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
January 2017
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I. Introduction

This document is intended for:

- Commercial processors who 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 representatives authorized to act on behalf of such commercial processors\(^2\).

Commercial processors who manufacture, process, or pack AF and/or LACF are subject to the registration requirements of 21 CFR 108.25(c)(1) (for AF) or 21 CFR 108.35(c)(1) (for LACF), as well as the process filing requirements of 21 CFR 108.25(c)(2) (for processors of AF) or 21 CFR 108.35(c)(2) (for processors of LACF). These provisions require two basic types of submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using the following forms:
  - Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)
  - Form FDA 2541e (Food Process Filing for Acidified Method)
  - Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method)
  - Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems)

This document provides detailed instructions on how to:

- Register a new Food Canning Establishment (FCE) by electronic submission using Form FDA 2541;
- Change registration information 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 “Guidance for Industry: Submitting Form FDA 2541 (Food Canning

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\(^1\) 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.

\(^2\) Individuals who act as authorized representatives may do so for more than one commercial processor. Reference 1 identifies the responsibilities of each type of authorized user.
Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format” (Ref. 1 and the appendices to Reference 1).

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 the systems that we discuss in this document, users complete and submit 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 an establishment 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 registration requirement in 21 CFR Part 108 for FCEs that manufacture, process, or pack AF or LACF product is not the same as the FFR system. The FFR system stems from the requirement in section 415 of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with FDA. The registration requirement in section 415 of the FD&C Act was created by the Public Health Security and Bioterrorism Preparedness Act of 2002 (the “BT Act”) and amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). AF and LACF commercial processors must register with FDA as required in 21 CFR Part 108 using FDA Form 2541, and must also register with FDA under the FFR system using FDA Form 3537 as required by section 415 of the FD&C Act. We use the term “FFR” interchangeably with the term “BT Act registration.”

The design of the electronic AF/LACF registration system links it to the FFR system. Specifically, the electronic system for submission of Form FDA 2541 is limited to facilities that are registered as food facilities pursuant to section 415 of the FD&C Act.

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3 See the requirements in 21 CFR Part 1, subpart H (FDA’s food facility 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 pursuant to section 415 of the FD&C Act.
Facilities that register in the FFR system receive a facility registration number and PIN. During the FFR process, or during an update to a facility’s FFR submission, you can identify your facility as an Acidified Food Processor and/or Low-Acid Food Processor under Section 9a “General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility” and/or 9b “General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility”.

The electronic AF/LACF registration system in FURLS becomes available to you if your registration in the FFR system identifies your facility as an Acidified Food Processor and/or Low-Acid Food Processor. If your facility is registered in the FFR system, but you have not yet identified yourself as an Acidified Food Processor and/or Low-Acid Food Processor, you can update your FFR information to add this information.

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

- Register voluntarily and obtain an FFR number (an 11 digit 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/](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 an “Establishment Contact Person” (ECP) and their position for the establishment being registered. For information about the role of the ECP and why we recommend you take care in determining who will serve as ECP, refer to Section IV.D in Reference 1. The ECP 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 ECP can authorize a different FDA Account ID to change registration information. To do so, the ECP 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 ECP. The electronic AF/LACF system enters this information automatically from the ECP’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 ECP’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 ECP’s account profile. When this happens, all information already entered into the electronic registration system is lost and must be re-entered when the ECP 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 ECP’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 a choice 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 ECP’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 ECP) 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 makes a choice by clicking on a circle next to the choice. 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

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/](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

![AF/LACF Main Menu](image)

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 Establishment 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 establishment location to be registered. (See Figure 4 for a picture of the computer screen asking whether the establishment currently has an FCE number.)
- Select No.
- Select 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 of the ECP. (See Figure 5 for a picture of the computer entry screen for the establishment’s FFR number and PIN and the position of the ECP.) The system then checks the FFR registration information to determine whether it identifies Acidified Food Processor and/or Low Acid Food Processor under Section 9a “General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility” and/or 9b “General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility.” 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 Food Processor and/or Low Acid Food Processor under the section referenced above, the user will not be able to proceed.
Figure 5: Step 1 – AF/LACF Establishment Registration - Type of Submission

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 ECP’s FDA Account ID in the FIS electronic portal must be linked to the electronic AF/LACF system. If you are uncertain on how to proceed, refer to Section IV.A in Reference 1. The ECP 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 that explains how to obtain additional assistance.)

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 of the ECP.)

In Section 1 - Type of Submission:
• Enter the FFR number and PIN

• Select one of the following positions from the drop-down menu: Owner, Technologist, Manager, Director, President/Vice President, Other Employee, or Authorized Third Party (see Figure 6.)

Figure 6 - Position Definitions for the Establishment Contact Person

<table>
<thead>
<tr>
<th>Position</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owner</td>
<td>Owner of the processing plant or the corporate office.</td>
</tr>
<tr>
<td>Technologist</td>
<td>Technologist employed at the processing plant or the corporate office.</td>
</tr>
<tr>
<td>Manager</td>
<td>Manager employed at the processing plant or the corporate office.</td>
</tr>
<tr>
<td>Director</td>
<td>Director employed at the processing plant or the corporate office.</td>
</tr>
<tr>
<td>President/Vice President</td>
<td>President/Vice President employed at the processing plant or the corporate office.</td>
</tr>
<tr>
<td>Other Employee</td>
<td>An employee of the processing plant or corporate office who is NOT the Owner, Technologist, Manager, Director, or President/Vice President.</td>
</tr>
<tr>
<td>Authorized Third Party</td>
<td>A person other than an Owner, Technologist, Manager, Director, President/Vice President, or Other Employee who has been authorized by the commercial processor.</td>
</tr>
</tbody>
</table>

• Check the entered information. Users will be able 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 7 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 (*) below under this section of the instructions 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 Establishment.
- Follow the instructions in Step 1 – Section 1 in section VI.B.1 of this document to begin a new registration form.
Figure 7: Step 2 - Section 2 Food Processing Plant Location

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 Parkdawn Dr 403-11
*ADDRESS LINE2:
*ZIP (or other Postal Code):* 20852
*CITY:* Rockville
*STATE:* Maryland
*TELEPHONE NUMBER:* 301-1212121

**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. This preferred mailing address will be used for all FDA correspondence regarding registration and process filing. (See Figure 8 for a picture of the computer entry screen for the ECP’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. You may enter a Post Office (P.O.) box number instead of street address and number, if applicable.

See a list of required and optional fields immediately below. Fields marked with an asterisk (*) below under this section of the instructions 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.
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 AF and/or LACF products that are manufactured, processed, or packed at the FCE location. Products processed under the continuous inspection of the meat and poultry inspection program of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act are not covered by 21 CFR 108.25 or 108.35. Therefore, do not list meat
and poultry foods under the jurisdiction of the FSIS. The user can perform three functions: (1) Add Product; (2) Edit Product; and (3) Remove Product. (See Figure 9 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 10 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 11 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.
Section 4: Foods Processed at This Location - Add First Product

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.

Food Product Name, Form or Style, and Packing Medium

Please click Add Product button to add products.

Subject to the terms of 21 CFR 108.33(c)(1) and (2) and/or CFR 108.35(c)(1) and (2), no commercial processor shall engage in the processing of acidified foods or low-acid canned foods until the completed forms FDA 2541 and the appropriate forms (FDA 2541E, FDA 2541G, FDA 2541H, FDA 2541J) have been filed with the FDA within the applicable time frames specified in these regulations.
Figure 10: Step 4 - Section 4 Foods Processed At This Location

Figure 11: Step 4 - Section 4 Foods Processed At This Location - Add More Products
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 an opportunity to (1) add products, (2) edit products, or (3) remove products. (See Figure 12 for a picture of an example of the computer screen listing all products processed at the location.)

Figure 12: Step 4 - Section 4 Foods Processed At This Location - All Products Listed

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 13 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.
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 14 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.
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 12 for a picture of the computer screen showing all products listed.)

**F. Step 5 - Section 5 –Establishment Contact Person**

Section 5 of the electronic registration system has data entry fields for contact information for the ECP. An informational message alerts the user that the electronic AF/LACF system automatically enters the contact information for the ECP from the ECP’s FDA Account for the FIS electronic portal. (See Figure 15 for a picture of the computer entry screen for contact information for the ECP with an alert that the system will automatically enter contact information from the ECP’s FDA Account.)

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

*Establishment Name - The name of the company identified in the ECP’s FDA Account.
*Country/Area - The country or area identified in the ECP’s FDA Account.
*Address Line 1 - The street address identified in the ECP’s FDA Account.
*Address Line 2 – The second address line identified in the ECP’s FDA Account (if applicable).
*Zip (or other Postal Code) - The Zip Code (domestic) or Postal Code (foreign) identified in the ECP’s FDA Account.
*City - The city identified in the ECP’s FDA Account.
*State/Province/Territory - The state, province or territory identified in the ECP’s FDA Account.
*Telephone Number - The telephone number identified in the ECP’s FDA Account.
TeleFax Number - The fax number identified in the ECP’s FDA Account. The telefax number is optional. If the ECP did not include a telefax number in the FDA Account, the ECP may add a telefax number here.

Figure 15: Step 5 - Section 5 Establishment Contact Person

The informational message alerting the user that the system automatically enters the contact information for the ECP from the ECP’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 16 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 16: 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 ECP 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 17 for a picture of the FIS Account Management screen.)
Figure 17: 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 2541d, 2541e, 2541f, and/or 2541g 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 5 - Section 6.
- Check the “I understand” box.
- Select Continue.

Figure 18: Step 6 - Section 6 Please Note the Following

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 19 for a picture of an example of the computer screen showing a complete summary of the electronic AF/LACF registration information.)
Figure 19: 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 (an 11 digit number) and PIN and identify the position of the ECP. 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 ECP. 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 20 for a picture of an example of a computer screen showing a “Registration Successfully Completed” message with the establishment’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 ECP or any authorized representative for the FCE number as part of any communication regarding the establishment’s registration and process filings.
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 21 for a picture of an example of the computer screen for viewing and printing a completed electronic registration form.)
**Figure 21: View Completed Form for Printing**

<table>
<thead>
<tr>
<th><strong>SECTION 1</strong></th>
<th><strong>TYPE OF SUBMISSION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>FCE NUMBER:</td>
<td>21040</td>
</tr>
<tr>
<td>FFRM REGISTRATION NUMBER:</td>
<td>16657090512</td>
</tr>
<tr>
<td>POSITION HELD AT PLANT LOCATION:</td>
<td>Director</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>SECTION 2</strong></th>
<th><strong>FOOD PROCESSING PLANT LOCATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ESTABLISHMENT NAME:</td>
<td>Test Company</td>
</tr>
<tr>
<td>ADDRESS LINE 1:</td>
<td>11820 Pantnaw Dr Ste 300</td>
</tr>
<tr>
<td>CITY:</td>
<td>Rockville</td>
</tr>
<tr>
<td>ZIP (or other Postal Code):</td>
<td>20852</td>
</tr>
<tr>
<td>TELEPHONE NUMBER:</td>
<td>1 301 1212121</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>SECTION 3</strong></th>
<th><strong>PREFERRED MAILING ADDRESS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>SAME AS PLANT LOCATION</td>
<td></td>
</tr>
<tr>
<td>ESTABLISHMENT NAME:</td>
<td>Test Company</td>
</tr>
<tr>
<td>ADDRESS LINE 1:</td>
<td>11820 Pantnaw Dr Ste 300</td>
</tr>
<tr>
<td>CITY:</td>
<td>Rockville</td>
</tr>
<tr>
<td>ZIP (or other Postal Code):</td>
<td>20852</td>
</tr>
<tr>
<td>TELEPHONE NUMBER:</td>
<td>1 301 1212121</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>SECTION 4</strong></th>
<th><strong>FOODS PROCESSED AT THIS LOCATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(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.)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>SECTION 5</strong></th>
<th><strong>ESTABLISHMENT CONTACT PERSON</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTACT NAME:</td>
<td>Tester Test</td>
</tr>
<tr>
<td>ADDRESS LINE 1:</td>
<td>11820 Pantnaw Dr</td>
</tr>
<tr>
<td>CITY:</td>
<td>Rockville</td>
</tr>
<tr>
<td>ZIP (or other Postal Code):</td>
<td>20852</td>
</tr>
<tr>
<td>TELEPHONE NUMBER:</td>
<td>301 1212121</td>
</tr>
<tr>
<td>EMAIL ADDRESS:</td>
<td><a href="mailto:OIM-DOSFURLSSupport@fda.hhs.gov">OIM-DOSFURLSSupport@fda.hhs.gov</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>SECTION 6</strong></th>
<th><strong>PLEASE NOTE THE FOLLOWING</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Subject to the terms of 21 CFR 108.25(c)(1) and (2) and/or CFR 108.35(c)(1) and (2), no commercial processor shall engage in the processing of acidified foods or low-acid canned foods until the completed forms FDA 2541 and the appropriate forms (FDA 2541d, FDA 2541e, FDA 2541f, FDA 2541g) have been filed with the FDA within the applicable time frames specified in these regulations.</td>
<td></td>
</tr>
<tr>
<td>Forms, Instructions, regulations, and information can be secured online at <a href="http://www.fda.gov/food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedCanned/ad67/default.htm">http://www.fda.gov/food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedCanned/ad67/default.htm</a>.</td>
<td></td>
</tr>
<tr>
<td>For more information, contact LACF Registration Coordinator by e-mail at <a href="mailto:lacf@fda.hhs.gov">lacf@fda.hhs.gov</a>.</td>
<td></td>
</tr>
</tbody>
</table>

| **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 22 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 22: View and Print Copy of AF/LACF Registration (Form FDA 2541)
VII. How to Change or Cancel Registration Information

Using the electronic AF/LACF system, the ECP 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 ECP for more than one FCE). (See Figure 23 for a picture of an example of the Change Registration screen with a list of FCE numbers associated with an FDA Account ID.)

As noted in Reference 1, the ECP can authorize an individual to access the electronic AF/LACF system for a particular FCE by assigning a role to the individual as Super Authorized Representative (Super AR), an Authorized Representative (AR), or a Read Only Access Representative (ROAR). (See Table 1 in Reference 1 for the authorized functions associated with each of these assigned roles). Importantly, only a Super AR may act on behalf of the ECP with respect to registration. At this time, the electronic AF/LACF system is not configured in a way to enable a Super AR to change or cancel registration information electronically. The process for a Super AR to change or cancel registration information electronically is to submit a paper Form FDA 2541, contact FDA as described in Section IX of this document, or both. For instructions on submitting a paper Form FDA 2541, see Reference 3.
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 24 for a picture of an example of the Change Registration screen.)
A. Change Registration Information

To change registration information for an existing FCE number, select Change Registration Information from the Change Registration 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. Only Sections 3 and 4 are available for update by using the “Edit” button. For any additional changes needed, you should contact us for assistance (see section IX for how to contact us). Follow the instructions in Section VI.H.1 of this document to correct registration information. (See Figure 19 for a picture of a computer screen showing an example of a complete summary of the electronic AF/LACF registration form.)

B. Cancel Registration

You must notify us not later than 90 days after you cease or discontinue the manufacture, processing, or packing of the foods in any establishment, except that you need not do so for temporary cessations due to the seasonal character of your production or due to temporary conditions (e.g., labor disputes or fire) (21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)).

There are two reasons for canceling a registration: 1) your establishment moves to a new location; 2) your establishment ceases or discontinues the manufacture, processing, or packing of foods.
If you have a previously registered FCE number and you are moving to a new location, you must cancel the existing registration and register the new location. We will provide you with a new FCE number for the new location. We will work with you on a case-by-case basis to determine the impact of the relocation of the establishment on the SIDs you previously filed by contacting us using the contact information provided in Section IX.

To cancel registration, select Cancel Registration from the Change Registration 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 25 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 25: 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 26 for a picture of an example of a computer screen showing a cancelled registration message.)
VIII. How to Search Registrations

The ECP, and a user authorized to act on behalf of the ECP, 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 Establishment Registrations. The system will display the Search Registration screen. Figure 27 shows a picture of an example of the Search Registration screen with data entry boxes for FCE number, Establishment Name, and Establishment 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 establishment name, enter either the complete name of the establishment or a partial name for the establishment. Enter a partial name from the beginning of the name. For example, 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 (in this example, the system would not return any records for “Tester Fester”).
  - To search on the name of the Establishment Contact Person, enter either the complete name of the ECP or the first name of the ECP. Entering a first name such as “John” will return all FCEs that have an ECP named John. The system does not return any records if only the last name of the ECP is entered.

- The system will display one or more FCEs that match the search criteria. Figure 27 shows a picture of the search results when the search criterion in the Establishment Name is “Mr. Tester.”
The system will display the results of the search by listing the applicable registrations and their status. (See Figure 28 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 28: Search Registration - Search Results
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  
5001 Campus Drive  
College Park, Maryland 20740-3835

X. References

1. Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format. Accessible at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm309376.htm
