrived in a separate email

Once your US Agent has completed all of the above steps, the person who entered the registration information will receive an email with the Facility Registration number and Personal Identification Number (PIN) .



# Agent Confirmation

Choose the option: **Confirm Notification Receipt**

FFR Home
Register a Food Facility
Biennial Registration Renewal - 2016
Cancel Registration
Search Facility Registrations
Link Registration to your Account
Manage Registrations Among Accounts
<b>Confirm Notification Receipt</b>
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.

**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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

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

For assistance, please contact the FDA Industry Systems Help Desk:  
1-800-216-7331  
301-575-0156  
[furts@fda.gov](mailto:furts@fda.gov)

(Technical, Computer & General Questions)  
Help desk hours are Monday to Friday from 7:30 am to 11:00 pm Eastern Standard Time



## The next time you need to:

- Modify your account information
- Carry out the Biannual Renewal of the Registration (always on even-numbered years and between October and December)
- Modify your registration information
- Register another facility
- Cancel a registration
- Link an account to an existing record

You will have to log in with your user ID (which was assigned to you by the FDA) and password (which you created) as explained in the following link:

<https://www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1>



## FDA Industry Systems

[System Status](#)

08/31/2016 See [The 2016 Food Facility Registration Biennial Renewal period begins at 12:00 AM on October 1st 2016.](#)

08/04/2016 See [CDERECATS is not accepting applications or issuing export certificates for the Foreign Exported CPP.](#)

1. Enter your  
User ID



### 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 your password](#)

2. Enter your  
Password



3. Check:  
I understand

### 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 contact **AskCTP at 1-877-287-1373 or AskCTP@fda.hhs.gov** and the AskCTP 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.



# Registration Renewal



**FFRM MAIN MENU**

Biennial Registration Renewal

Register a Food Facility

Update Facility Registration

Cancel Registration

Search Facility Registrations

Link Registration to your Account

Manage Registrations Among Accounts

Confirm Notification Receipt

**Form Approval: OMB No.0910-0502**

Expiration date: 08/31/2013  
See OMB Statement at end of form

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.

**Please Note:**

The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.



Get Help ?

Please review your registration. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 09/20/2012 11:09:02

**SECTION 1 TYPE OF REGISTRATION** **EDIT**

1a: DOMESTIC REGISTRATION  
1b: INITIAL REGISTRATION Registration number will be generated upon submission

ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY?  Yes  No

1c: PREVIOUS OWNER'S TITLE: PREVIOUS OWNER'S NAME: PREVIOUS OWNER'S REGISTRATION NUMBER:

**SECTION 2 FACILITY NAME / ADDRESS INFORMATION** **EDIT**

FACILITY NAME: GlobalMed  
FACILITY NAME SUFFIX: Corporation FACILITY NAME SUFFIX OTHER:  
FACILITY STREET ADDRESS, Line1: 123 Main Street  
FACILITY STREET ADDRESS, Line2:  
CITY: Rockville STATE/PROVINCE/TERRITORY: Maryland  
ZIP CODE (POSTAL CODE): 20852  
COUNTRY/AREA: UNITED STATES  
PHONE NUMBER (Include Area/Country Code): 001 301 7705555  
FAX NUMBER (Optional, Include Area/Country Code):  
E-MAIL ADDRESS: pianer@gnai.com

**SECTION 3 PREFERRED MAILING ADDRESS INFORMATION (Optional)** **EDIT**

Complete this section if different from Section 2 Facility Name/Address Information (OPTIONAL)

If information is the same as section 2, check the box:

NAME:  
ADDRESS, Line1:  
ADDRESS, Line2:  
CITY: STATE/PROVINCE/TERRITORY:  
ZIP CODE (POSTAL CODE):  
COUNTRY/AREA:  
PHONE NUMBER (Include Area/Country Code):  
FAX NUMBER (Optional, Include Area/Country Code):  
E-MAIL ADDRESS (Optional):

You can update the information whenever the “edit” option is enabled



The screenshot shows a web browser window with the URL `access.fda.gov/ffm/registerNewFacility-flow.htm?execution=e3s17`. The page header includes the U.S. Department of Health and Human Services logo and the FDA FURLS logo. The main heading is "Food Facility Registration". A navigation menu on the left lists options: "FFR Home", "Register a Food Facility" (highlighted), "Update Facility Registration", "Cancel Registration", "Search Facility Registrations", "Link Registration to your Account", "Manage Registrations Among Accounts", "Confirm Notification Receipt", and "Retrieve Registration PIN". The main content area displays a green heading: "Registration Submitted - Verification Pending". Below this, a green italicized message states: "In accordance with 21 CFR 1.231(a)(5) and (b)(7), FDA will not confirm a registration or provide a registration number until the person identified as the U.S. agent for a foreign facility confirms that person has agreed to serve as the U.S. agent. The U.S. agent that you have listed has been contacted and should respond to our confirmation request by 03/17/2017. Upon successful confirmation, the registration number and pin will be issued." A second green italicized message follows: "Once received, please keep the registration number and PIN for your records." The Windows taskbar is visible at the bottom of the browser window.

Done!

To complete the process, your US agent must confirm your role.  
Remember that you need to renew your registration every two years.



# How to Get Help

## Contact FDA Industry Systems Helpdesk

1-800-216-7331

301-575-0156

[furls@fda.gov](mailto:furls@fda.gov)

(For general and technical questions on the registration process)

Hours: Monday to Friday from 7:30 am to 11:00 pm- Atlantic time

## How to access the system:

[www.fda.gov/furls](http://www.fda.gov/furls)

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>

## How to retrieve your PIN, if necessary: “How to Retrieve Registration PIN”:

<http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm408769.htm>

## Step-by-step instructions, in English and Spanish:

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073706.htm>

GRACIAS GRACIAS  
Gracias Gracias Gracias

THANK YOU