How to Access and Use the Electronic Systems for Acidified Foods and Low-Acid Canned Foods

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

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I.   Introduction

A.   Purpose of this Document

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];

- Commercial processors who manufacture, process, or pack products that they have determined are not AF, but who wish to voluntarily submit information about such products to FDA; and

- Persons who are authorized to act on behalf of such commercial processors[2].

Commercial processors who manufacture, process, or pack AF and 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 AF) or 21 CFR 108.35(c)(2) (for LACF). These provisions require two basic types of submissions:

- Food Canning Establishment Registration using Form FDA 2541; and

- Process filings using the following forms, as applicable:

- 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)

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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. Appendix 1 identifies the responsibilities of each type of authorized user.

This document provides information about:

- Portals for Electronic Submissions;

- How to Obtain an FDA Industry Systems (FIS) Account Through the FIS Electronic Portal;

- How to Enter the Electronic AF/LACF System Through the FIS Electronic Portal;

- General Information About Navigating the Process Filing Section of an Establishment's AF/LACF Online System;

- How the Establishment Contact Person for an Establishment Manages User Role and Access and Assigns User to Process Filings for the Establishment's Electronic AF/LACF Online System;

- General Information About the Organization of the Process Filing Folders;

- How to Manage Process Filings; and

- How to Search Process Filings.

This document does not provide:

- Instructions for submitting Forms FDA 2541d, FDA 2541e, FDA 2541f, and 2541g in either electronic or paper format;

- Instructions for submitting registration Form FDA 2541 in either electronic or paper format;

- Administrative details about requirements for commercial processors of AF and LACF to register food canning establishments and submit process filings for products that are manufactured, processed, or packed at the facility.

B. Abbreviations

Abbreviation	Full Term
AF	Acidified Food
AR	Authorized Representative
ECP	Establishment Contact Person
FCE	Food Canning Establishment
FFR	Food Facility Registration
FIS	FDA Industry System
FURLS	FDA Unified Registration and Listing Systems
LACF	Low-Acid Canned Foods
ROAR	Read Only Authorized Representative
SID	Submission Identifier
SUPER AR	Super Authorized Representative

C. Additional Resources

For additional information about registration and process filing for commercial processors of AF and LACF, see our guidance entitled "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" (Ref. 1 and the appendices in 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.

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 electronic AF/LACF system is one of the FURLS system components. In addition to using the electronic AF/LACF system to register a facility, you can use it to submit process filings.

III. How to Obtain an FDA Industry Systems (FIS) Account Through the FIS Electronic Portal

Each person who uses the electronic AF/LACF system accesses the system using a personal FDA Account 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 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. When a commercial processor has more than one establishment at distinct physical locations (e.g., in New Jersey and Virginia,) a single individual may serve as ECP for more than one establishment.

After FDA receives Form FDA 2541, we assign a Food Canning Establishment (FCE) number to the establishment. The ECP can authorize other individuals to submit or view process filings in the FCE's AF/LACF Online System. Any individual authorized by the ECP to submit or view process filings would enter the FIS electronic portal using his or her own FDA Account.

IV. How to Enter the Establishment's AF/LACF Online 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 your FDA Account ID and password.

- Check the "I understand" box.

- Select Login.

- The system displays the Main FURLS Menu. Figure 1 shows an example of the computer screen when you are logged into FURLS.

- Select Acidified/Low-Acid Canned Foods.

Figure 1 - FDA Unified Registration and Listing Systems (FURLS)
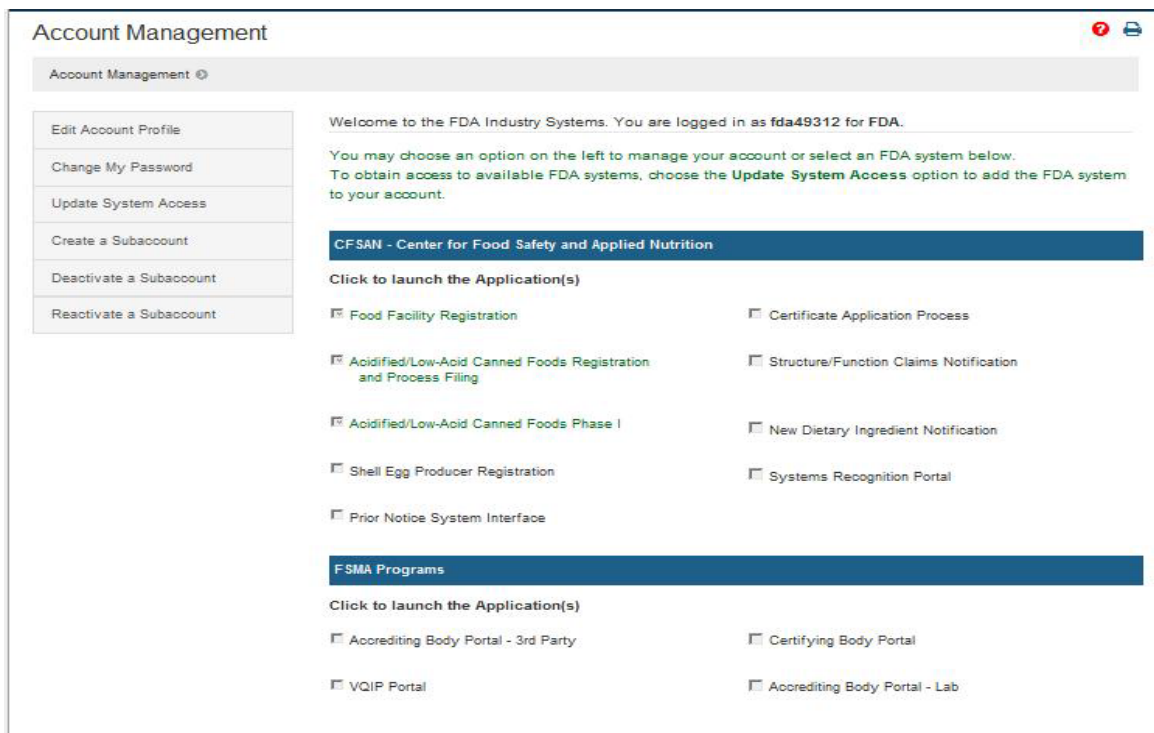
The system will display the AF/LACF Main Menu. See Appendix B for a flow chart illustrating navigation within the AF/LACF Online System. Figure 2 shows an example

of a computer screen when you select Acidified/Low-Acid Canned Foods from the Main FURLS Menu.

Figure 2 - AF/LACF Main Menu
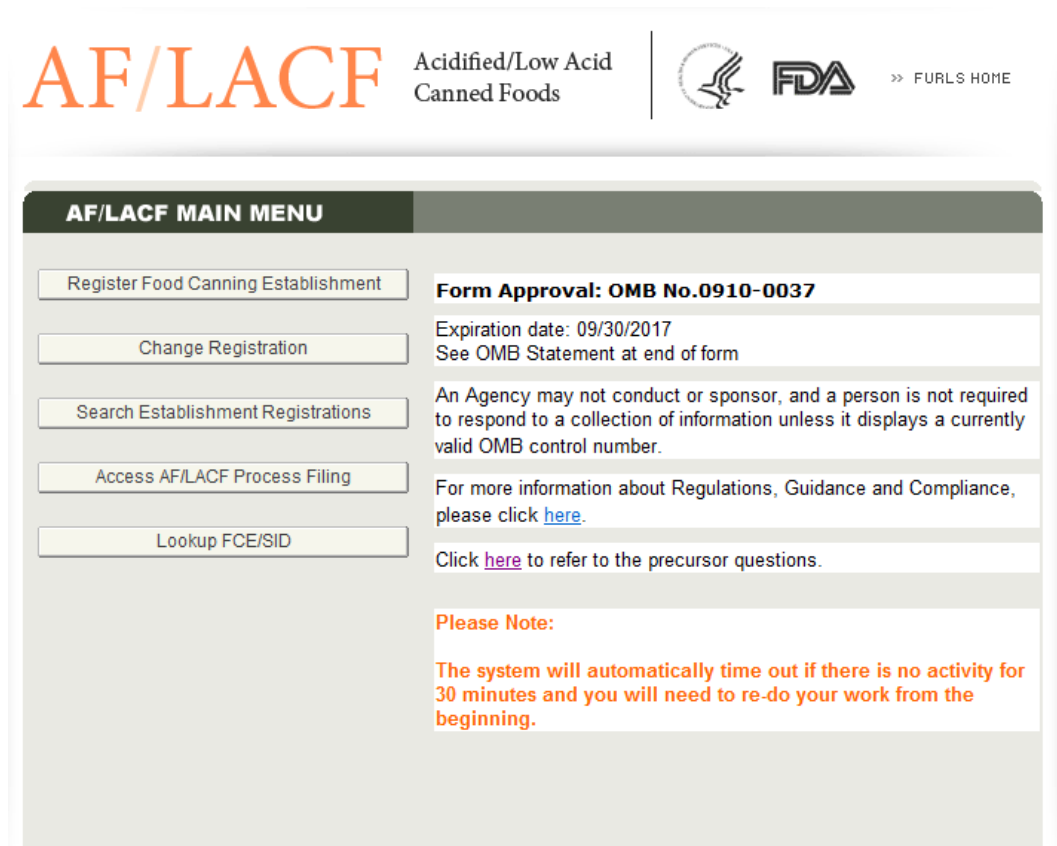
V. General Information About Navigating the Process Filing Section of an Establishment's AF/LACF Online System

A. General Navigation Links on Main Menus in the Process Filing Section

To navigate to the process filing section, select Access AF/LACF Process Filing from the AF/LACF Main Menu. The Process Filing section of the FCE's AF/LACF Online System will contain either one or two main menus, each with buttons or links for navigation:

- FCE List Main Menu, which only displays when you have an authorized role at more than one establishment; and

- FCE Process Filing Folder Main Menu, which displays unless your authorized role is as a Read Only Authorized User (ROAR).

Both main menus provide the following general navigation links:

- FURLs Home, located in the upper right portion of the screen, which takes you to the FURLS Main Menu and exits the AF/LACF electronic system; and

- AF/LACF Home, located in the upper right portion of the screen, which takes you to the AF/LACF Main Menu.

On some screens, you enter information into a data entry field. On other screens, you select applicable information already entered into the system by clicking on a drop-down menu that displays a List of Values or by clicking on a circle or a square next to the applicable information. We call these circles "radio buttons" and the squares "check boxes."

B.   FCE List Main Menu

Figure 3 shows a picture of an example of a computer screen showing the FCE List Main Menu that the system would display to authorized users. The screen displays both the general navigation links listed above in section V.A (i.e., FURLS Home and LACF Home) (located in the upper right portion of the screen) and three navigation buttons (located in the lower left portion of the screen). The navigation buttons are determined by your role as follows:

- Back to Main. This button is available to all authorized users and returns you to the AF/LACF Main Menu;

- Manage User Role and Access. This button is only available if you are authorized as the ECP. This button takes the ECP to a menu where the ECP authorizes access to an FCE's AF/LACL Online System and assigns a role to each authorized user;

- Manage SIDS. This function is only available if you are authorized as the ECP. It provides the ability for the ECP to assign existing process filings to an AR, if necessary.

Figure 3 - Example of the FCE List Main Menu
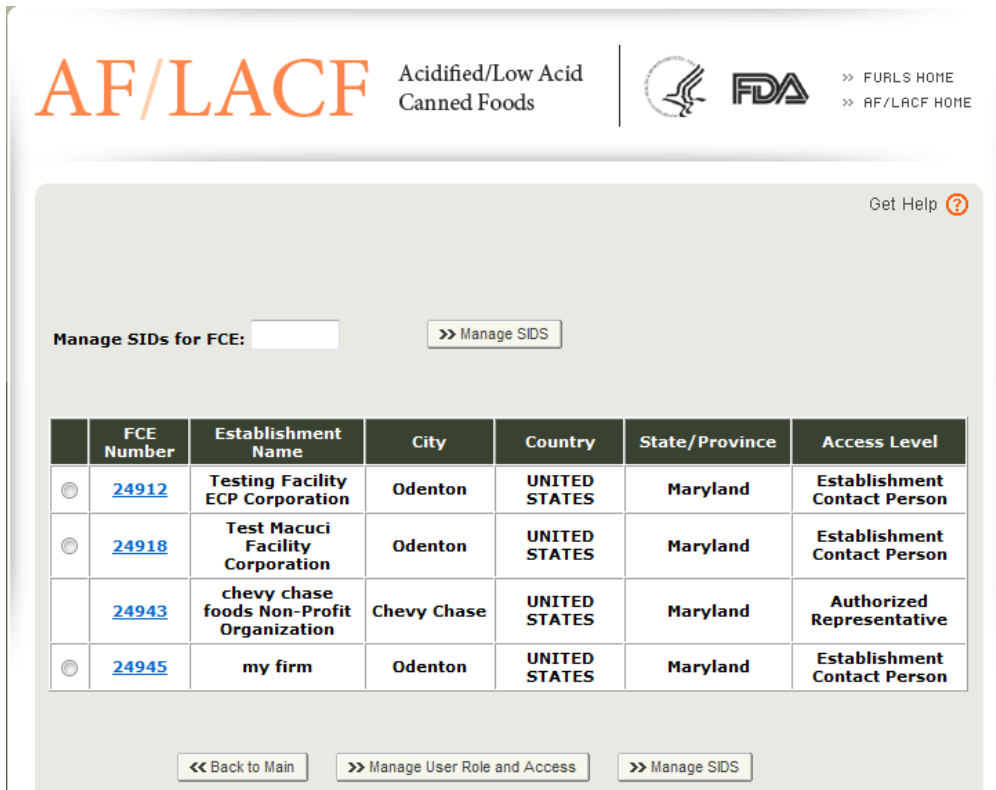
C.   FCE Process Filing Folder Main Menu

The AF/LACF system organizes process filing forms in folders according to the status of the process filing form. The FCE Process Filing Folder Main Menu contains four folders: (1) Draft, (2) Filed, (3) Filed with Inquiry, and (4) Cancelled. It displays both the general navigation links listed above in section V.A (i.e., FURLS Home and LACF Home) and specific navigation buttons (located at the bottom of the screen). See section VII, below, for information about the specific navigation buttons in the FCE Process Filing Main Menu.

D.   Adding Process Filing Forms

There are navigation buttons to direct you to continue, go back to a previous screen (i.e., previous step in entering a new process filing), save the entered information to your Draft Folder, or start the submission process over. At any step in entering a new process filing, you can navigate to a previous step by selecting the Back navigation button (located at the bottom left of the screen for each step). Each step provides a link to the instructions for submitting process filing forms.

There are two general navigation links (i.e., FURLS Home and LACF Home; see section V.A) along with a status bar and specific navigation buttons (see the list below). When you are entering a new process filing, the general navigation links and the Status Bar

appear at the top of every screen and the specific navigation buttons appear at the bottom of every screen.

- Status Bar. The status bar tracks the progress through each step of entering a new process filing.

- Clear button. Selecting "Clear" will erase all information you entered on the current screen display. You then would start over with new information.

- Back button. Selecting "Back" takes you back one screen where you can add or change information on a previous screen. The system will <u>not</u> save information entered on the current screen (before selecting the "Back" button) unless you enter information in all required fields on the current screen and select "Continue" before selecting "Back." Thus, if you do not select "Continue" before selecting "Back," you will need to re-enter the information.

- Continue button. Selecting "Continue" retains the information entered on the current screen and takes you to the next screen.

- Save and Exit button. Selecting "Save and Exit" saves the information entered so far, stores the submission in the Draft Folder, and displays a message screen stating the form has been saved and providing buttons for continued navigation.

- Cancel & Start Again button. Selecting "Cancel & Start Again" deletes all information you entered for this submission, without saving any of the information, and takes you to the AF/LACF Process Filing Folder Main Menu.

VI. How the Establishment Contact Person Manages User Roles and Access and Assigns User to Process Filings for the Establishment's AF/LACF Online System

A. General Information About User Roles and Assignment to Process Filings

The ECP may authorize one or more individuals to access an FCE's electronic AF/LACF Online System and perform designated functions related to process filing. Doing so is not necessary and is at the discretion of the ECP. Such individuals may either be the establishment's employees or its authorized third party.[3] At this time only the ECP and a

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[3] An authorized third party is a person other than an Owner, Technologist, Manager, Director, President/Vice President, Other Employee, or Authorized Third Party who has been authorized by the commercial processor to submit forms on behalf of the commercial processor. [4] The email address entered for an individual must be a valid email address in the FIS system. See sections III and IV for additional information.

Super Authorized Representative (Super AR) can be authorized to perform functions related to registration. All other persons who access an FCE's AF/LACF Online System can only be authorized to perform functions related to process filings.

The ECP authorizes an individual to access an FCE's AF/LACF Online System by assigning a role to the individual as Super AR, an Authorized Representative (AR), or a Read Only Access Representative (ROAR). A particular FCE can only have a single ECP, but may have more than one Super AR, AR and/or ROAR. The assigned role determines the functions the individual can perform electronically and when contacting FDA on behalf of the ECP. Table 1 in the Appendix shows the authorized functions that can be performed by the ECP, Super AR, AR, and ROAR.

B.   Functions Available to the Establishment Contact Person

The ECP has access to functions to: (1) Manage User Role and Access and (2) Manage SIDS. Under Manage User Role and Access there are three functions available to an ECP: (1) Add User Role; (2) Change User Role; and (3) Remove User Role.

When the ECP authorizes an individual to access an FCE's AF/LACF Online System, the ECP assigns a role to that individual. If the role assigned is an AR, then the ECP has the ability to assign existing SIDs to an AR, if necessary. In general:

- The ECP may only assign a single role to a specific user authorized to access a specific FCE. The system identifies a user by the email address in the user's FIS Account. Note: The email address for any user in an AF/LACF Online System may only be associated with one FIS Account ID. If a user's email address is linked to more than one FIS Account, the AF/LACF Online System will not grant access to that user. An ECP who has difficulty granting access to a user should contact the FURLS help desk for assistance. See section VI.B.1 for details on how the ECP provides access to an FCE's AF/LACF Online System and assigns a role to each user authorized to access the system.

- After the ECP authorizes an individual to access an FCE's AF/LACF Online System and assigns a role to that individual, the ECP may change the user's role (see section VI.B.2) or remove that individual's access to the FCE's AF/LACF Online System (see section VI.B.3).

- The ECP can use the Manage SIDS function to assign access to existing process filings to an AR when that AR had not submitted the process filing but needs access to it. The ECP only needs to use the Manage SIDS function for users identified as an AR, because users who are identified as a Super AR or ROAR have access to all SIDS.

1. Manage User Role and Access: Add User Role

To authorize a user to access an FCE's AF/LACF Online System, the ECP:

- Enters the FCE's AF/LACF Online System through the FIS electronic portal and selects Manage User Role and Access.

- Selects an FCE from a list of FCE numbers, which contains the FCE number, Facility Name, City, Country, State/Province, and Access Level (see Figure 4) and then clicks "Manage User Role and Access." If the ECP manages a single FCE, the ECP will not see a dropdown list.

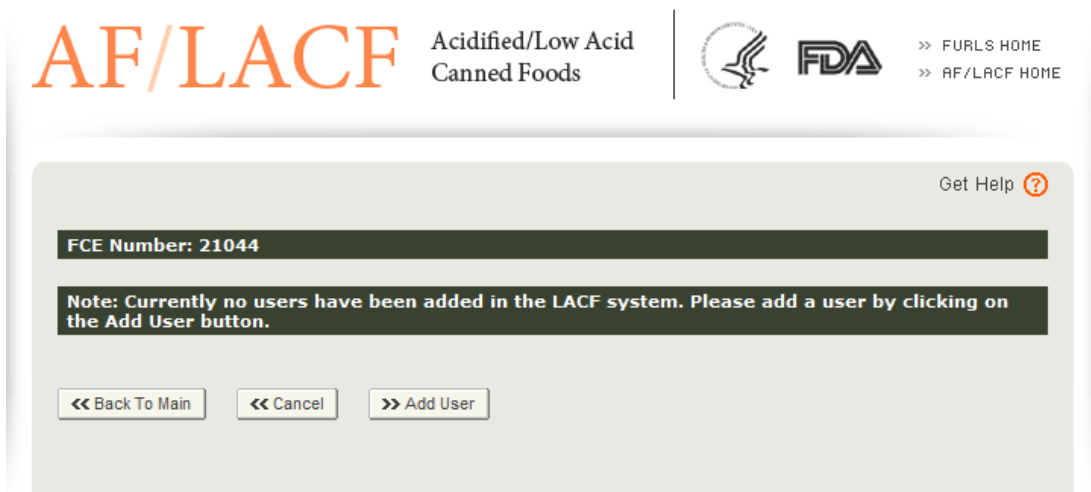**Figure 4 – Manage User Role and Access - Select FCE from List of FCE Numbers**
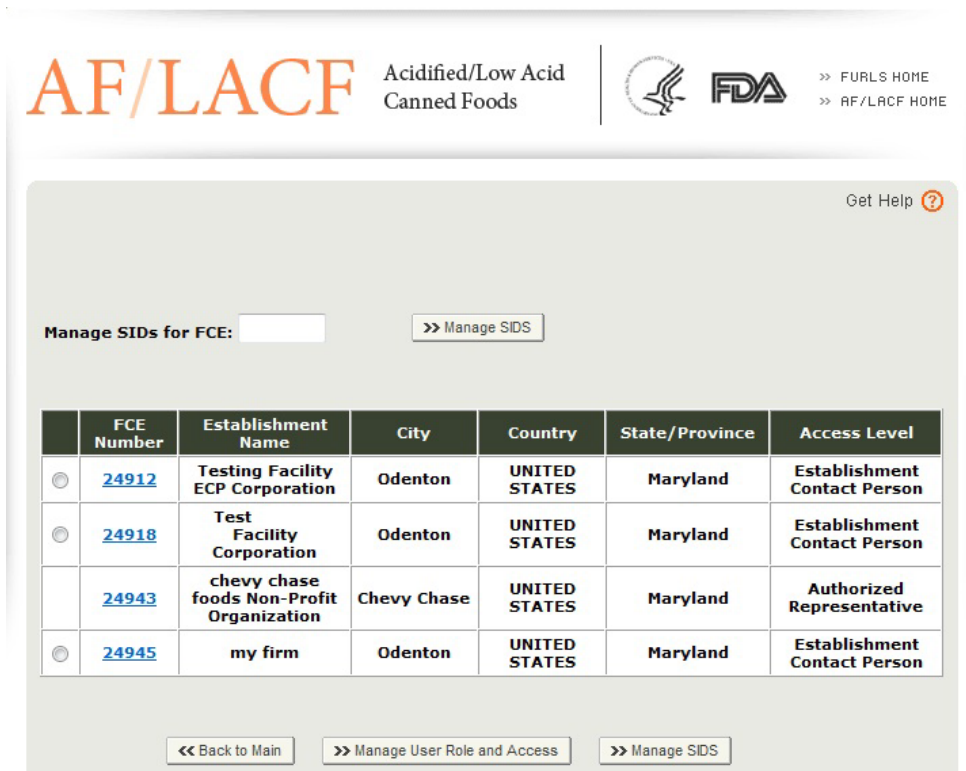
For a given FCE, the system display depends on whether the ECP has already authorized a user to access that FCE's AF/LACF Online System.

- The first time the ECP accesses an FCE's AF/LACF Online Manage User Role and Access to authorize a user for that FCE, the system displays an "Add User" screen (see Figure 5).

- After an ECP authorizes at least one user for an FCE's electronic AF/LACF Online System, the system displays a "List of Users and Roles (see Figure 6). To add a user from this screen, the ECP selects "Add User" (located at the bottom of the screen).

Figure 5 - Manage User Role and Access –Add User for the First Time

Figure 6 – Manage User Role and Access - FCE List of Users and Roles
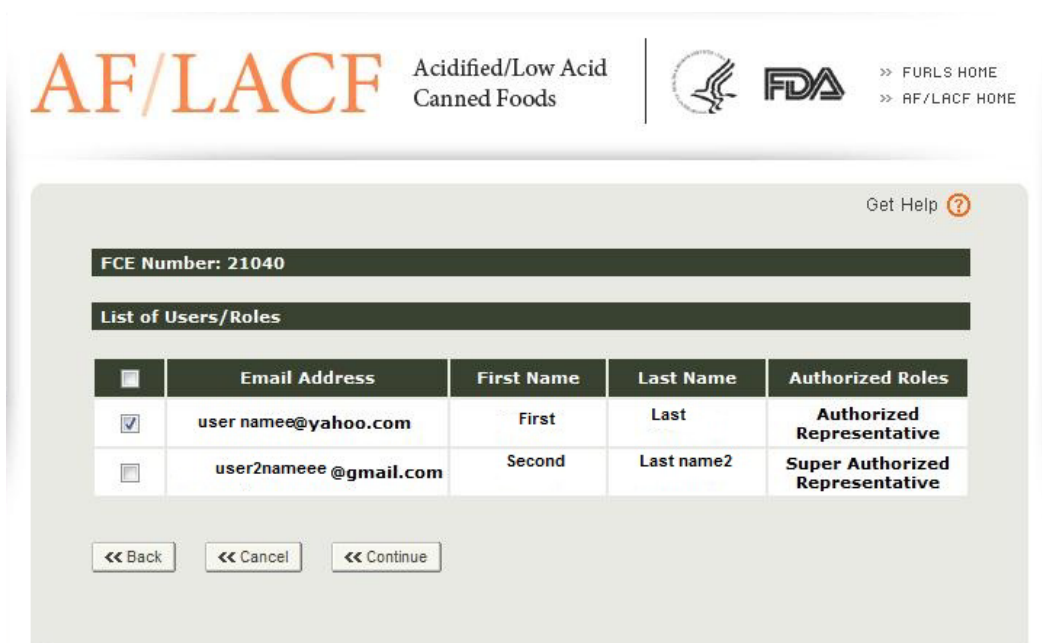
The system enables the ECP to add either a single user or multiple users. The system display for "Add New Users" contains: (1) a text box where the ECP adds an email address; (2) a dropdown list for the ECP to select a user role for that email address; and (3) a button to add another email address for another user. The system display also includes navigation links and selection buttons. Figure 7 shows a picture of an example

of a computer data entry screen to add a user's email address [4] and role (Super AR, AR, or ROAR).

Figure 7 – Manage User Role and Access - Add a New User and Assign User Role

- To add a single user to an FCE, the ECP:

1. Enters the email address for an FIS account holder

2. Identifies the user's role from the List of Values

3. Selects "Submit" to add a user or "Cancel" to stop the process and return the ECP to the screen where the ECP began the process by selecting "Manage User Role and Access." The system will display a warning message to the ECP and ask to confirm cancelation.

- To add multiple users to an FCE (see Figure 8 below), the ECP repeats steps 1 and 2 above, then selects "Add Another Email" to begin data entry for the next user. The ECP continues this process as needed to authorize additional users.

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[4] The email address entered for an individual must be a valid email address in the FIS system. See sections III and IV for additional information.

- If the ECP needs to delete a user during the process of adding users, the ECP can do so by selecting the "Delete" button next to the user's email address, as long as the ECP has not already selected "Submit" to complete the authorization process. To remove a user after the authorization process is complete, see section VI.B.3 below.

The ECP then selects "Submit" to complete the authorization process or "Cancel" to stop the process and return the ECP to the screen that initiated the Manage User Role and Access. The system will display a warning message to the ECP and ask to confirm cancelation.

Figure 8 – Manage User Role and Access - Add Multiple Users

The system will verify that each added email address is valid in the FIS system, check for an assigned role, and display an error message if there are any problems with the submitted information (see Figure 9).

Figure 9- Manage User Role and Access - Error Message
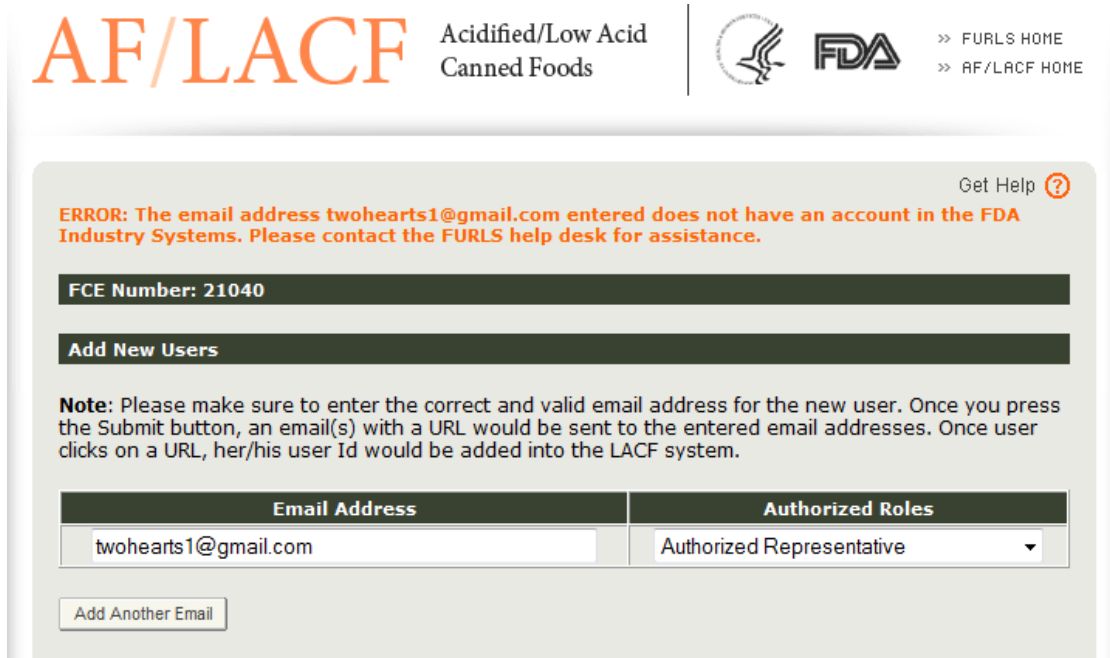
After the system verifies the submitted information, the system display depends on whether the ECP manages more than one FCE.

If the ECP manages a single FCE, the system displays a confirmation (see Figure 10) and provides links for the ECP to either add more users or navigate back to the "FCE Process Filing Folder Main Menu" screen.

Figure 10 - Manage User Role and Access – ECP Manages Single FCE and Add a User
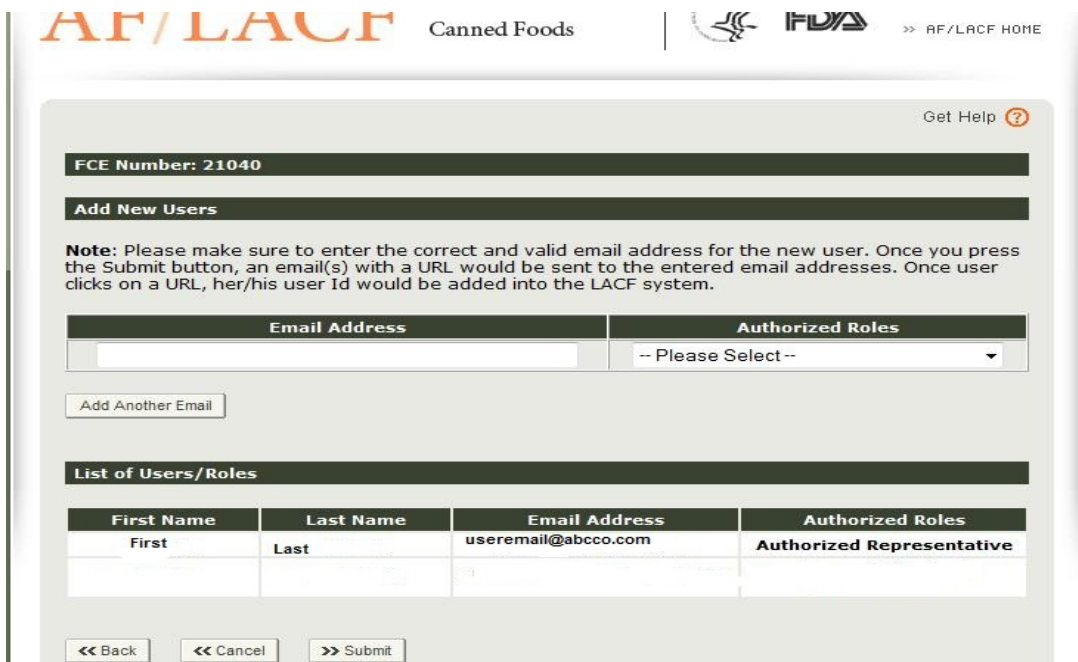
If the ECP manages multiple FCEs, the system displays a confirmation and prompts the ECP to add a user to a different FCE (see Figure 11).

Figure 11 - Confirmation When ECP Manages Multiple FCEs

- If ECP selects "Yes", the system will navigate the ECP to the screen for selecting an FCE.

- If ECP selects "No", the system will navigate the ECP to the screen where the ECP selected "Manage User Role and Access" and the process ends.

The system notifies each newly authorized individual about access to the AF/LACF Online System[5]. See section VI.C of this document for information on how an authorized user completes the access process.

2. Manage User Role and Access: Change User Role

- To change a user access role for an FCE, the ECP:

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[5] If a person with an FIS Account is authorized to access the AF/LACF Online System for more than one FCE, the system only sends this email notification the first time that person is granted access to the AF/LACF Online System for a particular FCE. When this person receives authorization to access the AF/LACF Online System for another FCE, the system notifies that person by displaying that new FCE in a List of FCEs that the person sees when entering the AF/LACF Online System.

- Selects the FCE number and "Manager User Role and Access" button.

Figure 12 - Manage User Role and Access – List of Users and Roles for a selected FCE
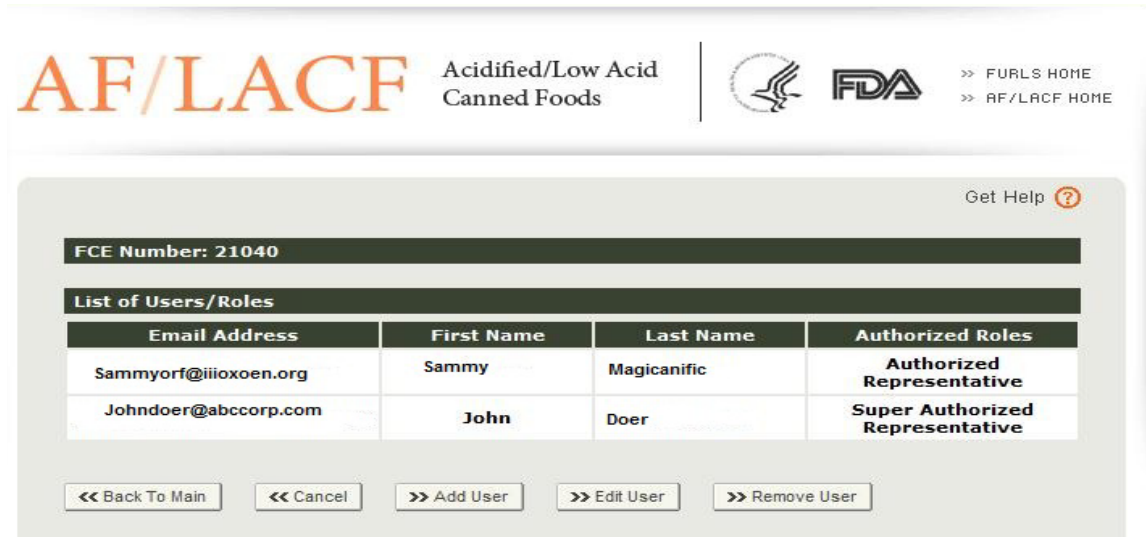
- Selects the "Edit User" button (see Figure 13) and displays a list of users and access roles.

Figure 13 – Manage User Role and Access - Edit User Role
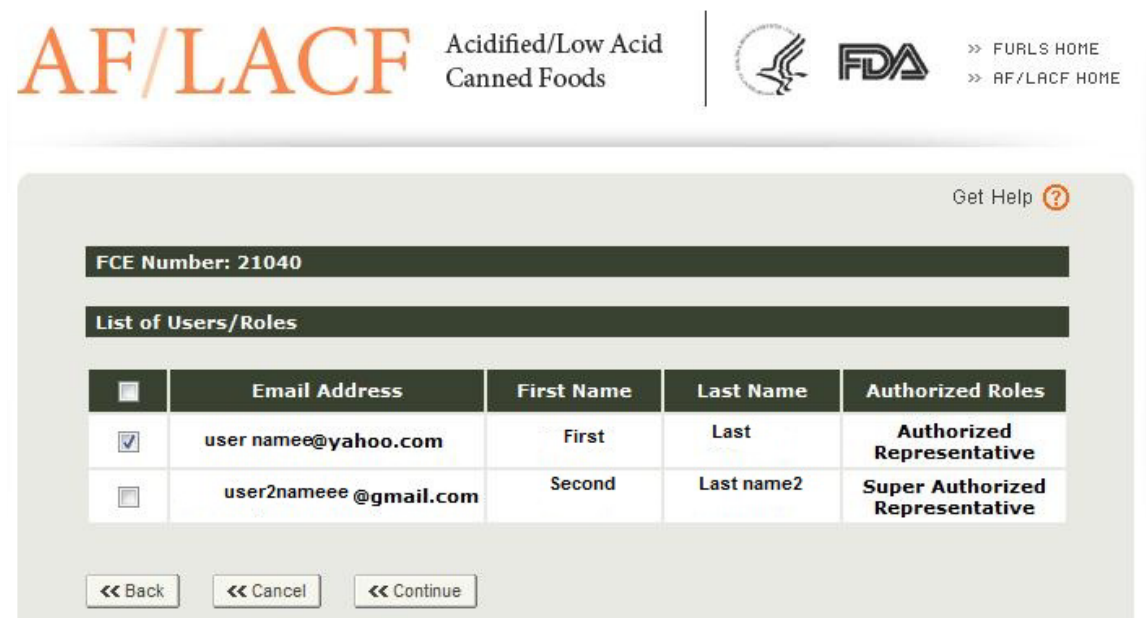
- Selects the check box next to the user to update and selects "Continue" button.

- Selects the dropdown arrow under the column heading of Authorized Roles to show the available roles.

- Selects the appropriate role to assign to the user and selects "Submit" button.

- If ECP selects "Cancel" button, a warning message will appear and ask to confirm cancelation.   The system deletes all information already entered and returns to the FCE list.

3. Manage User Role and Access: Remove User Role

To remove a user's authorized role within an FCE's AF/LACF Online System, the ECP must either: (1) reassign any existing SIDs submitted by the user to another valid FIS account holder[6] or (2) reassign any existing SIDs to the ECP. To remove access of a user to an FCE's AF/LACF Online System, the ECP:

- Enters the AF/LACF Online System through the FIS electronic portal (see section V) and selects Manage User Role and Access.

- Selects an FCE from a list of FCE numbers, which contains the FCE Number, Facility Name, City, Country, and State/Province   and then clicks "Manage User Role and Access." The system displays a List of Users and Roles for the selected FCE. If the ECP manages a single FCE, the ECP will not see a list of FCE numbers. Figure 14 shows a picture of an example of a computer screen displaying the menu for List of Users and Roles for the FCE.
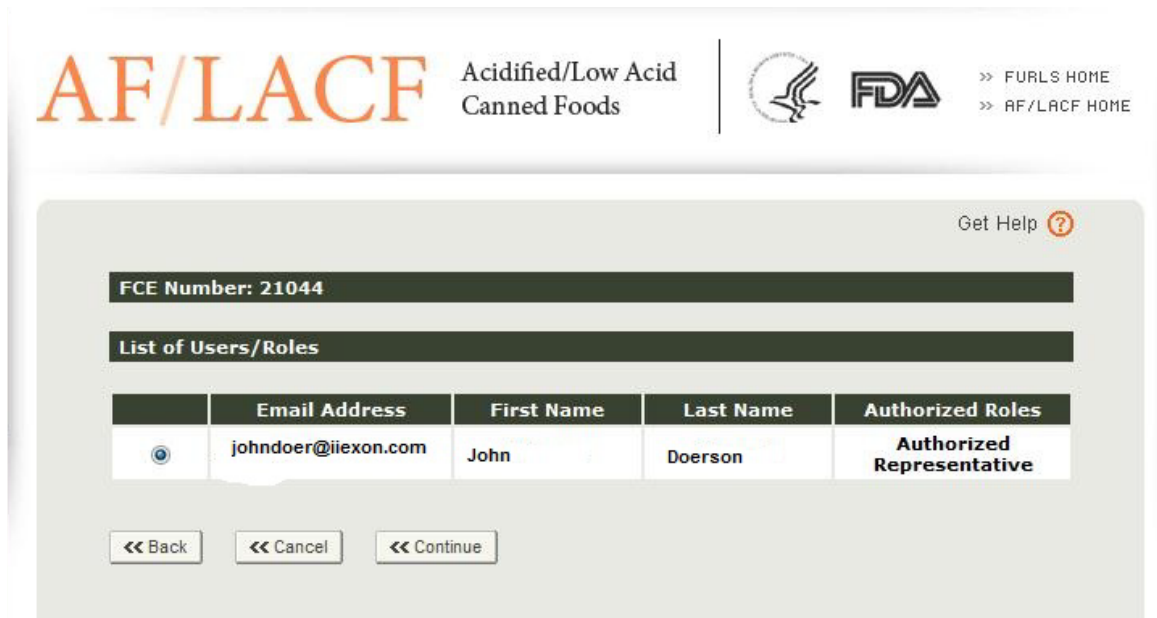
Figure 14 - Manage User Role and Access - List of Users and Roles

- Selects "Remove User" button.

- Selects the radio button next to the user whose access will be removed.

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[6] Each process filing submission must be assigned to a valid FIS email address. See sections III and IV for additional information.

- Selects the "Continue" button located at the bottom of the screen. The system displays the Remove/Reassign User screen listing the user's email, FCE, and assigned role (see Figure 15). The system also displays a message asking the ECP to enter the email address of the user who will be replacing the user who is being removed.

Figure 15 – Manage User Role and Access - Remove and Reassign User Role

- Enters the email address of another user who has the same authorization as the user being removed, or leaves the email address blank. Note:

  - If the email address is invalid, or the newly assigned user has a different user role than the user being removed (see section VI.B above), the system displays an error message (see Figure 16).

  - Leaving the email address blank automatically reassigns SIDs that had been submitted by the removed user to the ECP. The ECP, Super AR, and ROAR would have access to these SIDs.

Figure 16 – Manage User Role and Access - Error Message When an Email Address is Invalid

- Selects "Submit" to complete the process or "Cancel" to start over.

The system displays the List of Users and Roles showing the updated listing.

4. Manage SIDS

The Manage SIDS function allows the ECP to assign one or more existing SIDs to an AR to manage for the ECP even though the AR did not submit that SID. By default, all SIDs are accessible to the ECP, Super AR(s), and ROAR(s). Any SID created by an AR, by default, is automatically assigned to the AR who submitted it. To assign an AR to one or more existing SIDs, the ECP:

- Either:

  - 1) Enters the FCE number from the FCE List (with multiple FCE numbers) and selects "Manage SIDS" button (See Figure 17) to display the List of Values of Authorized Users Manage SIDS screen (see Figure 18); or

  - 2) Selects the "Manage SIDS" button from the Process Filing Folder Menu to display the List of Values of Authorized Users (see Figure 18);

Figure 17 - Manage SIDS Screen from Main FCE List
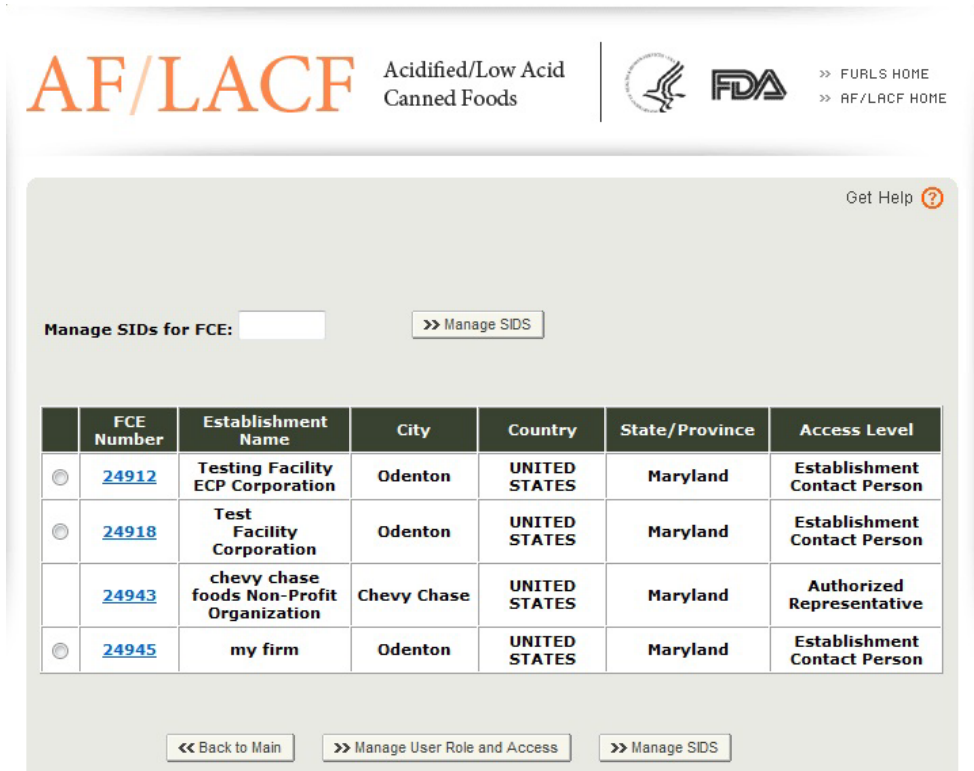
Once the system displays the "Assign SIDS" screen, the ECP:

- Selects the AR from the List of Values and selects the "Filter" button (See Figure 18)

Figure 18 - List of Values of Authorized Users to Assign SIDS
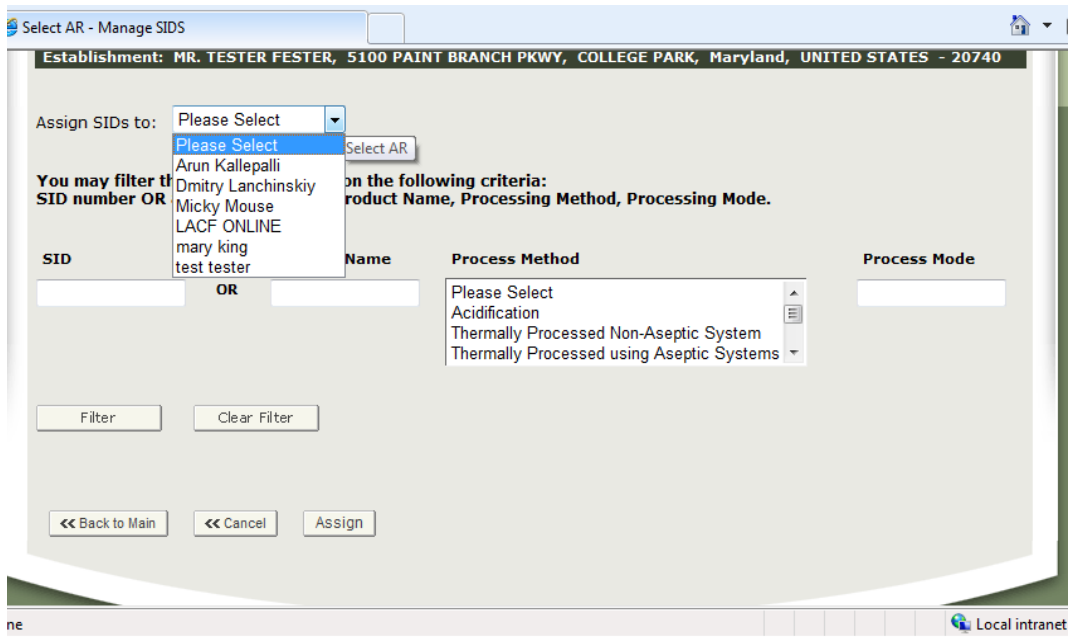
- The SID list appears on the screen with options to filter on specific fields (See Figure 19)

Figure 19 - Manage SIDS - Select AR to assign to SIDS

- Selects the SID(s) to assign to the AR

- Selects the "Assign" button at the bottom of the screen.

The system displays a message indicating the SID(s) assigned to the AR (See Figure 20)

Figure 20- Confirmation Screen for Assigning SIDS to AR

- Selects "Back" to Manage SIDS Menu or "Back to Main" to return to the AF/LACF Main Menu

C. Functions Available to Authorized Individuals

After the ECP authorizes a new user, the user receives an email requesting confirmation of the ECP's request to link the user's FIS account to an FCE's AF/LACF Online System. This confirmation email contains a link to the FCE's AF/LACF Online System. Figure 21 shows an example of a confirmation email.

Figure 21 - Notification to Newly Authorized User

<u>DEPARTMENT OF HEALTH AND HUMAN SERVICES</u>

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

September 17, 2014

Dear Sir or Madam,

A request was made to link FIS Account ID **gns58742** to AF/LACF Online.

In order to confirm this request please go to this link:

http://access.dev.fda.gov/lacf/addNewLacfUser.htm?lacfRepId=12345

If this email was sent in error please forward this request back to LACF@fda.hhs.gov.

Thanks.

- The user clicks on the link in the confirmation email. Doing so confirms and validates the user. The system then links the user's FIS account to the FCE's AF/LACF Online System with the specific role assigned by the ECP (see Figure 22).

Figure 22 - Message to User that FIS Account Is Linked to an FCE's AF/LACF Online System
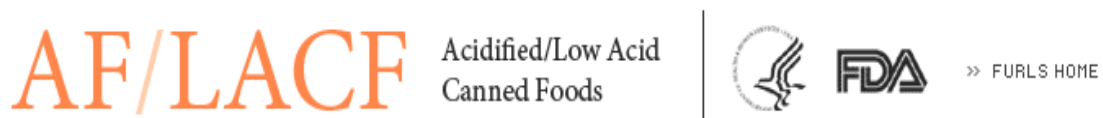
Your FURLS account Id has been successfully linked to LACF Online. You can now log into FURLS and access LACF.

After this confirmation process is complete, the user logs into the FIS electronic portal, navigates to the AF/LACF Main Menu system (see section IV) and selects Access AF/LACF Process Filing.

VII. General Information About the Organization of the Process Filing Folder Section of an Establishment's AF/LACF Online System

A. Process Filing Folder Main Menu

The AF/LACF system organizes process filing forms in folders according to the status of the process filing form. Figure 23 shows a picture of an example of the FCE Process Filing Folder Main Menu. One of the functions shown in Figure 23 is only available to an ECP (i.e., Manage User Role and Access). Each folder accessed from the FCE Process Filing Folder Main Menu identifies the number of forms in the folder. If there are no forms in that folder, the number will be zero (0). The functions available within a particular process filing folder may vary depending on the folder type (see section VII.B).

All users except those authorized as a ROAR have access to the Process Filing Folder Main Menu. A ROAR has access to a search function, with exported results, rather than a Process Filing Folder Main Menu. See section IX.B for instructions on how a ROAR can use this search function.

Figure 23 - FCE Process Filing Folder Main Menu for the ECP
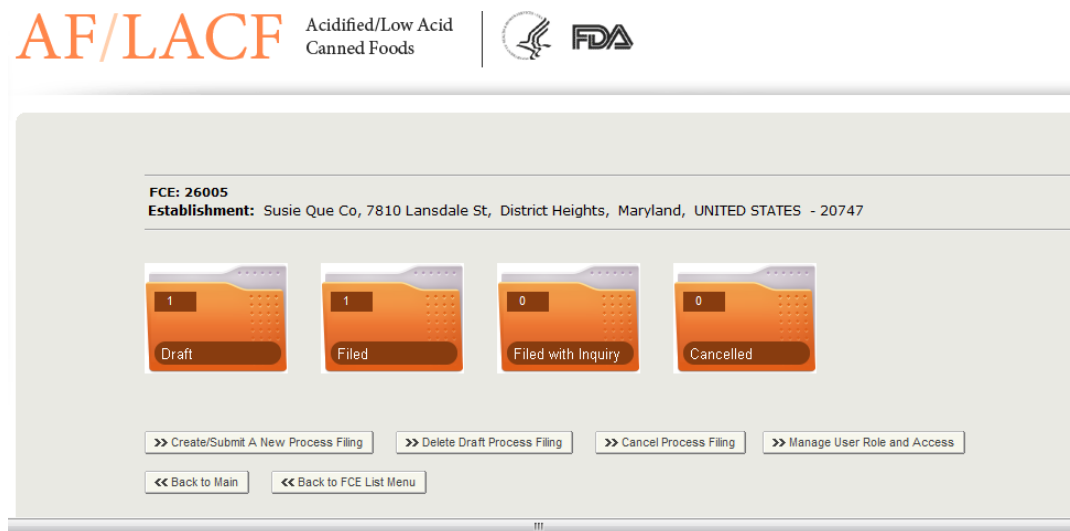
The process filings that an authorized user can view in the folders accessible from the FCE Process Filing Folder Main Menu depend on the user's authorization.

- ARs for a particular FCE may view the process filing forms they submitted and any process filing forms assigned to the AR by the ECP through Manage SIDS function.

- An ECP and a Super AR may see any process filing form regardless of who submitted the process filing form.

See section VII.B for a detailed discussion of Folder Types. See section VIII for information about how to manage process filings contained in each of these folders.

The Process Filing Folder Main Menu displays both the general navigation links listed above in section V.A (i.e., FURLS Home and LACF Home) and specific buttons to navigate to three specific functions: (1) Create/Submit a Process Filing; (2) Delete Draft Process Filing; and (3) Cancel Process Filing, however, the choice for Managing User Role and Access is only viewable to the ECP as shown in Figure 23. We discuss these three functions immediately below.

1. Create/Submit a New Process Filing

To create and submit a new process filing, select the button for Create/Submit a New Process Filing (located at the bottom of the screen). See References 2 through 5, and the appendices in those references, for detailed instructions on how to create and submit a new process filing using Forms FDA 2541d, 2541e, 2541f, and 2541g, respectively.

2. Delete Draft Process Filing

To delete a draft process filing:

- Select the Delete Draft Process Filing button (located at the bottom of the screen). The system displays a screen listing all Draft process filing forms accessible to that user, with a check box next to each form (see Figure 24). To locate a draft form, you can either (1) search for the Draft SID by the SID number; or (2) scroll down the list.

Figure 24 - Example of List of Draft Process Filings Available for Deletion

- Select the check box next to one or more specific SIDs to be deleted, or check "Select All" to delete all draft process filing forms accessible to that user.

- Select the Delete Process Filing button located at the bottom of the screen. The system prompts you to either accept or terminate the deletion (see Figure 25).

Figure 25 - Example of Screen Requesting Confirmation to Delete a Draft Process Filing
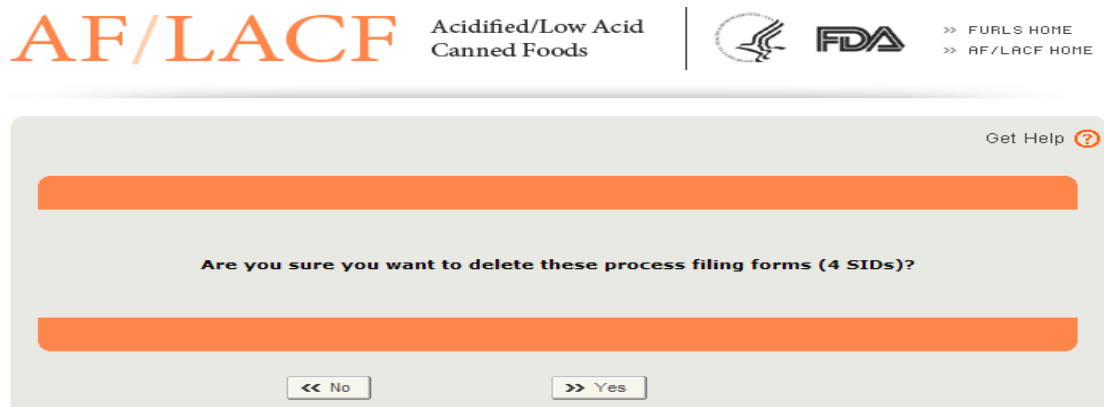
- Either:

  - 1) Select "Yes" to complete the deletion; the system will display a confirmation message (See Figure 26); or

  - 2) Select "No" to terminate the deletion; the system will return you to the Delete Process Filing List screen.

Figure 26 - Example of Message Confirming Deletion of a Draft Process Filing
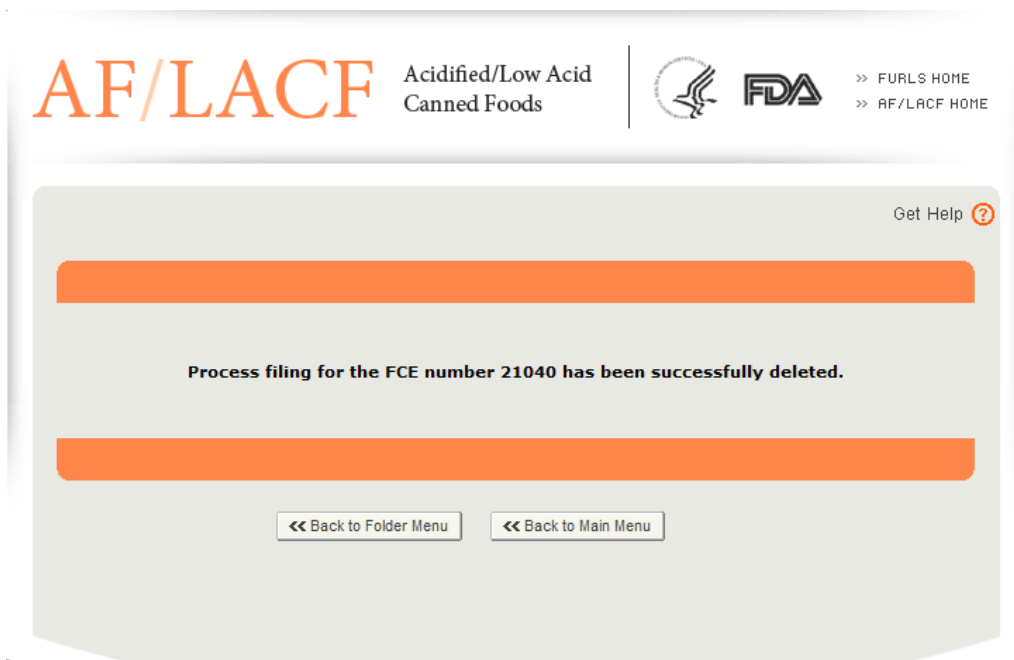
- Select Back to Folder Menu to return to the FCE Process Filing Folder Main Menu.

3. Cancel a Filed Submission

To cancel a filed submission:

- Select the Cancel Process Filing button (located at the bottom of the screen). The system displays a screen listing all filed process filing forms accessible to that user, with a check box next to each form. To locate a filed process filing, you can either: (1) search for a SID number and/or product name; or (2) scroll down the list.

- Select the check box next to each filed submission to be cancelled, or check "Select All" to cancel all filed submissions accessible to you (see Figure 27).

Figure 27 - Example of List of Filed Submissions Available for Cancelation

- Select the Cancel Process Filing button located at the bottom of the screen. The system prompts you to either accept or terminate the cancelation (see Figure 28).

Figure 28 - Example of the Screen Requesting Confirmation to Cancel a Filed Submission

- Either:

  - Select "Yes" to complete the cancelation; the system will display a confirmation message (see Figure 29) and send confirmation notices to the ECP and Super AR when the user is not the ECP or Super AR; or

  - Select "No" to terminate the cancelation; the system returns you to the Cancel Process Filing List screen.

Figure 29 - Example of Message Confirming Cancelation of a Filed Submission
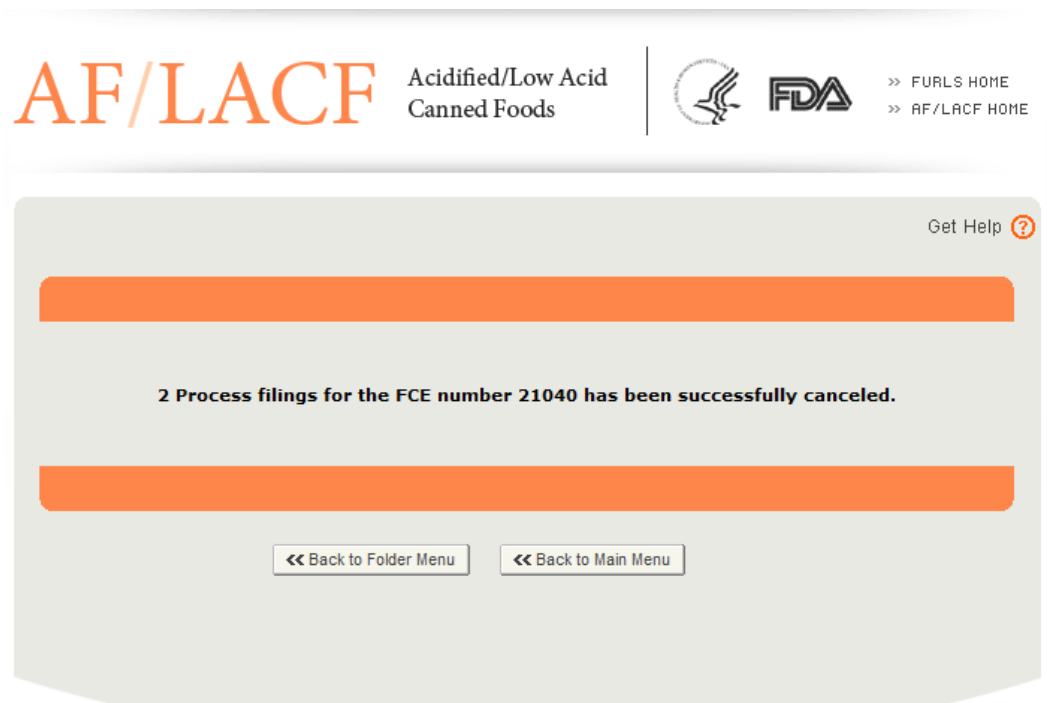
- Select Back to Folder Menu to return to the FCE Process Filing Folder Main Menu.

B.   Folder Types

1.   Draft

The Draft Folder contains and displays any process filing form that has not been submitted to FDA - e.g., because you are still working on the form. Users can view and edit information in the Draft folder but FDA cannot see any process filings in the Draft Folder. The only users who can see or edit process filings in the Draft folder are the users who created and saved the process filing, or the ECP and Super AR. In other words, if User A creates a process filing and saves it in his or her Draft Folder, Users B and C cannot see or edit User A's draft process filing unless User B or C are authorized in the FCE's AF/LACF Online System as the ECP or a Super AR. Figure 30 shows a picture of an example of the FCE Process Filing Draft Folder Screen.

The functions available in the Draft Folder are: (1) Complete Process Filing; (2) Delete Process Filing; (3) Copy; (4) Print; and (5) Export. For more information on how to perform these functions, see section VIII.B.

Figure 30 –Draft Folder Screen
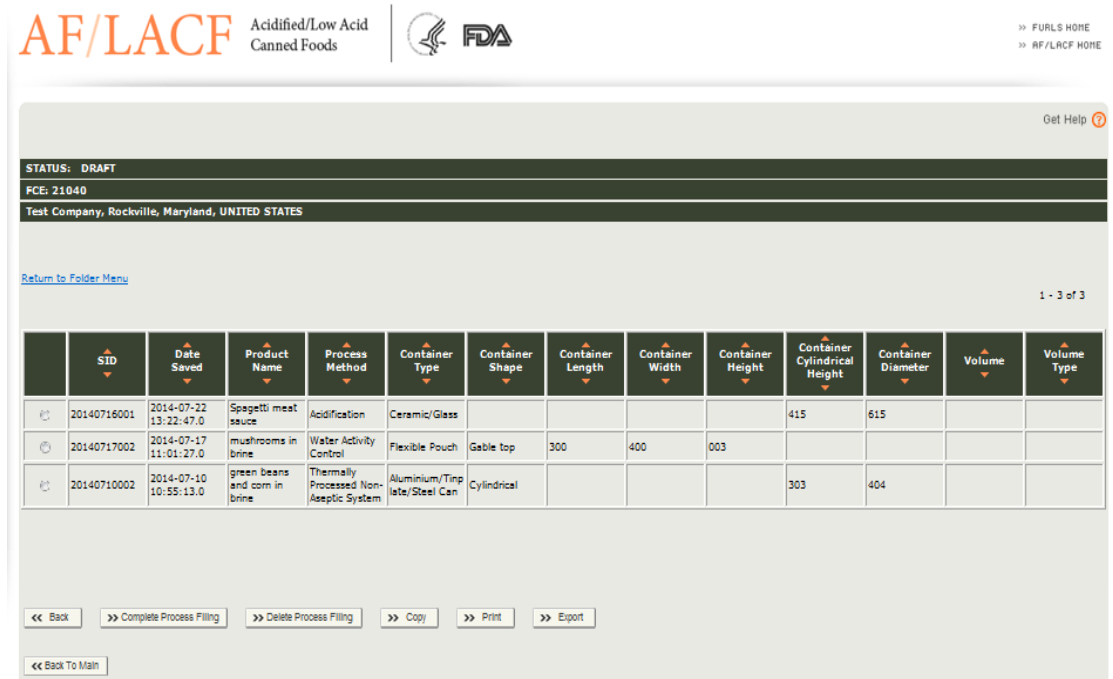
You can create new process filing forms and place them in the Draft Folder by: (1) creating and saving a new process filing; (2) copying a previously submitted process filing from the Filed Folder; or (3) copying a process filing form from the Draft Folder. For detailed instructions on how to enter a new process filing, see References 2 through 5, and the appendices in those references, when using Forms FDA 2541d, 2541e, 2541f, and 2541g, respectively.

2. Filed

The Filed folder contains and displays any process filing form that has been submitted to FDA and is considered complete. For additional information about FDA's review of submitted process filing forms, see Reference 1.

The functions available in the Filed folder are: (1) View; (2) Copy; (3) Print; (4) Export. For more information on how to perform these functions, see section VIII.B.

3. Filed with Inquiry

The Filed with Inquiry folder contains and displays a copy of any process filing form that is in the Filed Folder (because it is submitted and complete) when FDA has reviewed the process filing form and requested additional information about the process it describes. FDA continues to treat any form in the Filed with Inquiry folder as "filed" and the original submission remains in the Filed Folder.

The process filing forms in the Filed with Inquiry Folder will identify the additional information requested by FDA and the filer's responses and/or changes to the process filing form. When FDA has no further questions, the process filing form in the Filed

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Folder will be updated with the user's changes and the system will remove the copy of the form from the Filed with Inquiry folder. For additional information about FDA's review of submitted process filing forms, see Reference 1.

The available functions in the Filed with Inquiry folder are: (1) View; (2) Edit; and (3) Export. For more information on how to perform these functions, see section VIII.B.

4. Cancelled

The Cancelled folder contains and displays any submitted process filing form for a product that the FCE no longer manufactures, processes, or packs. Three years after the establishment cancels a process filing or notifies FDA that a product is cancelled, the FCE's AF/LACF Online System will archive the applicable form and the process filing will no longer be considered filed.

The only functions available in the Cancelled Folder are: (1) View; and (2) Export. For more information on how to perform these functions, see section VIII.B.

VIII.   How to Manage Process Filings

A.   Filter and Sort Process Filings in a Folder

Specific functions are available within each folder (see section VII.B). Figure 31 shows a picture of an example of the Filed Folder. The top of the screen identifies the status of the process filing forms (in this example, the status is "Filed" because these are forms in the Filed Folder). The main screen identifies data entry fields available for you to filter when there are more than 25 process filing forms in the displayed folder. For information about the "filter" function, see section VIII.A.1

Figure 31 - Example of Display Screen in the Filed Folder

For each process filing form in the folder, the system displays the:

a   SID;

b   Inquiry (if applicable);

c   Submission Date / Date Saved (For the draft folder, the heading will be Date Saved - i.e., the date the submission was last saved. The heading for all other folders will be Submission Date - i.e., the date the form was submitted to FDA) ;

d   Product name;

e   Paper or Electronic submission;

f   Processing method;

g   Container type;

h   Container shape; and

i   Dimensions, Volume and Volume Type.

You can navigate to other available folders using the Back to Folder Menu link located on the left hand side above the filtered list in the middle of the screen.

1.   Filtering Process Filing Forms

You can filter process filing forms (i.e., select and display process filings based on criteria entered in the filter data entry boxes located at the top of the screen). After applying one filter, you can apply an additional filter to further refine the filtered results.

As an example of how to apply a filter, below we provide instructions for how to apply a filter for the criterion "Process Methods":

1. Click on "Process Method."

2. Select the Process Method (in this example, Acidified) from the available List of Values in the drop-down menu and click on "Filter."

3. The system will display only those process filings[7] that are contained in the folder and are processed using an "Acidified" process method. Figure 32 shows a picture of an example of a list of process filings in the Filed Folder filtered for Acidified Process Method.

Figure 32 - Example of Display Screen after Applying the "Process Method" Filter

2.   Sorting Process Filing Forms

Within a folder, you can sort the list of process filings by the title of each display column by selecting the "up arrow" or "down arrow" in the applicable column heading. Selecting the "up arrow" sorts the forms in ascending order (alphabetical, numerical, or date, as applicable); selecting the "down arrow" sorts the forms in descending order (alphabetical, numerical, or date, as applicable). The default sort order is descending order by submission date (i.e., from the most recent submission to the earliest submission).

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[7] The system limits the results to display 25 process filing forms per page. Use the page number link in the upper left section of the results to view the next screen of results.

As an example of how to sort a list of process filings, below we provide instructions for how to sort process filings by the column heading "Product Name":

- Select the "up arrow" in the applicable column heading (in this example, Product Name).

- The display changes to reflect the sorting of the forms in ascending alphabetical for the selected column heading (in this case, Product Name). A down arrow appears under the column heading. Figure 33 shows a picture of an example of a list of process filings in the Filed Folder sorted in ascending order by Product Name.

- To re-sort the items in descending order, select the down arrow above the column heading. The list of process filings will re-sort in descending order.

- To sort on another column heading, select that column heading.

Figure 33 - Example of Display Screen after Sorting Process Filings by Product Name

B.   Available Functions

The functions available are:

- View;

- Edit;

- Copy;

- Print;

- Export;

- Next; and

- Previous.

1.   View Function

The View function is available for process filings in all folders. To view a process filing:

- Select the Folder containing the SID to be viewed.

- Select the SID radio button to the left of the SID to be viewed.

- Select the View button at the bottom of the screen.

- To view the SID, use the Page Down, Page Up, or scroll bar to the right of the browser screen to find the information of interest. You may need to look at multiple screen displays to find all the information of interest.

- At the bottom of the view screen, you can select one of the available buttons: 1) Back; 2) Print. Depending on the reason for viewing a SID, you may prefer to print the process filing rather than view it on multiple screens.

- To view a different SID, select the Back button to return to the list of process filings in the selected folder.

2.   Edit Function

The Edit function is only available for process filings in two folders – i.e., the Draft Folder and the Filed with Inquiry Folder. To edit a process filing:

- Select the Folder containing the SID to be edited.

- Select the radio button to the left of the SID to be edited.

- Select the Edit button at the bottom of the screen.

- Select the Edit button adjacent to the section of the form to be updated. For more detailed instructions, see References 2 through 5 and the appendices to those references.

- After completing the changes, select the "Save and Exit" button (only available in the Draft Folder) if you are not yet ready to submit the SID to FDA. Select the "Submit" button to send the SID to FDA.

3. Copy Function

The Copy function is only available for process filings in two folders – i.e., the Draft Folder and the Filed Folder. The system places any copy that you make in the Draft Folder. In essence, by copying a submission you create a new draft form with data already entered in all the data entry fields. You can then edit any section in the newly created draft form to reflect parameters associated with another product. The system identifies the sections that you can edit using an Edit button adjacent to that section. Any attachments associated with the original form will remain associated with the newly created draft.

To copy a process filing:

- Select the Folder containing the SID to be copied.

- Select the radio button to the left of the SID to be copied.

- Select the Copy button at the bottom of the screen.

- The system will display the following message. "Filing has been copied into Draft Folder".

- Select Back to Folder Menu to return to the Process Filing Folder Main Menu.

- Select the Draft Folder to see the copied process filing.

4. Export Function

The Export function is available in all folder types and will identify a spreadsheet application listing the process filing forms identified under the specified folder selected.

To export the listing of the process filing forms:

- Select the Folder.

- Select the Export button. The system will display a "pop up window" asking whether you want to "open" or "save" the exported information and provide a default name for the spreadsheet format file being created. Figure 34 displays an example of the Open and Save "pop up window" after you select the Export button.

Figure 34 - Export - File Download
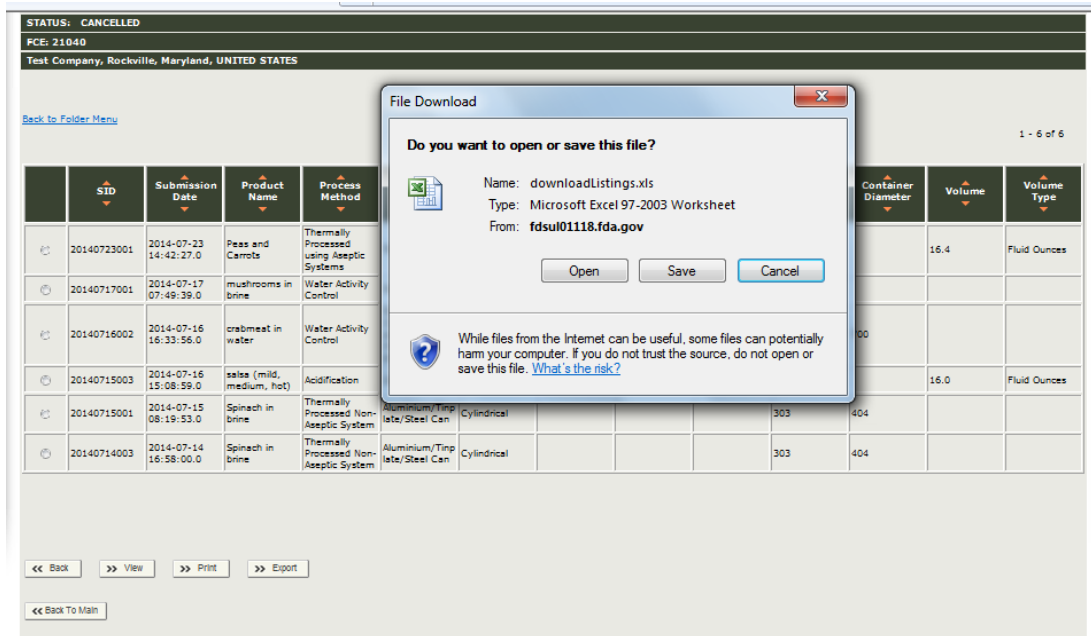
- Select Open. The system will open an Excel spreadsheet of the lists of process filings. Figure 35 displays an example of the output of the exported information after you select "Open."

Figure 35 - Export- Output

- To save the file in a spreadsheet format, select File in the upper left corner of this screen and then select Save.

- Identify the location of where the file should be stored in the "Save In" field and enter a file name in the "File Name" field. Then select Save again. The system will display the "Save As" dialog box as shown in Figure 36.

Figure 36 - Export – Specifying Location for File and File Name
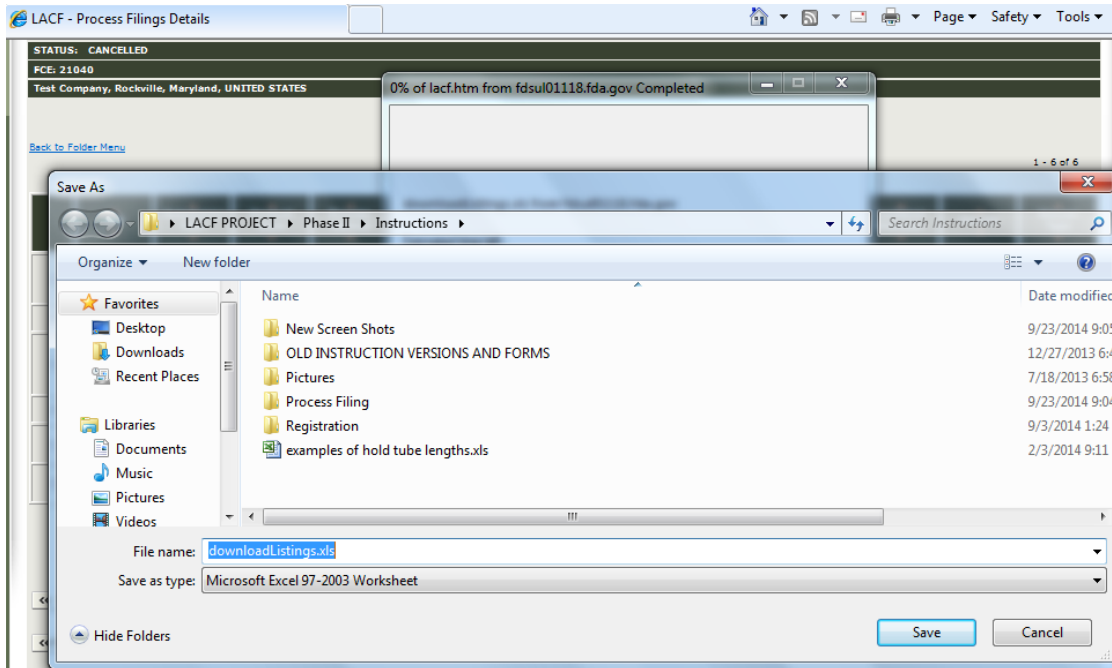
The system will complete the download and save the file in the location you specified, using the file name that you specified. A dialog box informs you that the download is complete and provides an opportunity for you to open the file, open the folder containing the file, or close the dialog box without opening either the file or the folder. Figure 37 displays an example of the display screen when download is completed.

- Select Closed and the system will return you to the list of SIDs.

Figure 37 -Export - Download Complete
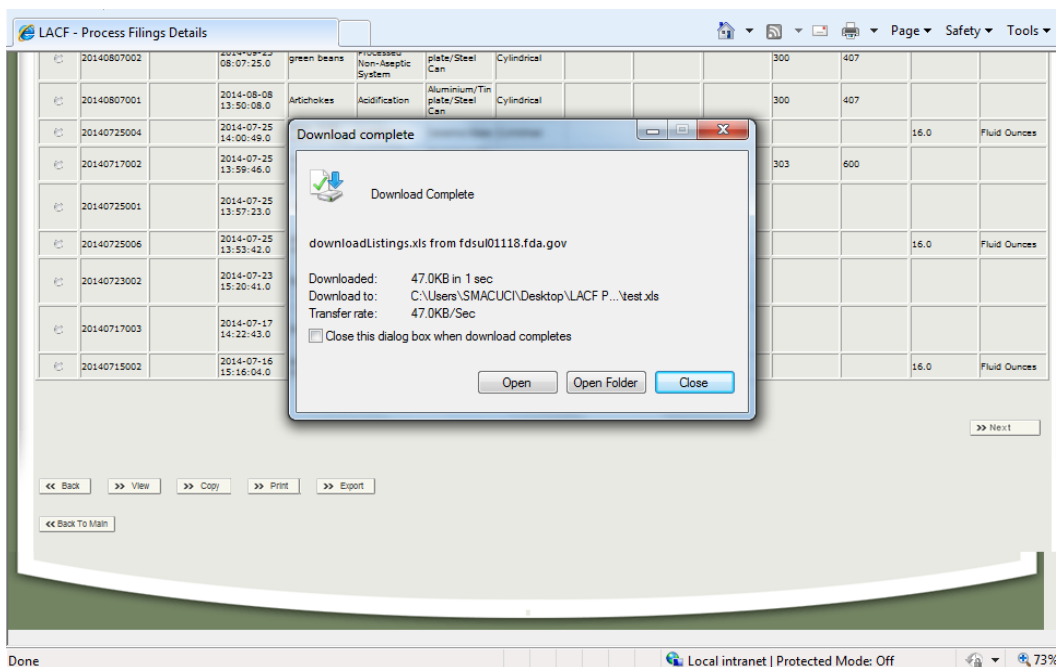
IX. Searching Process Filings

A.   Two Ways to Search Process Filings

There are two basic ways to search process filings. The first search function (which we call "Lookup FCE/SID") provides a "Yes" or "No" answer when the user selects the "Lookup FCE/SID" function to see whether a particular process filing was submitted. This function is available to any FIS account holder including AF/LACF Online System users. However, you do not need authorization by the ECP as an AR, ROAR, or Super AR for a particular FCE to use this function to see if a particular process filing was submitted for that FCE. For example, an importer who has purchased AF/LACF goods for distribution and wants confirmation that appropriate process filing forms are filed with FDA may use this search function to search the electronic AF/LACF system for that process filing using this search function. See section IX.A below details on how to use the "Lookup FCE/SID" search function, including what information you need before you can use this search function.

The second search function (which we call the "ROAR search function") provides the SID, Status, Product Name, Container Dimensions and/or Volume when a ROAR selects one or more criteria to filter filed SIDs. To use the second search function, you must be specifically authorized to access an FCE's AF/LACF Online System as a ROAR. As already noted (see section VII.A), a ROAR is authorized to view submitted process filings in its entirety using a limited search function. (see Table 1 in the Appendix). A ROAR who has any questions about the status of a submission may contact FDA about

the status in addition to, or in place of, using this search function (see section X for how to contact FDA). See section IX.B below for details on how the ROAR uses this search function.

B.   "Lookup FCE/SID" Search Function

You can see the AF/LACF Main Menu from the FURLS Main Menu screen (see Figure 1) provided that you:

- Have an FDA Account ID;

- Specified "Food and Drug Facility Registration" as part of the FDA Account ID profile; and

- Selected "Acidified/Low-Acid Canned Foods Registration and Process Filing" as part of the FDA Account ID profile, can see the AF/LACF Main Menu after selecting "Acidified/Low-Acid Canned Foods."

For example, you may want to use this search function if you are an importer. Figure 38 shows a picture of an example of the computer screen that you would see after selecting Acidified/Low-Acid Canned Foods from the FURLS Main Menu if you have an FDA Account ID, but are not authorized to access a particular establishment's AF/LACF Online System. Note the bottom button on the left side of the computer screen - i.e., "Lookup FCE/SID."

Figure 38 - AF/LACF Main Menu for Users Who Are Not Authorized to Access an FCE's AF/LACF Online System
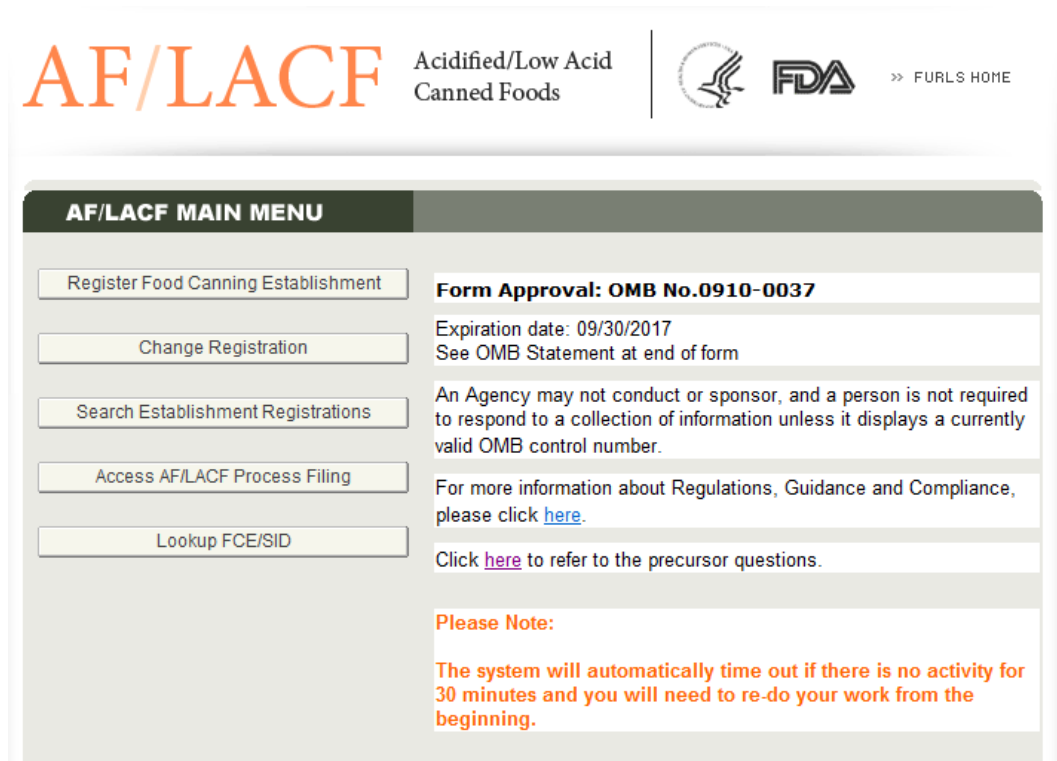
To use this search function, you must know certain specific information about the FCE – i.e., the FCE number and the SID assigned to the product of interest, generally through a business relationship with the FCE.

To search for the status of a process filing:

- Select Lookup FCE/SID button from the AF/LACF Main Menu. Figure 39 shows a picture of an example of the Lookup FCE/SID screen.

Figure 39 – Display Screen for Lookup FCE/SID

- Enter the complete FCE number and the complete SID in the appropriate data entry boxes. When entering a SID, enter numbers only. Do not enter any hyphens, spaces, or special symbols such as a forward slash.

- Select Submit.

The system displays one of two messages:

- If the specified SID is on the File for the specified FCE, the system will display a message that the FCE/SID is on file. Figure 40 shows a picture of an example of the computer screen when the specified FCE/SID is on file.

Figure 40 - Example of Search Results When a Specified FCE/SID is on File

- If the specified SID is not on File with FDA for the specified FCE, the system will display a message that the FCE/SID is not on file. Figure 41 shows a picture of an example of the computer screen when the specified FCE/SID is not on file. If you are not authorized to access an FCE's AF/LACF Online System, you may contact FDA (see section X) to check on the status of process filings reported as "not on file."

Figure 41 - Example of Search Results When a Specified FCE/SID is Not on File

B. ROAR Search Function

A ROAR who selects Access AF/LACF Process Filings from the AF/LACF Main Menu would see the FCE List Main Menu with a list of FCE numbers (Figure 42). When the ROAR has access to multiple FCEs, the ROAR first selects the applicable FCE. The system then displays the FCE's listing of filed process filings with a link on the SID to view a process filing.

Figure 42 - Example of the FCE Account List Main Menu that the ROAR Would See

To search for the status of a process filing when the listing has more than 25 process filings, the ROAR:

- Enters information in one or more data entry fields: (1) SID, (2) Product Name, or (3) Container Dimensions and/or Volume (see Figure 43).

Figure 43 - SID Search Screen for ROAR

| STATUS: FILED |
| FCE: 00001 |
| Establishment: MR. TESTER FESTER, 5100 PAINT BRANCH PKWY, COLLEGE PARK, Maryland, UNITED STATES - 20740 |

| | Non-Cylindrical Size | | | Cylindrical Size | | | |
| SID | Product Name | Length | Width | Height | Diameter | Height | Volume | Volume Type |

Filter   Clear Filter

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	SID	Status	Product Name	Paper / Electronic	Container Length	Container Width	Container Height	Container Cylindrical Height	Container Diameter	Volume	Volume Type
↻	20151002001	Cancelled	soy sauce	P	505	404	007				
↻	20151103003	Inquiry-Replied	fish guts	E				606	404		
↻	20151013001	Inquiry-Yes	mango salsa	E						35.0	Fluid Ounces
↻	20151103007		Sardines	E				606	404		
↻	20151103006		cream of spinach soup	E				505	404		
↻	20151103005		test F subzero	E				400	300		

- Selects the Filter button to search for the specified criteria. When entering a SID, enter numbers only. Do not enter any hyphens, spaces, or special symbols such as a forward slash.

The system display depends on whether any product in the system matches the search criteria.

- If the system finds the specified criteria, the system will display the SID, Status, Product Name, Container Dimensions and/or Volume. Figure 44 shows a picture of an example of the computer screen when the specified criteria are found for the FCE selected.

Figure 44 – Example of Results Using Search Function Available to a ROAR

Get Help ?

| STATUS: FILED |
| FCE: 00001 |
| Establishment: MR. TESTER FESTER, 5100 PAINT BRANCH PKWY, COLLEGE PARK, Maryland, UNITED STATES - 20740 |

1 - 2 of 2

	SID	Status	Product Name	Paper / Electronic	Container Length	Container Width	Container Height	Container Cylindrical Height	Container Diameter	Volume	Volume Type
↻	20151002002		soy sauce	P	505	404	007				
↻	20151002001		soy sauce	P	505	404	007				

≫ Print   ≫ Export

≪ Back to Main

- If the system does not find the specified criteria, the system will display a message at the bottom of the screen that "No records found for the selected filter criteria." Figure 45 shows a picture of an example of the computer screen when the specified filter criteria are not found. A ROAR may contact FDA as described in section X to check on the status of a process filing reported as "no records found."

Figure 45 – Example of Display Screen When the Search Function Available to a ROAR Does Not Find the Specified Criteria
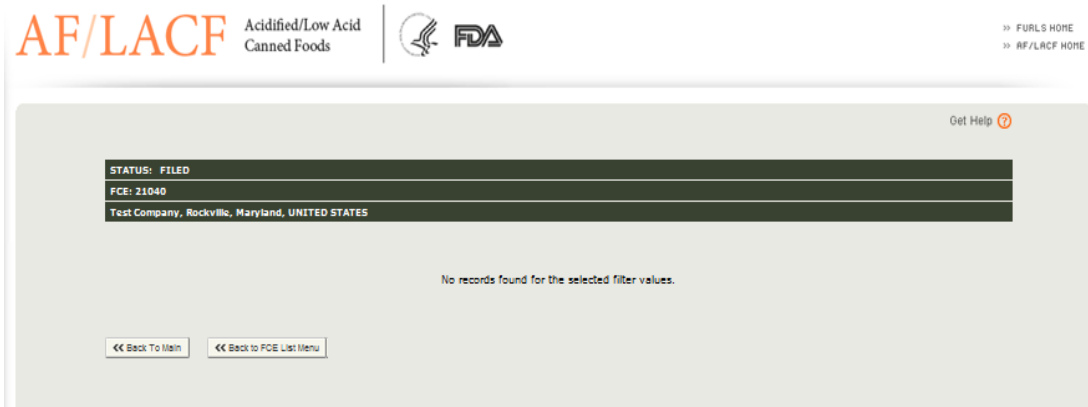
X.   How to Contact FDA or Obtain Help

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

XI. 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

2. Electronic Instructions – Form FDA 2541d. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM418475.pdf

3. Electronic Instructions – Form FDA 2541e. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM418476.pdf

4. Electronic Instructions – Form FDA 2541f. Accessible at http://www.fda.gov/downloads/Food/http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM418477.pdf

5. Electronic Instructions – Form FDA 2541g. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM418478.pdf

XII. Appendix

A.   Roles and Privileges

Table 1: Authorized Functions Associated with Assigned Roles

Authorized Functions	Establishment Contact Person(ECP)	Super Authorized Representative (Super AR)	Authorized Representative (AR)	Read-Only Authorized Representative (ROAR)
Submit initial FCE Registration Form 2541	Yes	No	No	No
Access the FCE's electronic AF/LACF Online System	Yes	Yes	Yes	Yes
Assign roles	Yes	No	No	No
Assign AR to Process Filing	Yes	No	No	No
Update FCE registration information	Yes*	Yes*	No	No
Discuss FCE registration information with FDA	Yes	Yes	No	No
Submit process filings	Yes	Yes	Yes	No
Discuss process filings with FDA	Yes	Yes	Yes	No
Search, print, and view process filing in the FCE's electronic AF/LACF Online System	Yes	Yes	Yes	Yes
Provide additional information to FDA (e.g., upon request) by mail, E-mail, or fax	Yes	Yes	Yes	No

*At this time, the system only allows the ECP to update registration information electronically.   A Super AR who needs to discuss and/or update the registration

information electronically needs to contact FDA using the contact information provided in section X of this document.

B.   Flow Chart

Table 2: How to Navigate to AF/LACF Online System

```
┌─────────────────────────────────────┐
│        FDA Industry Systems          │
│        www.access.fda.gov            │
└─────────────────────────────────────┘
                  │
                  ▼
┌─────────────────────────────────────┐
│   Create an FDA account or Log in    │
│   with existing account ID and       │
│   password                           │
└─────────────────────────────────────┘
                  │
                  ▼
┌─────────────────────────────────────┐
│   Select Acidified/Low Acid Canned   │
│   Foods                              │
└─────────────────────────────────────┘
                  │
                  ▼
┌─────────────────────────────────────┐
│   Select Access AF/LACF Process      │
│   Filing                             │
└─────────────────────────────────────┘
                  │
                  ▼
┌─────────────────────────────────────┐
│ For multiple FCE:                    │
│   Select FCE                         │
│   Select Create/Submit Process Filing│
│ For single FCE:                      │
│   Select Create/Submit Process Filing│
└─────────────────────────────────────┘
```