

Instructions for Electronic Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low-Acid Food Canning Establishment

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
September 2012**

Table of Contents

| | | |
|------|--|----|
| I. | Introduction | 4 |
| II. | Portals for Electronic Submissions | 5 |
| A. | FDA’s Industry Systems (FIS) | 5 |
| B. | FDA’s Unified Registration Listing Systems (FURLS) | 5 |
| C. | Relationship Between the Electronic Acidified/Low-Acid Canned Food System and Food Facility Registration | 5 |
| III. | How to Obtain an FDA Account at the FIS Electronic Portal | 6 |
| IV. | General Information About Navigating the Registration Section of the Electronic AF/LACF System..... | 7 |
| V. | How to Enter the AF/LACF System Through the FIS Electronic Portal | 9 |
| VI. | How to Register a New Acidified/Low-Acid Food Canning Establishment (Submit Form FDA 2541) | 10 |
| A. | Navigate to the Page for an Establishment Without an FCE Number | 10 |
| B. | Step 1 - Section 1 – Type of Submission | 11 |
| 1. | Section 1 - Link the FDA Account ID to the Electronic AF/LACF System..... | 13 |
| 2. | Section 1 - Type of Submission | 14 |
| C. | Step 2 - Section 2 – Food Processing Plant Location | 15 |
| D. | Step 3 - Section 3 – Preferred Mailing Address | 17 |
| E. | Step 4 - Section 4 – Foods Processed at the Location | 19 |
| 1. | Add Product(s)..... | 19 |
| 2. | Edit Product | 22 |
| 3. | Remove Product..... | 23 |
| 4. | Continue | 24 |
| F. | Step 5 - Section 5 –Facility Contact Person | 24 |
| G. | Step 6 - Section 6 – Please Note the Following | 28 |
| H. | Complete Registration Process | 31 |
| 1. | Correct Registration Information..... | 31 |
| 2. | Submit Registration..... | 31 |
| 3. | Print Submitted Form FDA 2541 | 32 |
| VII. | How to Change or Cancel Registration Information | 35 |
| A. | Change Registration Information | 36 |

| | | |
|-------|--|----|
| B. | Cancel Registration..... | 36 |
| VIII. | How to Search Registrations..... | 38 |
| IX. | How to Contact FDA or Obtain Help..... | 40 |
| X. | References..... | 40 |

List of Figures

| | | |
|------------|--|----|
| Figure 1: | Example of Navigation Tools and Step by Step Tracker in Section 2 of the Registration Section..... | 8 |
| Figure 2: | FDA Unified Registration and Listing Systems (FURLS)..... | 9 |
| Figure 3: | AF/LACF Main Menu..... | 10 |
| Figure 4: | Current FCE - Yes/No..... | 11 |
| Figure 5: | Step 1 – AF/LACF Facility Registration - Type of Submission..... | 12 |
| Figure 6: | Step 2 - Section 2 Food Processing Plant Location..... | 16 |
| Figure 7: | Step 3 - Section 3 Preferred Mailing Address..... | 18 |
| Figure 8: | Step 4 - Section 4 Foods Processed At This Location - Add First Product..... | 20 |
| Figure 9: | Step 4 - Section 4 Foods Processed At This Location..... | 20 |
| Figure 10: | Step 4 - Section 4 Foods Processed At This Location - Add More Products..... | 21 |
| Figure 11: | Step 4 - Section 4 Foods Processed At This Location - All Products Listed..... | 22 |
| Figure 12: | Step 4 - Section 4 Foods Processed At This Location - Edit Product..... | 23 |
| Figure 13: | Step 4 - Section 4 Foods Processed At This Location - Remove Product..... | 24 |
| Figure 14: | Step 5 - Section 5 Facility Contact Person..... | 26 |
| Figure 15: | Warning Message When Navigating to FIS Account Management..... | 27 |
| Figure 16: | FDA Industry Systems Account Management..... | 28 |
| Figure 17: | Step 6 - Section 6 Please Note the Following..... | 29 |
| Figure 18: | Complete summary of the electronic AF/LACF Registration Information..... | 30 |
| Figure 19: | Registration Successfully Completed with Assigned FCE number..... | 32 |
| Figure 20: | View Completed Form for Printing..... | 33 |
| Figure 21: | View and Print Copy of AF/LACF Registration (Form FDA 2541)..... | 34 |
| Figure 22: | Change Registration - List of FCE Numbers Associated With an FDA Account ID...35 | 35 |
| Figure 23: | Change Registration Options..... | 36 |
| Figure 24: | Cancel Registration Warning Message..... | 37 |
| Figure 25: | Cancelled Registration Message..... | 37 |
| Figure 26: | Search Registration..... | 39 |
| Figure 27: | Search Registration - Search Results..... | 39 |

I. Introduction

This document is intended for:

- Commercial processors that manufacture, process, or pack acidified foods (AF) and/or thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as “low-acid canned foods” or “LACF”)¹; and
- Persons who are authorized to act on behalf of such commercial processors.

The products manufactured, processed, or packed by such commercial processors are subject to the registration and process filing requirements of 21 CFR 108.25(c)(2) (for AF) or 21 CFR 108.35(c)(2) (for LACF). There are two basic types of such required submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using Forms FDA 2541a and FDA 2541c.

This document provides detailed instructions on how to:

- Register a new Food Canning Establishment (FCE) by electronic submission of Form FDA 2541;
- Change the preferred mailing address for the FCE;
- Change the list of products manufactured, processed or packed at the FCE; and
- Cancel registration for an FCE (e.g., if production ceases or there is a change in ownership).

This document does not provide instructions for submitting Form FDA 2541 in paper format or for submitting process filing forms in either electronic or paper format. You can obtain information about submitting Form FDA 2541 in paper format, and about submitting process filing forms in either electronic or paper format, from our guidance entitled “Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format” (Ref. 1 and the appendices to Reference 1).

¹ Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as “cans,” the term “low-acid canned foods” has been used for decades as a shorthand description for “thermally processed low-acid foods packaged in hermetically sealed containers,” and we continue to use that term (and its abbreviation, LACF) for the purposes of this document.

II. Portals for Electronic Submissions

A. FDA’s Industry Systems (FIS)

An electronic portal called “FDA Industry Systems” (FIS) provides general entry to a series of specific systems for electronic submissions to FDA. For some systems (including the Acidified/Low Acid Food (AF/LACF) system), users can submit information by completing electronic forms while the user is logged into the system. For other systems (such as the Electronic Submission Gateway), users submit electronic files (such as a food additive petition) that are prepared in advance by the user (rather than completed using electronic forms while the user is logged into the system).

B. FDA’s Unified Registration Listing Systems (FURLS)

FDA’s Unified Registration Listing System (FURLS) is a specific component of the general FIS electronic portal. Persons with an FDA Account ID and password for the FIS electronic portal use systems within the FURLS components to register a facility electronically. The two FURLS systems that are relevant to this document are:

- Food Facility Registration (FFR); and
- Acidified/Low Acid Canned Foods (AF/LACF).

C. Relationship Between the Electronic Acidified/Low-Acid Canned Food System and Food Facility Registration

The design of the electronic AF/LACF registration system links it to the FFR system established to implement the requirements for facility registration under section 415 of the Federal Food, Drug, and Cosmetic Act.² Specifically, the electronic system for submission of Form FDA 2541 is limited to facilities that are registered as food facilities under FDA’s section 415 registration regulations in 21 CFR part 1, subpart H. Facilities that register in the FFR system receive an FFR number and PIN. During the section 415 registration process or during an update to a facility’s section 415 registration, you can identify your facility as an Acidified/Low-Acid Food Processor.

The electronic AF/LACF registration system in FURLS only becomes available to you if your registration in the FFR system identifies your facility as an Acidified/Low Acid Food Processor. If your facility is registered under FDA’s section 415 registration regulations, but you have not yet identified yourself as an Acidified/Low Acid Food Processor, you can update your section 415 registration information to add this information.

² See the requirements in 21 CFR part 1, subpart H (FDA’s section 415 registration regulations) and FDA’s guidance entitled “What You Need to Know About Registration of Food Facilities” (Ref. 2) to determine whether you are subject to the requirement to register as a food facility.

If you are not required to register as a food facility under FDA's section 415 registration regulations, and you want to access the electronic AF/LACF system, you may either:

- Register voluntarily and obtain an FFR number and PIN so that you can submit Form FDA 2541 electronically; or
- Submit Form FDA 2541 using a paper form, tell us that you want to access the electronic AF/LACF system when you send us your paper registration form, and provide FDA with your FDA Account ID for the FIS electronic portal.

III. How to Obtain an FDA Account at the FIS Electronic Portal

Each person who uses the electronic AF/LACF system accesses the system using a personal FDA Account ID and password. To access the FIS electronic portal:

- Use an Internet Browser to access the FIS Web site at <https://www.access.fda.gov/>
- Select Account Management Help.
- Follow the instructions for obtaining an FDA Account ID and password.

The registration Form FDA 2541 requires identifying a “facility contact person” (FCP) for the establishment being registered. The FCP can use the electronic AF/LACF system to register a new FCE using his or her FDA Account ID and password. After the establishment is registered and has an FCE number, the FCP can authorize a different FDA Account ID to change registration information. To do so, the FCP contacts FDA as described in section IX of this document and provides FDA with the FDA Account ID for the individual who is authorized to represent the FCE. After FDA has updated the authorization, the newly authorized individual would enter the FIS electronic portal using his or her own FDA Account ID.

The registration Form FDA 2541 also requires contact information (such as telephone number and email address) for the FCP. The electronic AF/LACF system enters this information automatically from the FCP's FDA Account ID at the FIS electronic portal. There is no manual override to correct the contact information from within the electronic AF/LACF system.

If the contact information in the FCP's FDA Account is incorrect, that incorrect information will automatically be entered in the electronic AF/LACF system. The only way to correct the information is to exit the electronic AF/LACF system, return to FIS Account Management, and edit the FCP's account profile. When this happens, all information already entered into the electronic registration system is lost and must be re-entered when the FCP returns to the electronic AF/LACF system. This includes product descriptions for all products manufactured, processed, or packed at the establishment. Thus, it is very important to ensure that the contact information in the FCP's FDA

Account in the FIS electronic portal is correct before using the electronic AF/LACF system to submit Form FDA 2541.

IV. General Information About Navigating the Registration Section of the Electronic AF/LACF System

The Registration section of the electronic AF/LACF system consists of six steps for the user to enter information. The electronic AF/LACF registration system does not provide an option for users to save a partially completed form without submitting it. Any time that the user exits the electronic AF/LACF system, all data already entered into the system without submission to FDA of a completed registration is lost. For example, a user may exit the electronic AF/LACF system to correct information in the facility's FFR registration or in the FCP's FDA Account in the FIS electronic portal. In addition, the system will log a user out after 30 minutes of inactivity. We recommend that users read these instructions to identify all information they need to either have available (such as descriptions of products) or correct (such as FFR registration information and contact information for the FCP) before beginning the registration process.

The items listed below appear at the top of every page in the registration section of the electronic AF/LACF system:

- A status bar that tracks the progress through each step of the on-line registration process;
- A link to FURLS HOME, which navigates the user to the FURLS Home Page;
- A link to AF/LACF HOME, which navigates the user to the AF/LACF Main Menu
- A "Get Help" link that provides page specific help. Three navigation buttons (which also appear at the bottom of each screen):
 - Back to Step “##” - This takes the user back one screen where the user continues entering information. Information entered on the current screen (before selecting the “Back to ..” navigation button) will remain on the screen when the user returns.
 - Continue - This takes the user to the next screen where the user continues entering information.
 - Cancel & Start Again- The system will return to Step 1 and any information the user entered in any step beyond Step 1 will not be saved.

On some screens, the user selects an option by clicking on a circle next to the option. We call these circles “radio buttons.”

For an overview of all the help files available see the FDA Industry Systems Index of Help Pages.

See Figure 1 for a picture of an example of a computer screen when a user is at Step 2 of the registration procedure, including the navigation tools and the Step-by-Step Tracker.

Figure 1: Example of Navigation Tools and Step by Step Tracker in Section 2 of the Registration Section

The screenshot displays the AF/LACF registration interface. At the top, the logo 'AF/LACF' is in orange, followed by 'Acidified/Low Acid Canned Foods'. To the right is the FDA logo and links for 'FURLS HOME' and 'AF/LACF HOME'. Below this is a step-by-step tracker with six steps: Step 01, Step 02 (highlighted with an orange bar and four right-pointing arrows), Step 03, Step 04, Step 05, and Step 06. A 'Get Help ?' link is in the top right corner.

Navigation buttons include: '<< Back to Step 01', '>> Continue', and '<< Cancel & Start Again'.

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.

SECTION 2 FOOD PROCESSING PLANT LOCATION

| | |
|----------------------|---------------|
| *ESTABLISHMENT NAME: | GNSI |
| *COUNTRY/AREA: | UNITED STATES |
| *ADDRESS LINE1: | 123 Main St |
| ADDRESS LINE2: | 12345 |
| *ZIP CODE: | 20852 |
| *CITY: | Rockville |
| *STATE: | Maryland |
| *TELEPHONE NUMBER: | 301-5551212 |
| TELEFAX NUMBER: | |

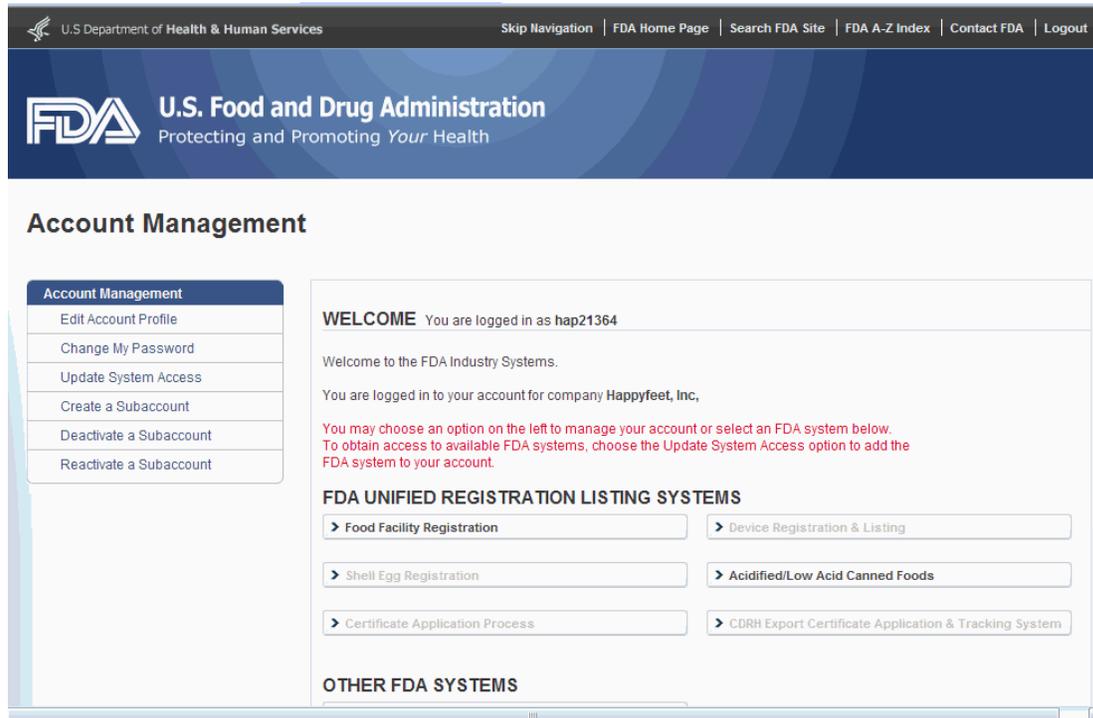
Navigation buttons at the bottom include: '<< Back to Step 01', '>> Continue', and '<< Cancel & Start Again'.

V. How to Enter the AF/LACF System Through the FIS Electronic Portal

To access the AF/LACF system through the FIS electronic portal:

- Use an Internet Browser to access the FIS Web site at <https://www.access.fda.gov/>
- Select Login under Acidified/Low Acid Canned Foods.
- Enter the FDA Account ID and password.
- Check the “I understand” box.
- Select Login.
- Select Acidified/Low Acid Canned Foods. (See Figure 2 for a picture of an example of the computer screen when a user is logged into FURLS.)

Figure 2: FDA Unified Registration and Listing Systems (FURLS)



The system will display the AF/LACF Main Menu. (See Figure 3 for a picture of the AF/LACF Main Menu as it displays on a computer screen.)

Figure 3: AF/LACF Main Menu



VI. How to Register a New Acidified/Low-Acid Food Canning Establishment (Submit Form FDA 2541)

A. Navigate to the Page for an Establishment Without an FCE Number

- Select Register Food Canning Facility from the AF/LACF Main Menu. The system will navigate to the next screen, where it asks if there is a current FCE number for the facility location to be registered. (See Figure 4 for a picture of the computer screen asking whether the facility currently has an FCE number.)
- Select No.
- Select Continue.

Figure 4: Current FCE - Yes/No

The screenshot shows a web interface for the AF/LACF (Acidified/Low Acid Canned Foods) registration system. At the top left, the text "AF/LACF" is displayed in large orange letters, followed by "Acidified/Low Acid Canned Foods" in smaller black text. To the right of this text is the FDA logo, which includes a stylized eagle head and the letters "FDA". Further right, there are two links: "» FURLS HOME" and "» AF/LACF HOME". In the top right corner of the main content area, there is a "Get Help" link with a question mark icon. The main content area contains a question: "Do you currently have a Food Canning Establishment (FCE) number for the facility location you are trying to register?". Below the question are two radio button options: "Yes" and "No". At the bottom of the form, there are two buttons: "<< Back to Main" and ">> Continue".

B. Step 1 - Section 1 – Type of Submission

Section 1 of the electronic registration system has data entry fields for the establishment's FFR number and PIN and the position held by the FCP. (See Figure 5 for a picture of the computer entry screen for the establishment's FFR number and PIN and the position held by the FCP.) The system then checks the FFR registration information to determine whether it identifies Acidified/Low Acid Food Processor as a Type of Activity conducted by the establishment. If the user does not have an FFR number, or the FFR information for the user does not identify the user's establishment as an Acidified/Low Acid Food Processor, the user will not be able to proceed.

Figure 5: Step 1 – AF/LACF Facility Registration - Type of Submission

AF/LACF Acidified/Low Acid Canned Foods | >> FURLS HOME >> AF/LACF HOME

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06

Get Help ?

<< Back to Main >> Continue

Scenario #1: If you are not required to register with FDA under 21 CFR Part 1, Subpart H (Food Facility Registration)(FFR), you may either register voluntarily by following the link in Scenario #2 or click [here](#) to download the form that you would use to submit Form FDA 2541 in paper format.

Scenario #2: If you are required to register with FDA under 21 CFR Part 1, Subpart H (Food Facility Registration) (FFR) but have not yet done so, click [here](#) and follow the procedures to use Form FDA 3537 to register in the FFR system. In section 10a/b of Form FDA 3537, identify your facility as an Acidified/Low Acid Food Processor.

Scenario #3: If you are required to register with FDA under 21 CFR Part 1, Subpart H (Food Facility Registration) (FFR) and have already done so, but have not identified your facility as an Acidified/Low Acid Food Processor as part of your FFR registration, click [here](#) and follow the procedures to use Form FDA 3537 to update your FFR registration information. In section 10a/b of Form FDA 3537, identify your facility as an Acidified/Low Acid Food Processor.

Please enter the Food Facility Registration (FFR) Number and FFR PIN below. If you do not remember your FFR Number and Pin, please click [here](#) to go to FFRM.

If you have any questions please contact the FDA Industry Systems Help Desk by clicking [here](#).

SECTION 1 TYPE OF SUBMISSION

*These fields are required.

***FFR NUMBER**

***FFR PIN**

***POSITION HELD AT PLANT LOCATION**
-- Please Select --

<< Back to Main >> Continue

1. Section 1 - Link the FDA Account ID to the Electronic AF/LACF System

To use the electronic AF/LACF system to register a new FCE, the FCP's FDA Account ID in the FIS electronic portal must be linked to the electronic AF/LACF system. There are three scenarios with respect to what the user may need to do to link the FCP's FDA Account ID to the electronic AF/LACF system. Three informational messages on the screen for Step 1- Section 1 address these three scenarios. Using the links in the informational messages, the FCP can access the FFR system in FURLS to complete FFR information electronically and, when applicable, obtain paper forms that can be sent to FDA to obtain access to the electronic AF/LACF system without submitting the registration electronically. (See Figure 5 for a picture of the computer entry screen showing these three informational messages.)

- Scenario 1: The facility is not required to register as a food facility and obtain an FFR number and PIN. The FCP has options to (1) register using a paper form and ask FDA to link the FCP's FDA Account ID to the electronic AF/LACF system; or (2) voluntarily register as a food facility in the FFR system.
 - Option 1: Register using a paper form and ask FDA to link the FCP's FDA Account ID to the electronic AF/LACF system.
 - Select the "here" link in the first informational message to download a copy of the paper Form FDA 2541.
 - Fill out the paper Form FDA 2541.
 - Send the paper Form FDA 2541 to FDA by mail, together with the FCP's FDA Account ID and a request for FDA to link the FCP's FDA Account ID to the electronic AF/LACF system. See section IX of this document for the mailing address.
 - Upon receipt of the paper Form FDA 2541, FDA will link the FCP's FDA Account ID to the electronic AF/LACF system, send the FCP the FCE number, and inform the FCP when access to the electronic AF/LACF system is available.
 - After FDA links the FCP's FDA Account ID to the electronic AF/LACF system, the registration process is complete. The FCP can follow the instructions in this document to change the FCE's registration information or to search for his or her registered FCEs.
 - Option 2: Voluntarily register as a food facility in the FFR system using Form FDA 3537 by following the instructions in Scenario 2.
- Scenario 2: The facility is required to register as a food facility and obtain an FFR number and PIN, but has not yet done so. Using the link in the informational note about this scenario, the FCP can access the FFR section in FURLS to obtain an FFR number and PIN.
 - Select the "here" link in the second informational message to navigate to the FURLS Main Menu.
 - Follow the instructions to register as a food facility using Form FDA 3537.
 - In Section 10a (Food for Human Consumption) and/or Section 10b (Food for Animal Consumption) of the FFR submission Form FDA 3537, select the Type of Activity Conducted at the Facility as an Acidified/Low Acid Food Processor

- Save the FFR number and PIN associated with your registration as a food facility.
- Proceed to the instructions in section VI.B.2 of this document.
- Scenario 3: The facility is already registered as a food facility and has an FFR number and PIN, but has not yet identified Acidified/Low Acid Food Processor as a Type of Activity conducted by the facility. Using the link in the informational note about this scenario, the FCP can access the FFR section in FURLS to update the facility registration to add Acidified/Low Acid Food Processor as a Type of Activity.
 - Select the “here” link in the third informational message to navigate to the FURLS Main Menu.
 - Select Food Facility Registration.
 - Select Update Facility Registration.
 - Select the FFR number to update.
 - Select Edit under Section 10a (Food for Human Consumption) and/or Section 10b (Food for Animal Consumption) of the FFR submission Form FDA 3537.
 - Select the Type of Activity Conducted at the Facility as an Acidified/Low Acid Food Processor.
 - Select Review Changes and review the changes.
 - Select Submit to update the information.
 - Proceed to the instructions in section VI.B.2 of this document.

2. Section 1 - Type of Submission

Enter the FIS electronic portal and access the AF/LACF Main Menu as described in section V of this document. Navigate to the page for an establishment without an FCE number as described in section VI.A of this document, and proceed to Section 1 - Type of Submission. (See Figure 5 for a picture of the computer entry screen for the establishment’s FFR number and PIN and the position held by the FCP.)

In Section 1 - Type of Submission:

- Enter the FFR number and PIN
- Select one of the following options from the drop-down menu: President/Vice President; Director; Manager; Technologist; Owner.
- Check the entered information. Users will have an option to review the completed registration information before submitting it to FDA, but if the user’s review of the completed registration form identifies incorrect information in Section 1, the procedure to correct the information is to cancel the registration and start over. All data entered without submitting the form to FDA will be lost.
- Select Continue.

C. Step 2 - Section 2 – Food Processing Plant Location

Section 2 of the electronic registration system has data entry fields for the location of the food processing plant. The electronic AF/LACF system automatically enters the location of the food processing plant for the required and optional fields in Section 2 using information from the FFR registration system. (See Figure 6 for a picture of the computer entry screen for the location of the food processing plant.)

See a list of required and optional fields immediately below. Fields marked with an asterisk (*) are required.

- *Establishment Name - The name of the food processing plant at the location being registered.
- *Country/Area - The country or area where the food processing plant is located.
- *Address Line 1 - The physical address of the food processing plant at the location being registered. This is normally a street address, but may be some other physical/geographical designation used in rural locations.
- *Address Line 2 – The second address line if applicable.
- *Zip (or other Postal Code) - The Zip Code (domestic) or Postal Code (foreign) corresponding to the food processing plant at the location being registered.
- *City - The city where the food processing plant is located.
- *State/Province/Territory - The state, province or territory where the food processing plant is located.
- *Telephone Number - The telephone number where the food processing plant is located as reported on the FFR registration.
- TeleFax Number - The fax number, if applicable.

If any of the information in Section 2, Food Processing Plant Location, is not correct:

- Select FURLS Home to navigate to the FURLS Home Page.
- Select Food Facility Registration to update the FFR information with the correct information.
- Select AF/LACF Home to navigate to the Main AF/LACF Menu.
- Select Register Food Canning Facility.
- Follow the instructions in Step 1 – Section 1 in section VI.B.1 of this document to begin a new registration form.

Figure 6: Step 2 - Section 2 Food Processing Plant Location

AF/LACF Acidified/Low Acid Canned Foods |  >> FURLS HOME
>> AF/LACF HOME

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06

Get Help ?

<< Back to Step 01 >> Continue

<< Cancel & Start Again

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.

SECTION 2 FOOD PROCESSING PLANT LOCATION

| | |
|-------------------------------|--------------------------|
| *ESTABLISHMENT NAME: | CFSAN |
| *COUNTRY/AREA: | UNITED STATES |
| *ADDRESS LINE1: | 11820 Parklawn Dr 403-11 |
| ADDRESS LINE2: | |
| *ZIP (or other Postal Code) : | 20852 |
| *CITY: | Rockville |
| *STATE: | Maryland |
| *TELEPHONE NUMBER: | 301-1212121 |
| TELEFAX NUMBER: | |

<< Back to Step 01 >> Continue

<< Cancel & Start Again

D. Step 3 - Section 3 – Preferred Mailing Address

Section 3 of the electronic registration system has data entry fields for the preferred mailing address, which may be different from the physical location of the establishment. (See Figure 7 for a picture of the computer entry screen for the FCP’s preferred mailing address.) There are two scenarios with respect to the preferred mailing address:

- Scenario 1: If the preferred mailing address is the same as the food processing plant location identified in Section 2, check the “Same as Plant Location” box. The system will automatically populate the required and optional fields with the information from Section 2.
- Scenario 2: If the preferred mailing address is different from the food processing plant location identified in Section 2, do not check the “Same as Plant Location” box. Instead, enter the applicable information in the required and optional fields.

See a list of required and optional fields immediately below. Fields marked with an asterisk (*) are required.

*Establishment Name - The name of the company as you wish it to appear on any mailing information.

*Country/Area - The country or area for all mail correspondence.

*Address Line 1 - The street address for all mail correspondence.

*Address Line 2 – The second address line if applicable.

*Zip (or other Postal Code) - The Zip Code (domestic) or Postal Code (foreign) for all mail correspondence.

*City - The city for all mail correspondence.

*State/Province/Territory - The state, province or territory for all mail correspondence.

*Telephone Number - The applicable telephone number.

TeleFax Number - Any applicable fax number.

Figure 7: Step 3 - Section 3 Preferred Mailing Address



Acidified/Low Acid
Canned Foods



>> FURLS HOME
>> AF/LACF HOME

Step 01
Step 02
Step 03 >>>>
Step 04
Step 05
Step 06

[Get Help ?](#)

<< Back to Step 02
>> Continue

<< Cancel & Start Again

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.

SECTION 3 PREFERRED MAILING ADDRESS

SAME AS PLANT LOCATION

***ESTABLISHMENT NAME**

***COUNTRY/AREA**

***ADDRESS LINE1**

ADDRESS LINE2

***ZIP (or other Postal Code)**

***CITY**

***STATE/PROVINCE/TERRITORY**

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

| | Country Code | Area/City Code | Phone Number | Extension |
|-------------------|----------------------|----------------------------------|--------------------------------------|----------------------|
| *TELEPHONE NUMBER | <input type="text"/> | <input type="text" value="301"/> | <input type="text" value="1212121"/> | <input type="text"/> |
| TELEFAX NUMBER | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

<< Back to Step 02
>> Continue

<< Cancel & Start Again

E. Step 4 - Section 4 – Foods Processed at the Location

Section 4 of the electronic registration system has data entry fields to create a list of all the acidified food products and low-acid canned food products that are processed at the FCE location. The user can perform three functions: (1) Add Product; (2) Edit Product; and (3) Remove Product. (See Figure 8 for a picture of the computer screen that starts the procedure to add product, edit product, or remove product.)

When adding or editing products, identify each product by (1) the Food Product Name, Form, or Style and (2) Packing Medium. Enter all of this information within the same box on the form (e.g., “Beans, cut, green or waxed in brine”). (See Figure 9 for a picture of the product information entry screen.) The packing medium is usually the liquid portion(s) of the product that is added over, or added to, the solid portion(s) of the product. Examples of packing medium include: water, brine, sauces, and other liquid coverings. If there is no packing medium, enter “solid pack” as the packing medium. As the user adds products, the system will display the previous product above the entry box. (See Figure 10 for a picture of an example of the computer screen displaying the previous product above the product entry box.)

1. Add Product(s)

To add products:

- Select Add Product.
- Enter the Food Product Name, Form or Style, and Packing Medium* of the product within the same box. The system will automatically wrap the product information when it exceeds the length of the first line in the box.
- Select either Low Acid or Acidified, depending on whether the product is a low-acid food or an acidified food.
- Select Add Product to add more products.
- Continue with the steps above until all products are listed.
- After all products are listed, select Continue.

Figure 8: Step 4 - Section 4 Foods Processed At This Location - Add First Product

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06

Get Help ?

<< Back to Step 03 >> Continue

<< Cancel & Start Again

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.

SECTION 4 FOODS PROCESSED AT THIS LOCATION

(Do not list meat and poultry foods under the jurisdiction of the Food Safety and Inspection Service of the U.S. Department of Agriculture. Listing products processed at this location to obtain an FCE number does not constitute filing individual processes.)

Food Product Name, Form or Style, and Packing Medium **Low-Acid** **Acidified**

Please Click Add Product button to add products.

Add Product Edit Product Remove Product

Subject to the terms of 21 CFR 108.25(c)(1) and (2) and 108.35(c)(1) and (2), no commercial processor shall engage in the processing of low-acid or acidified foods until the completed forms FDA 2541 and 2541a or 2541c have been filed with the FDA within the applicable time frames specified in these regulations.

<< Back to Step 03 >> Continue

<< Cancel & Start Again

Figure 9: Step 4 - Section 4 Foods Processed At This Location

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06

Get Help ?

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.

SECTION 4 FOODS PROCESSED AT THIS LOCATION

Food Product Name, Form or Style, and Packing Medium

Mushrooms, pieces and stems, in brine

LOW-ACID

ACIDIFIED

<< Back Add Product

>> Continue

Figure 10: Step 4 - Section 4 Foods Processed At This Location - Add More Products

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06

Get Help ?

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.

SECTION 4 FOODS PROCESSED AT THIS LOCATION

| Food Product Name, Form or Style, and Packing Medium | Low-Acid | Acidified |
|--|----------------------------------|-----------------------|
| Mushrooms, pieces and stems, in brine | <input checked="" type="radio"/> | <input type="radio"/> |

Food Product Name, Form or Style, and Packing Medium

LOW-ACID

ACIDIFIED

<< Back Add Product >> Continue

After the user has finished adding products, the system presents the list of products for review and confirmation that the information entered is correct and again provides options to (1) add products, (2) edit products, or (3) remove products. (See Figure 11 for a picture of an example of the computer screen listing all products processed at the location.)

Figure 11: Step 4 - Section 4 Foods Processed At This Location - All Products Listed

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06

Get Help ?

<< Back to Step 03 >> Continue

<< Cancel & Start Again

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.

SECTION 4 FOODS PROCESSED AT THIS LOCATION

(Do not list meat and poultry foods under the jurisdiction of the Food Safety and Inspection Service of the U.S. Department of Agriculture. Listing products processed at this location to obtain an FCE number does not constitute filing individual processes.)

| <input type="checkbox"/> | Food Product Name, Form or Style, and Packing Medium | Low-Acid | Acidified |
|--------------------------|--|-----------------------|-----------------------|
| <input type="checkbox"/> | Mushrooms, pieces and stems, in brine | <input type="radio"/> | <input type="radio"/> |
| <input type="checkbox"/> | beans cut green or waxed in brine | <input type="radio"/> | <input type="radio"/> |
| <input type="checkbox"/> | artichokes, whole in vinegar brine | <input type="radio"/> | <input type="radio"/> |
| <input type="checkbox"/> | corn, whole kernel in brine | <input type="radio"/> | <input type="radio"/> |

Add Product Edit Product Remove Product

Subject to the terms of 21 CFR 108.25(c)(1) and (2) and 108.35(c)(1) and (2), no commercial processor shall engage in the processing of low-acid or acidified foods until the completed forms FDA 2541 and 2541a or 2541c have been filed with the FDA within the applicable time frames specified in these regulations.

<< Back to Step 03 >> Continue

<< Cancel & Start Again

2. Edit Product

To edit one or more specific products on the list of products processed at the location, check the box next to the product(s). To edit all products, click on the column heading “Food Product Name, Form or Style, and Packing Medium,” which will place a check mark next to all products listed.

- Select Edit Product. The system will display the product entry screen to make changes to the product information for each product selected. (See Figure 12 for a picture of an example of the product entry screen for changing information about two products.)
- Select Edit Product on the product entry screen after the changes are complete. The system will display the list of all products with the updated information.

Figure 12: Step 4 - Section 4 Foods Processed At This Location - Edit Product

AF/LACF Acidified/Low Acid Canned Foods | FDA >> FURLS HOME >> AF/LACF HOME

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06

Get Help ?

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.

SECTION 4 FOODS PROCESSED AT THIS LOCATION

Food Product Name, Form or Style, and Packing Medium
Mushrooms, pieces and stems, in brine

LOW-ACID
 ACIDIFIED

Food Product Name, Form or Style, and Packing Medium
artichokes, whole in vinegar brine

LOW-ACID
 ACIDIFIED

<< Back Edit Product

3. Remove Product

To remove one or more products from the list of products processed at the location, check the box next to the product(s). To remove all products, click on the column heading “Food Product Name, Form or Style, and Packing Medium,” which places a check mark next to all products listed.

- Select Remove Product. The system will display the product information for the product(s) being removed together with a warning about the total number of products that would be removed. (See Figure 13 for a picture of an example of the computer screen showing a product that will be deleted and the associated system warning.)

- Select Remove Product again to permanently remove the selected products.

To cancel the request to remove the product(s), select Back. The system will make no changes and will display the complete list of products.

Figure 13: Step 4 - Section 4 Foods Processed At This Location - Remove Product

The screenshot shows the AF/LACF (Acidified/Low Acid Canned Foods) web application interface. At the top, the logo 'AF/LACF' is displayed in orange, followed by 'Acidified/Low Acid Canned Foods' and the FDA logo. Navigation links include 'FURLS HOME' and 'AF/LACF HOME'. A progress bar at the top indicates the current step is Step 04, with other steps (01-03, 05-06) shown as inactive. Below the progress bar, a warning message states: '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.' A red notification says: 'You will delete 1 product(s). Click Remove Product to continue.' The main content area is titled 'SECTION 4 FOODS PROCESSED AT THIS LOCATION'. It features a dropdown menu for 'Food Product Name, Form or Style, and Packing Medium' with the selected item 'Mushrooms, pieces and stems, in brine'. Below the dropdown are two radio button options: 'LOW-ACID' (selected) and 'ACIDIFIED'. At the bottom of the form are two buttons: '<< Back' and 'Remove Product'. A 'Get Help' link with a question mark icon is located in the top right corner of the main content area.

4. Continue

After the user finishes editing and removing products, or if there are no products to be edited or removed, select Continue while on the screen showing all products listed. (See Figure 11 for a picture of the computer screen showing all products listed.)

F. Step 5 - Section 5 –Facility Contact Person

Section 5 of the electronic registration system has data entry fields for contact information for the FCP. An informational message alerts the user that the electronic AF/LACF system automatically enters the contact information for the FCP from the FCP’s FDA Account for the FIS electronic portal. (See Figure 14 for a picture of the

computer entry screen for contact information for the FCP with an alert that the system will automatically enter contact information from the FCP's FDA Account.)

See a list of required and optional fields immediately below. Fields marked with an asterisk (*) are required.

*Establishment Name - The name of the company identified in the FCP's FDA Account.

*Country/Area - The country or area identified in the FCP's FDA Account.

*Address Line 1 - The street address identified in the FCP's FDA Account.

*Address Line 2 - The second address line identified in the FCP's FDA Account (if applicable).

*Zip (or other Postal Code) - The Zip Code (domestic) or Postal Code (foreign) identified in the FCP's FDA Account.

*City - The city identified in the FCP's FDA Account.

*State/Province/Territory - The state, province or territory identified in the FCP's FDA Account.

*Telephone Number - The telephone number identified in the FCP's FDA Account.

TeleFax Number - The fax number identified in the FCP's FDA Account. The telefax number is optional. If the FCP did not include a telefax number in the FDA Account, the FCP may add a telefax number here.

Figure 14: Step 5 - Section 5 Facility Contact Person

AF/LACF

Acidified/Low Acid
Canned Foods

>> FURLS HOME
>> AF/LACF HOME

Step 01
Step 02
Step 03
Step 04
Step 05
Step 06

[Get Help ?](#)

<< Back to Step 04
>> Continue

<< Cancel & Start Again

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.

SECTION 5 FACILITY CONTACT PERSON

The Facility Contact Person name and address information shown below is auto-populated from the FDA Industry Systems (FIS) Account Management. If this information is not correct, click [here](#) to return to Account Management and edit your account profile.

***CONTACT NAME**

***COUNTRY/AREA**

***ADDRESS LINE1**

ADDRESS LINE2

***ZIP (or other Postal Code)**

***CITY**

***STATE/PROVINCE/TERRITORY**

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

| | Country Code | Area/City Code | Phone Number | Extension |
|--------------------------|----------------------|----------------------------------|--------------------------------------|----------------------|
| | (e.g.033) | (e.g.101) | (e.g.5551111) | (e.g.1111) |
| *TELEPHONE NUMBER | <input type="text"/> | <input type="text" value="301"/> | <input type="text" value="1212121"/> | <input type="text"/> |

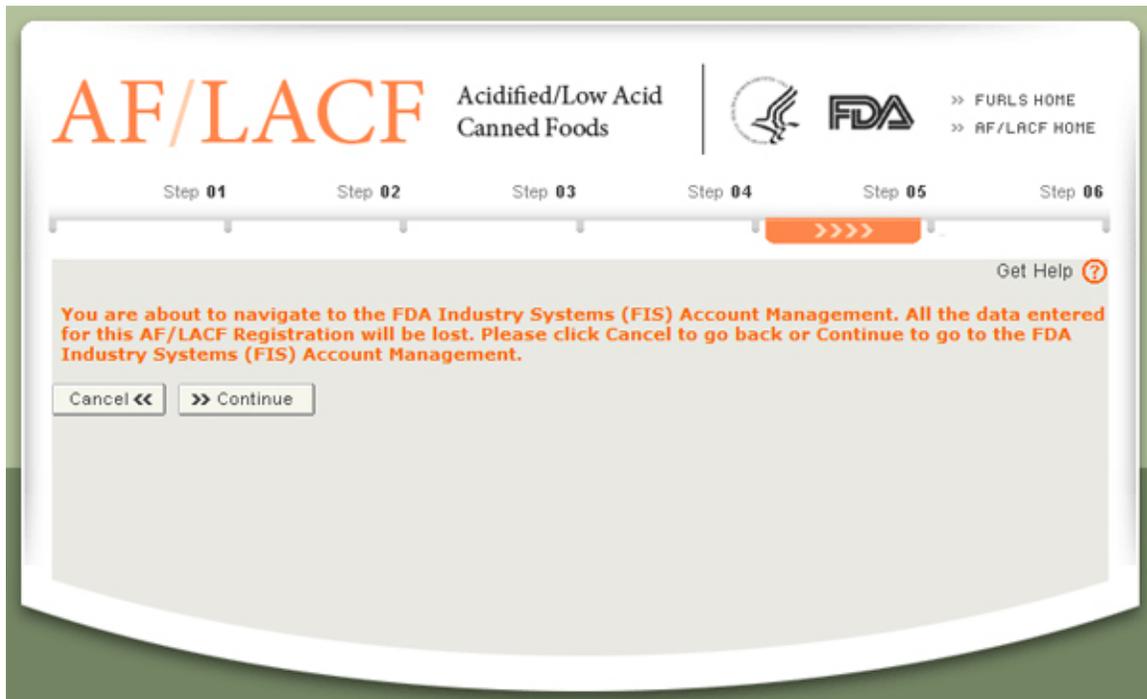
Numbers only. No spaces, dashes or parentheses. Country Code not required for US FAX numbers.

| | Country Code | Area/City Code | Fax Number |
|-------------------|----------------------|----------------------|----------------------|
| | (e.g.033) | (e.g.101) | (e.g.5551111) |
| FAX NUMBER | <input type="text"/> | <input type="text"/> | <input type="text"/> |

***EMAIL ADDRESS**

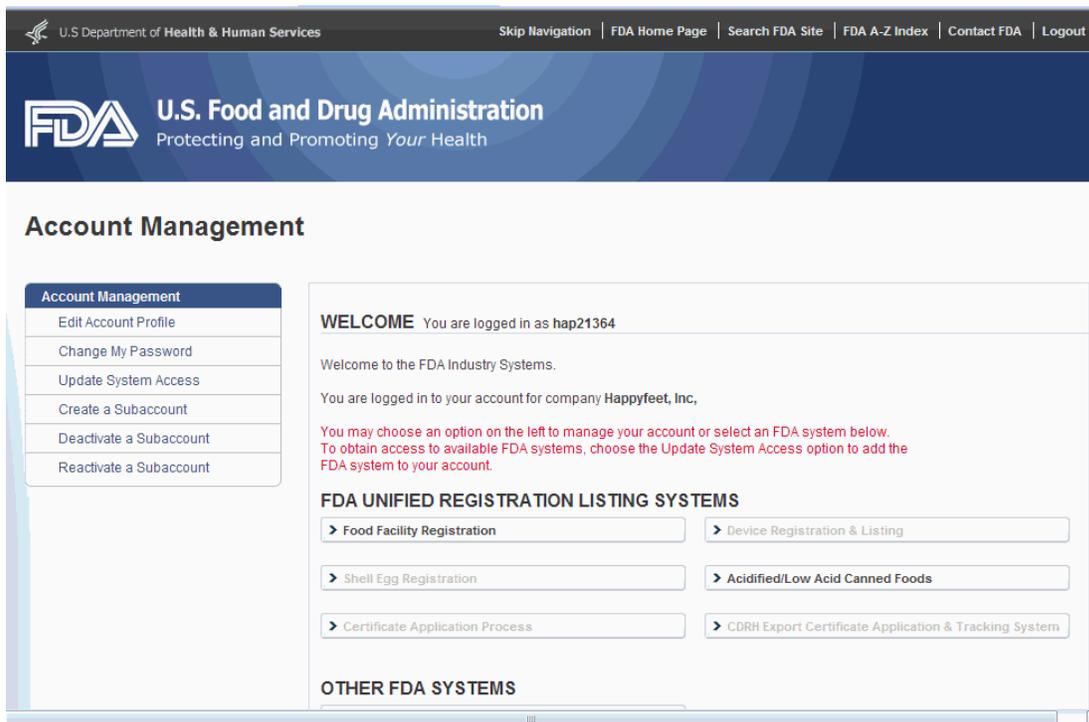
The informational message alerting the user that the system automatically enters the contact information for the FCP from the FCP’s FDA Account ID includes a “here” link for navigation to the Account Management section of the FIS electronic portal. If the information displayed is not correct, select the “here” link. The system will navigate to the Account Management section of the FIS electronic portal and display a warning message: “You are about to navigate to the FDA Industry Systems (FIS) Account Management. All the data entered for this AF/LACF Registration will be lost.” (See Figure 15 for a picture of the computer screen warning that navigation to the FIS Account Management will result in losing all data entered into the system.)

Figure 15: Warning Message When Navigating to FIS Account Management



If the user selects “Cancel,” none of the information already entered will be lost. However, if the contact information for the FCP is not correct, the only way to correct it is to proceed to Account Management in the FIS Electronic Portal and correct the information in that system. (See Figure 16 for a picture of the FIS Account Management screen.)

Figure 16: FDA Industry Systems Account Management



To remain in the electronic AF/LACF registration system and not lose the information entered, select Cancel.

To correct the information:

- Select Continue to navigate to FIS Account Management.
- Select Edit Account Profile.
- If you need help, select FDA Industry Systems Home for access to Account Management Help.
- Return to the AF/LACF Main Menu and navigate to the page for an establishment without an FCE number as described in sections V and VI.A of this document.

G. Step 6 - Section 6 – Please Note the Following

Section 6 is the final section of the electronic AF/LACF registration system. Section 6 advises the user that:

The requester hereby presents and acknowledges that the company is aware that in making this request the company is subject to the terms and provisions of Title 18, Section 1001, United States Code which makes it a criminal offense to falsify, conceal, or cover up a material fact; make any false, fictitious, or fraudulent statement or

representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

Subject to the terms of 21 CFR 108.25 (c)(1) and (2) and 108.35 (c)(1) and (2), no commercial processor shall engage in the processing of low-acid or acidified foods until the completed forms FDA 2541 and 2541a or 2541c have been filed with the FDA within the applicable time frames specified in these regulations

To finish entering registration information:

- Read the statements on the screen in Step 6 - Section 6.
- Check the “I understand” box.
- Select Continue.

Figure 17: Step 6 - Section 6 Please Note the Following

SECTION 6 PLEASE NOTE THE FOLLOWING

The requester hereby presents and acknowledges that the company is aware that in making this request the company is subject to the terms and provisions of Title 18, Section 1001, United States Code which makes it a criminal offense to falsify, conceal, or cover up a material fact; make any false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

Subject to the terms of 21 CFR 108.25 (c)(1) and (2) and 108.35 (c)(1) and (2), no commercial processor shall engage in the processing of low-acid or acidified foods until the completed forms FDA 2541 and 2541a or 2541c have been filed with the FDA within the applicable time frames specified in these regulations.

I understand.

The system will display the completed registration information entered into each section of the form so that users can review the information and identify any incorrect information. (See Figure 18 for a picture of an example of the computer screen showing a complete summary of the electronic AF/LACF registration information.)

H. Complete Registration Process

1. Correct Registration Information

The procedure to correct information depends on the Section in which the information was entered. Start on the screen showing a complete summary of the electronic AF/LACF registration information.

- To correct information in Section 1, select Cancel and Start Again to return to Step 1 to enter the FFR number and PIN and identify the position held at the plant location. All information entered into the electronic AF/LACF system will be lost.
- To correct information in Section 2, select FURLS Home, enter the FFR registration section, and correct the information about the food processing plant location. All information entered into the electronic AF/LACF system will be lost.
- To correct information in Section 3, select Edit on the line for Section 3. The system will re-display the data entry screen for Section 3. Correct the applicable information and select Review Changes to return to the display of the complete registration form.
- To correct information in Section 4, select Edit on the line for Section 4. The system will re-display the data entry screen for Section 4. Correct the applicable information and select Review Changes to return to the display of the complete registration form.
- To correct information in Section 5, select FURLS Home, go to Account Management, and correct the contact information for the FCP. All information entered into the electronic AF/LACF system will be lost.
- The only information entered in Section 6 is a check in the “I understand.” In general, the system design should prevent a user from proceeding to a summary of the completed registration information unless the “I understand” box is checked. However, if the “I understand” box is not checked, select Cancel and Start Again to return to Step 1 to begin the registration process again. All information entered into the electronic AF/LACF system will be lost.

2. Submit Registration

After all information is correct, select Submit.

The system will display a message that the Registration was successful and provide the user with the assigned FCE number. (See Figure 19 for a picture of an example of a computer screen showing a “Registration Successfully Completed” message with the facility’s assigned FCE number.) The user will also receive an email with an attached copy of the completed form for future reference.

Save the FCE number for future reference. FDA will ask the FCP or any authorized representative for the FCE number as part of any communication regarding the establishment's registration and process filings.

Figure 19: Registration Successfully Completed with Assigned FCE number



3. Print Submitted Form FDA 2541

Users can view and print a copy of the registration form by selecting “View & Print Registration” on the screen for Registration Successfully Completed. The system will display a view of the completed FDA Form 2541, including a navigation button to Print Registration. (See Figure 20 for a picture of an example of the computer screen for viewing and printing a completed electronic registration form.)

Figure 20: View Completed Form for Printing

AF/LACF

Acidified/Low Acid
Canned Foods



» FURLS HOME
» AF/LACF HOME

Step 01
Step 02
Step 03
Step 04
Step 05
Step 06

>>>>

[Get Help ?](#)

Created Date: 06/14/2012 10:37:07 Registration Status: Valid

SECTION 1 TYPE OF SUBMISSION

FCE NUMBER: 27465
 FFRM REGISTRATION NUMBER: 18213857928
 POSITION HELD AT PLANT LOCATION: Director

SECTION 2 FOOD PROCESSING PLANT LOCATION

ESTABLISHMENT NAME: CFSAN
 ADDRESS LINE1: 11820 Parklawn Dr 403-11
 ADDRESS LINE2:
 CITY: Rockville STATE/PROVINCE/TERRITORY: Maryland
 ZIP (or other Postal Code) : 20852 COUNTRY/AREA: United States
 TELEPHONE NUMBER: 301 1212121
 TELEFAX NUMBER:

SECTION 3 PREFERRED MAILING ADDRESS

SAME AS PLANT LOCATION
 ESTABLISHMENT NAME: CFSAN
 ADDRESS LINE1: 11820 Parklawn Dr 403-11
 ADDRESS LINE2:
 CITY: Rockville STATE/PROVINCE/TERRITORY: Maryland
 ZIP (or other Postal Code) : 20852 COUNTRY/AREA: United States
 TELEPHONE NUMBER: 301 1212121
 TELEFAX NUMBER:

SECTION 4 FOODS PROCESSED AT THIS LOCATION

(Do not list meat and poultry foods under the jurisdiction of the Food Safety and Inspection Service of the U.S. Department of Agriculture. Listing products processed at this location to obtain an FCE number does not constitute filing individual processes.)

| Food Product Name, Form or Style, and Packing Medium | Low-Acid | Acidified |
|--|----------------------------------|----------------------------------|
| Green Bean, Cut, Glass | <input type="radio"/> | <input checked="" type="radio"/> |
| Chicken, Frozen, Tin | <input checked="" type="radio"/> | <input type="radio"/> |

SECTION 5 FACILITY CONTACT PERSON

CONTACT NAME: Shailendra Gohil
 POSITION HELD AT PLANT LOCATION: Director
 ADDRESS LINE1: 11820 Parklawn Dr
 ADDRESS LINE2: 403-11
 CITY: Rockville STATE/PROVINCE/TERRITORY: Maryland
 ZIP (or other Postal Code) : 20852 COUNTRY/AREA: United States
 TELEPHONE NUMBER: 301 1212121 FAX NUMBER:
 EMAIL ADDRESS: sgohil@gnsi.com

SECTION 6 PLEASE NOTE THE FOLLOWING

The requester hereby presents and acknowledges that the company is aware that in making this request the company is subject to the terms and provisions of Title 18, Section 1001, United States Code which makes it a criminal offense to falsify, conceal, or cover up a material fact, make any false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

Subject to the terms of 21 CFR 108.25 (c)(1) and (2) and 108.35 (c)(1) and (2), no commercial processor shall engage in the processing of low-acid or acidified foods until the completed forms FDA 2541 and 2541a or 2541c have been filed with the FDA within the applicable time frames specified in these regulations.

I understand

Not For Public Disclosure

« Back to Main
» Print Registration

To print the completed form, select Print Registration. A new, smaller browser window will open containing completed registration information formatted to look like the paper version of Form FDA 2541. To print Form FDA 2541, follow the instructions on the screen to select a printer and print. (See Figure 21 for a picture of an example of a printable registration Form FDA 2541.)

After printing is complete, return to the AF/LACF application by selecting the “X” (in the upper right corner of the pop-up in the smaller browser pop-up) to close the smaller browser window.

Figure 21: View and Print Copy of AF/LACF Registration (Form FDA 2541)

| | | | | | | | | |
|---|---|---|--|------------------------------------|----------------------|--|------------------------------------|--|
| FORM APPROVED: OMB No.0910-0037; EXPIRATION DATE:2/28/2015 | | | | | | | | |
| INITIAL REGISTRATION | DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration | FOR FDA USE ONLY | | | | | | |
| | FOOD CANNING ESTABLISHMENT REGISTRATION | FCE No. 27407 Date Received by FDA 05/02/2012 09:06:17 | | | | | | |
| FOOD PROCESSING PLANT LOCATION | | PREFERRED MAILING ADDRESS <input checked="" type="checkbox"/> Same as Plant Location | | | | | | |
| Establishment Name AFLACF Facility | | Establishment Name AFLACF Facility | | | | | | |
| Number and Street: 123 Main Street | | Number and Street: 123 Main Street | | | | | | |
| City and State or Province (or other Subdivision) Rockville, Maryland | | City and State or Province (or other Subdivision) Rockville, Maryland | | | | | | |
| Zip (or Other Postal Code) 20850 | | Zip (or Other Postal Code) 20850 | | | | | | |
| Country (if other than U.S.) United States | | Country (if other than U.S.) United States | | | | | | |
| Telephone No. 301 1212121 | | Telephone No. 301 1212121 | | | | | | |
| Telefax No. | | Telefax No. | | | | | | |
| <p style="text-align: center;">LOW ACID AND/OR ACIDIFIED FOODS PROCESSED AT THIS LOCATION Food Product name, form or Style, and packing Medium (Do not list meat and poultry foods under the jurisdiction of the Food Safety and Inspection Service of the U.S. Department of Agriculture)</p> <table border="1"> <tr> <td>Chicken, Frozen, Tin</td> <td>Low-Acid <input checked="" type="radio"/></td> <td>Acidified <input type="radio"/></td> </tr> <tr> <td>Green Bean, Cut, Tin</td> <td>Low-Acid <input checked="" type="radio"/></td> <td>Acidified <input type="radio"/></td> </tr> </table> | | Chicken, Frozen, Tin | Low-Acid <input checked="" type="radio"/> | Acidified <input type="radio"/> | Green Bean, Cut, Tin | Low-Acid <input checked="" type="radio"/> | Acidified <input type="radio"/> | <p>PLEASE NOTE THE FOLLOWING:</p> <p>1. The requester hereby presents and acknowledges that the company is aware that in making this request the company is subject to the terms and provisions of Title 18, Section 1001, United States Code which makes it a criminal offense to falsify, conceal, or cover up a material fact; make any false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.</p> <p>2. Subject to the terms of 21 CFR 108.25 (c)(1) and (2) and 108.35 (c)(1) and (2), no commercial processor shall engage in the processing of low-acid or acidified foods until the completed forms FDA 2541 and 2541a or 2541c have been filed with the FDA within the applicable time frames specified in these regulations.</p> <p>3. Forms, Instructions, regulations, and information can be secured online at: http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm</p> <p>4. For more information contact the LACF Registration Coordinator by e-mail at lacf@fda.hhs.gov</p> <p>Food and Drug Administration LACF Registration Coordinator (HFS-303) Center for Food Safety & Applied Nutrition 5100 Paint Branch Parkway College Park, Maryland 20740-3835</p> |
| | | Chicken, Frozen, Tin | Low-Acid <input checked="" type="radio"/> | Acidified <input type="radio"/> | | | | |
| Green Bean, Cut, Tin | Low-Acid <input checked="" type="radio"/> | Acidified <input type="radio"/> | | | | | | |
| FACILITY CONTACT PERSON | | | | | | | | |
| Name of Contact and Business Address: John Smith, 123 Main Street, Rockville, Maryland, 20850 United States | | | | | | | | |
| Position Held at Plant Location: <input checked="" type="checkbox"/> Owner <input type="checkbox"/> Technologist <input type="checkbox"/> Manager <input type="checkbox"/> Director <input type="checkbox"/> President/Vice President | | | | | | | | |
| Phone Number: 301 1212121 | Email Address: sgohil@gnsi.com | Created Date: 05/02/2012 09:06:17 | | | | | | |

VII. How to Change or Cancel Registration Information

The FCP, and a user authorized to act on behalf of the FCP, may change registration information or cancel a registration after the registration has been submitted to FDA. To do so, follow the instructions in Section V of this document to enter the electronic AF/LACF system through the FIS electronic portal. From the AF/LACF Main Menu, select Change Registration. The system will display a list of FCE numbers electronically associated with the FDA Account ID (e.g., if the user is the FCP for more than one FCE or is authorized to act on behalf of the FCP for more than one FCP). (See Figure 22 for a picture of an example of the Change Registration screen with a list of FCE numbers associated with an FDA Account ID.)

Figure 22: Change Registration - List of FCE Numbers Associated With an FDA Account ID

The screenshot shows the AF/LACF web interface. At the top left is the AF/LACF logo and the text "Acidified/Low Acid Canned Foods". To the right is the FDA logo and navigation links: ">> FURLS HOME" and ">> AF/LACF HOME". Below the header is a "CHANGE REGISTRATION" section with a "Get Help" link. A message says "Please click on FCE number to select a registration for update." Below this is a table with five columns: FCE No., Establishment Name, Food Processing Plant Location, Facility Contact Person Name, and E-mail. The table contains three rows of data. At the bottom left is a "Back to Main" button.

| FCE No. | Establishment Name | Food Processing Plant Location | Facility Contact Person Name | E-mail |
|-----------------------|--------------------|--|------------------------------|-----------------|
| 21565 | GNSI | 11820 Parklaen Dr, Room 400, N Bethesda, Maryland, UNITED STATES | Shailendra K Gohil | tregan@gnsi.com |
| 21664 | GNSI test | 11820 Parklaen Dr, Room 400, Rockville, Maryland, UNITED STATES | Shailendra K Gohil | tregan@gnsi.com |
| 21700 | GNSI | 11820 Parklaen Dr, Room 400, Rockville, Maryland, UNITED STATES | Shailendra K Gohil | tregan@gnsi.com |

Select the link to the applicable FCE number. The system will display the establishment name, FCE number, and location, with radio buttons to (1) change registration information and (2) cancel registration. (See Figure 23 for a picture of an example of the Change Registration option screen.)

Figure 23: Change Registration Options

AF/LACF Acidified/Low Acid Canned Foods | >> FURLS HOME >> AF/LACF HOME

Get Help ?

CHANGE REGISTRATION

Establishment Name : New Registration from Old
FCE Number: 27391
Plant Location: 1234 Main Street, Bysua, Busia, UGANDA - NONE

Please select one of the following options to make changes for registration.

Change Registration Information
 Cancel Registration

<< Back >> Continue << Back to Main

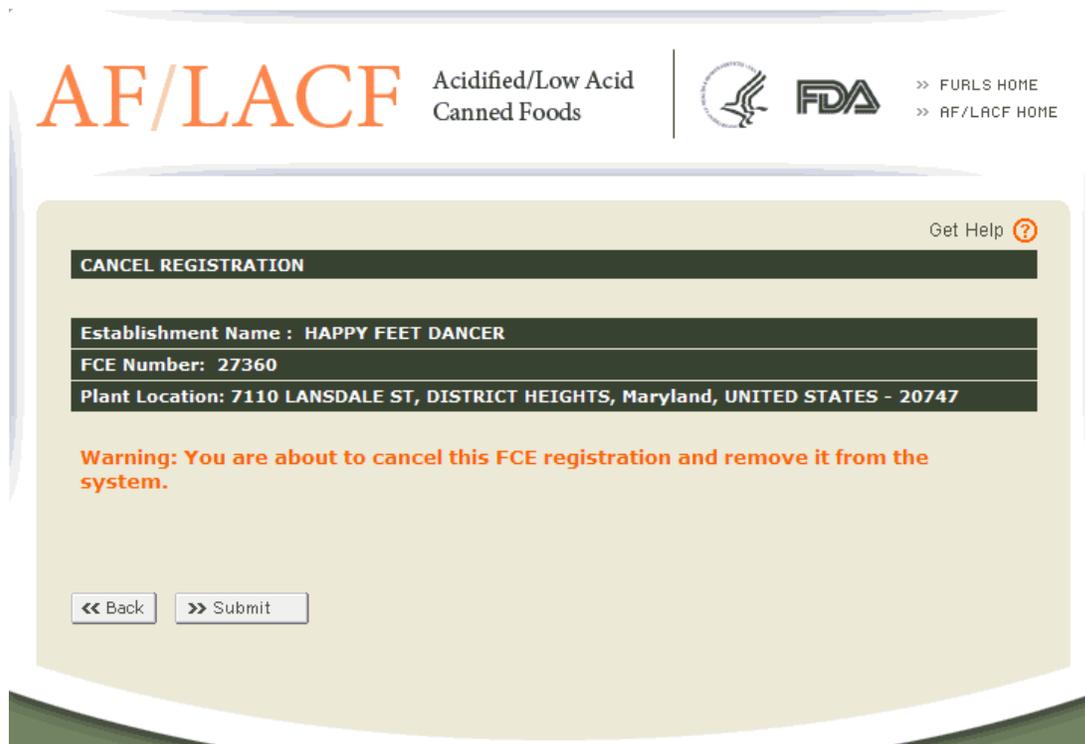
A. Change Registration Information

To change registration, select Change Registration Information from the Change Registration Options screen and then select Continue. The system will display a complete summary of the electronic AF/LACF registration form, similar to the system display after completing all six sections of the electronic registration form. Follow the instructions in Section VI.H.1 of this document to correct registration information. (See Figure 18 for a picture of a computer screen showing an example of a complete summary of the electronic AF/LACF registration form.)

B. Cancel Registration

To cancel registration, select Cancel Registration from the Change Registration Options screen and then select Continue. The system will display a warning message informing the user that the FCE for the selected establishment will be canceled and removed from the system. (See Figure 24 for a picture of an example of the Cancel Registration screen with the message warning that the FCE will be removed from the system.)

Figure 24: Cancel Registration Warning Message



To stop the Cancel Registration procedure, select Go Back.

To proceed with the Cancel Registration procedure, select Submit. The system will display a message that the selected FCE number has been successfully cancelled. (See Figure 25 for a picture of an example of a computer screen showing a cancelled registration message.)

Figure 25: Cancelled Registration Message



VIII. How to Search Registrations

The FCP, and a user authorized to act on behalf of the FCP, may search registration information. To do so, follow the instructions in Section V of this document to enter the FIS electronic portal and access the AF/LACF Main Menu. From the AF/LACF Main Menu:

- Select Search Facility Registrations. The system will display the Search Registration screen. Figure 26 shows a picture of an example of the Search Registration screen with data entry boxes for FCE number, Establishment Name, and Contact Person.
- Enter one or more search terms in the data entry boxes.
 - To search on the FCE number, enter the complete FCE number. The system does not return any matching records for a partial FCE number.
 - To search on facility name, enter either the complete name of the facility or a partial name for the facility. Enter a partial name from the beginning of the name. E.g., to find an establishment named “Mr. Tester Fester,” enter “Mr.” or “Mr. Tester” or “Mr. Tester Fester.” The system does not return any records for a partial name that does not start at the beginning of the name (e.g., in this example, the system would not return any records for “Tester Fester”).
 - To search on the name of the Facility Contact Person, enter either the complete name of the FCP or the first name of the FCP. Entering a first name such as “John” will return all FCEs that have a FCP named John. The system does not return any records if only the last name of the FCP is entered.
- The system will display one or more FCEs that match the search criteria. Figure 26 shows a picture of the search results when the search criterion in the Establishment Name is “Mr. Tester.”

Figure 26: Search Registration

The system will display the results of the search by listing the applicable registrations and their status. (See Figure 27 for a picture of an example of registration search results.) Select up and down arrows in the column headings to sort the registration list in ascending or descending order. Select the link to a particular FCE number to view the registration information for that FCE.

Figure 27: Search Registration - Search Results

| SEARCH REGISTRATIONS - SEARCH RESULTS | | | | | |
|---|------------------------|---|-------------------------|-----------------|------------|
| Search Results - Total Registrations: 3 | | | | | |
| The following Registrations match your search criteria. You can use the up and down arrows to sort the registration list. | | | | | |
| Page 1 of 1 | | | | | |
| ▲ FCE Number ▼ | ▲ Establishment Name ▼ | ▲ Plant Location ▼ | ▲ Contact Person Name ▼ | ▲ Email ▼ | ▲ Status ▼ |
| 21565 | GNSI | 11820 Parklaen Dr, Room 400, N Bethesda, Maryland, 20852, UNITED STATES | Shailendra K Gohil | tregan@gnsi.com | Valid |
| 21664 | GNSI test | 11820 Parklaen Dr, Room 400, Rockville, Maryland, 20852, UNITED STATES | Shailendra K Gohil | tregan@gnsi.com | Valid |
| 21700 | GNSI | 11820 Parklaen Dr, Room 400, Rockville, Maryland, 20852, UNITED STATES | Shailendra K Gohil | tregan@gnsi.com | Cancelled |

IX. How to Contact FDA or Obtain Help

You may contact us:

- By email at LACF@fda.hhs.gov;
- By telephone at 240-402-2411; and
- By mail at the address immediately below.

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

X. References

1. [Guidance for Industry: Submitting FDA Form 2541 \(Food Canning Establishment Registration\) and FDA Forms 2541a and 2541c \(Food Process Filing Forms\) to FDA in Electronic or Paper Format.](#)
2. FDA. 2003. [What You Need to Know About Registration of Food Facilities.](#)