

Instructions for Electronic Submission of Forms FDA 2541a and FDA 2541c (Process Filing Forms for Acidified and Low-Acid Foods) (AF/LACF), Authorizing Access to the Electronic AF/LACF System, and Searching Process Filings

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

Table of Contents

I.	Introduction.....	6
II.	Portals for Electronic Submissions	7
A.	FDA’s Industry Systems (FIS).....	7
B.	FDA’s Unified Registration Listing Systems (FURLS)	7
III.	How to Obtain an FDA Account at the FIS Electronic Portal	7
IV.	How to Enter the Electronic AF/LACF System Through the FIS Electronic Portal ..	8
V.	General Information About Navigating the Process Filing Section of the Electronic AF/LACF System	9
A.	General Navigation Links on Main Menus in the Process Filing Section.....	9
B.	FCE Account List Main Menu.....	10
C.	FCE Process Filing Main Menu.....	11
D.	Navigation Links When Adding Process Filing Forms	12
E.	Comment Boxes.....	12
VI.	How to Manage Access to the Electronic AF/LACF System by Authorized Representatives	13
A.	Steps for the Facility Contact Person.....	13
B.	Steps for Authorized Individuals	14
VII.	General Information About the Organization of the Process Filing Section of the Electronic AF/LACF System.....	17
A.	Process Filing Main Menu	17
B.	Folder Types	18
1.	Draft	18
2.	Submitted	19
3.	Returned.....	19
4.	Re-Submitted	20
5.	Filed	20
6.	Discontinued	20
VIII.	How to Submit New Process Filing Forms to FDA	20
A.	Step 1 - Product Name, Processing Method, and Container Type.....	22
B.	Step 2 - pH, Sterilizer, Container, and Process Establishment Source.....	23

1.	Step 2 - Any Food Other Than an Acidified Food.....	25
2.	Step 2 - Acidified Foods	26
3.	Step 2 - Add Source for the Process Establishment.....	26
4.	Step 2 - Copy Source for the Process Establishment.....	27
C.	Step 3 - Acidified Factors	28
D.	Step 4 - Critical Factors	29
E.	Step 5 - Container Dimensions, Number of Scheduled Processes, and the Number of Steps in the Scheduled Process.....	30
F.	Step 6 - Scheduled Process Options and Related Critical Factors.....	32
G.	Step 7 - Critical Factors for Scheduled Process.....	33
H.	Confirmation Step.....	34
1.	Confirmation Step - Attach Document	35
2.	Confirmation Step - Attach New Document.....	35
3.	Confirmation Step - Copy an Existing Document	36
4.	Confirmation Step - Complete the Confirmation Step	37
I.	Confirmation of Submitted Process Filing Form.....	37
IX.	How to Manage Process Filings	38
A.	Filter and Sort Process Filings in a Folder.....	38
1.	Filtering Process Filing Forms.....	39
2.	Sorting Process Filing Forms.....	40
B.	Available Functions	41
1.	Edit Function.....	41
2.	Copy Function.....	41
3.	Submit Function.....	41
4.	Delete Function.....	42
5.	Discontinue Function	42
C.	View a Process Filing Form.....	42
X.	How to Search Process Filings	43
A.	Search Function When the User is Not Linked to the Electronic AF/LACF System.....	44
B.	Search Function When the User is Linked to the Electronic AF/LACF System as a Facility Contact Person, Authorized Representative, or Read Only Access Representative.....	46
XI.	How to Contact FDA or Obtain Help	48

XII. References.....	49
XIII.Appendix.....	49

List of Figures

Figure 1: FDA Unified Registration and Listing Systems (FURLS).....	8
Figure 2: AF/LACF Main Menu.....	9
Figure 3: Example of the FCE Account List Main Menu that the FCP Would See.....	11
Figure 4: FCE Process Filing Main Menu.....	11
Figure 5: Step 1 in the Procedure for Entering a New Process Filing.....	12
Figure 6: Menu for Managing Online Accounts.....	14
Figure 7: Adding a New User and Assigning Access Level.....	14
Figure 8: Example of a Data Entry Screen When an FDA Account ID Is Not Yet Linked to the Electronic AF/LACF System.....	15
Figure 9: Computer Screen Informing User that a Confirmation Email Has Been Sent.	15
Figure 10: Computer Screen Showing Confirmation Email to an FDA Industry User....	16
Figure 11: Successful Link to the Electronic AF/LACF System.....	16
Figure 12: FCE Account List Main Menu for an AR or ROAR.....	17
Figure 13: FCE Process Filing Main Menu.....	18
Figure 14: FCE Account List Main Menu for an AR or ROAR.....	21
Figure 15: FCE Process Filing Main Menu.....	21
Figure 16: Step 1 - Enter New Filing - Data Entry Screen for Product Name, Processing Method, and Container Type.....	22
Figure 17: Step 2 - Enter New Filing - Data Entry Screen for Low-Acid Food.....	24
Figure 18: Step 2 - Enter New Filing - Data Entry Screen for an Acidified Food.....	25
Figure 19: Step 2 - Enter New Filing - Data Entry Screen to Add a Process Establishment Source.....	27
Figure 20: Step 2 -Enter New Filing - Data Entry Screen to Copy an Existing Process Establishment Source.....	28
Figure 21: Step 3 - Enter New Filing - Acidified Factors.....	28
Figure 22: Step 4 - Enter New Filing - Example of Data Entry Screen for Critical Factors.....	30

Figure 23: Step 5 - Enter New Filing - Example of Data Entry Screen for Container Dimensions, Number of Scheduled Processes, and Number of Steps	32
Figure 24: Step 6 - Enter New Filing - Example of Scheduled Process Options and Related Critical Factors.....	33
Figure 25: Step 7 - Enter New Filing - Example of Critical Factors for Scheduled Process	34
Figure 26: Enter New Filing - Confirmation Page.....	35
Figure 27: Attach Documents - Add Document	36
Figure 28: Attach Documents - Copy Document	37
Figure 29: Confirmation of Submitted Process Filing Form	38
Figure 30: Example of List of Process Filings in the Filed Folder.....	38
Figure 31: Process Filing Folder Showing List of SIDS and Filter Options	39
Figure 32: Example of List of Process Filings in the Submitted Folder Sorted by Process	40
Figure 33: View Product Information and Critical Factors Entered on a Process Filing Form.....	43
Figure 34: Search Screen for Users Not Linked to the Electronic AF/LACF System	45
Figure 35: Example of Search Results When a Specified FCE/SID is on File.....	45
Figure 36: Example of Search Results When a Specified FCE/SID is Not on File.....	46
Figure 37: Example of the FCE Account List Main Menu that the FCP Would See	47
Figure 37: FCE and SID Validation of Form on File	48
Figure 38: FCE and SID Validation of Form Not on File	48

I. Introduction

This document is intended for:

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

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

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

This document provides detailed instructions on:

- How the Facility Contact Person (FCP) manages access to the electronic AF/LACF system for a particular establishment by individuals authorized to act on behalf of the establishment;
- How process filings are organized in the electronic AF/LACF system;
- How to submit process filings by electronic submission of Forms FDA 2541a and 2541c;
- How to manage process filings; and
- How to search process filings.

This document does not provide:

- Instructions for submitting Forms FDA 2541a and 2541c in paper format;
- Instructions for submitting registration Form FDA 2541 in either electronic or paper format; or
- 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.

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.

For additional information about registration and process filing for commercial processors of AF and LACF, see our guidance entitled “Submitting Form FDA 2541 (Food Canning Establishment Registration) and FDA Forms 2541a and 2541c (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. For some systems (including the Acidified/Low-Acid Food (AF/LACF) system), users can submit information by completing electronic forms while the user is logged into the system. For other systems (such as the Electronic Submission Gateway), users can submit electronic files (such as a food additive petition) that are prepared in advance by the user (rather than completed using electronic forms while the user is logged into the system).

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

FDA’s Unified Registration Listing System (FURLS) is a specific component of the general FIS electronic portal. Persons with an FDA Account ID and password for the FIS electronic portal use systems within the FURLS components to register a facility electronically. The electronic AF/LACF system is one of the FURLS system components. In addition to registering a facility electronically, users of the electronic AF/LACF system can submit process filings electronically.

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 and password. To access the FIS electronic portal:

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

The registration Form FDA 2541 requires identifying a “facility contact person” (FCP) for the establishment being registered. After the establishment is registered and has an FCE number, the FCP can authorize other individuals to submit or view process filings in the electronic AF/LACF system for that FCE. Any individual authorized by the FCP to

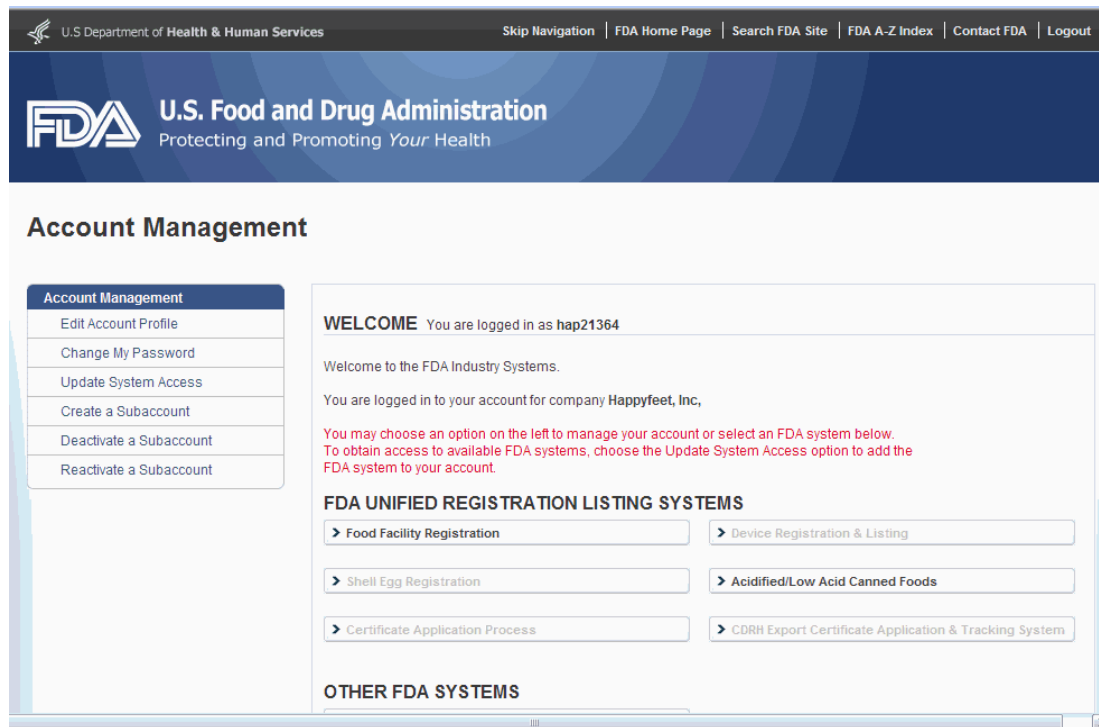
submit or view process filings would enter the FIS electronic portal using his or her own FDA Account.

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

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

- Use an Internet Browser to access the FIS Web site at <https://www.access.fda.gov/>
- Select Login under Acidified/Low-Acid Canned Foods.
- Enter the FDA Account ID and password.
- Check the “I understand” box.
- Select Login.
- Select Acidified/Low-Acid Canned Foods. Figure 1 shows an example of the computer screen when a user is logged into FURLS.

Figure 1: FDA Unified Registration and Listing Systems (FURLS)



The system will display the AF/LACF Main Menu. Figure 2 shows a picture of the AF/LACF Main Menu as it displays on a computer screen.

Figure 2: AF/LACF Main Menu



V. General Information About Navigating the Process Filing Section of the Electronic AF/LACF 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 Main AF/LACF Menu. The Process Filing section of the electronic AF/LACF system contains two main menus, each with specific navigation options:

- FCE Account List Main Menu; and
- FCE Process Filing Main Menu.

Both main menus provide the following general navigation tools:

- Frequently Asked Questions (FAQs);
- Email address for obtaining help;
- References;
- FCE/SID Validation;
- FURLS Menu; and
- Logout.

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

The options available to a user depend on the user’s authorization as a Facility Contact Person, Authorized Representative (AR), or Read Only Access Representative (ROAR). The user’s authorization is linked to the user’s FDA Account in the FIS electronic portal. For additional information about the type of user authorizations, see section VI of this document and Table 1 in the Appendix of this document.

B. FCE Account List Main Menu

Figure 3 shows a picture of an example of a computer screen showing the FCE Account List Main Menu that the FCP would see. On the FCE Account List Main Menu, the FCP would see a list of all FCEs that the FCP manages (e.g., if the FCP manages food canning establishments at multiple locations). The FCP also would see both the general navigation links listed above in section V.A of this document and two specific navigation links:

- View Profile – Shows the information in the user’s FDA Account.
- Manage Online Accounts –Navigates to screens for the FCP to manage access by authorized representatives. Only the FCP sees this link.

Figure 3: Example of the FCE Account List Main Menu that the FCP Would See

**Low Acid Canned Foods
Acidified Foods **ONLINE****

FCE ACCOUNT LIST: [View Profile](#) | [Manage Online Accounts](#)

Last Login: 05/08/12

(FCE) Food Canning Establishment List:
Record Count: 5

FCE	Name	City	Province	Country	Access Level
00001	MR. TESTER FESTER	COLLEGE PARK		UGANDA	Online - FCP
27375	MARY DANCE STUDIO COOKIE MACHINE	DISTRICT HEIGHTS			Online - FCP
27391	NEW REGISTRATION FROM OLD	BYSUA			Online - FCP
27417	TESTING FOR FOREIGN LACF	MAHAJANGA			Online - FCP
27428	HAPPY FEET DANCER	DISTRICT HEIGHTS			Online - FCP

For Assistance: LACF@fda.hhs.gov
[FAQs](#) - [User Guide](#) - [References](#)

[» FCE/SID Validation](#) [» FURLS Menu](#) [Log Out](#)

C. FCE Process Filing Main Menu

Figure 4 shows a picture of an example of the FCE Process Filing Main Menu. The links that a user would see depend on the types of process filings in the AF/LACF electronic system for a particular FCE rather than on the authorization of the user as a FCP or AR. On the FCE Process Filing Main Menu, the user would see both the general navigation links listed above in section V.A of this document and one specific navigation link:

- FCE Menu link – Navigates the user back to the FCE Account List Main Menu.

Figure 4: FCE Process Filing Main Menu

**Low Acid Canned Foods
Acidified Foods **ONLINE****

FCE: **27417** / [FCE Menu](#)

TESTING FOR FOREIGN LACF - MAHAJANGA, NONE ()

Process Filing Folders

Submitted 0 Filed 0

[Enter New Filing](#) * [Download the New LACF Online User Guide](#)
*Includes information on how to use the new document attachment features.
 Updated 5/13/2008.*

For Assistance: LACF@fda.hhs.gov
[FAQs](#) - [User Guide](#) - [References](#)

[» FCE/SID Validation](#) [» FURLS Menu](#) [Log Out](#)

D. Navigation Links When Adding Process Filing Forms

Within the section to enter a new process filing form, there are seven steps for the user to enter information. Each step provides links to explanations about data entry for that step. At any step in the process, the user can navigate to a previous step by selecting either the Previous navigation button (located at the top and bottom left of the screen for each step) or a specific Step link (located at the top of the screen for each step).

The links listed below appear at the top of every step in the system for entering a new process filing:

- A status bar that tracks the progress through each step of entering a new process filing;
- A link to Menu, which navigates the user to the FCE Process Filing Main Menu;
- A link to FURLS Menu, which navigates the user to the FIS Log in screen and logs the user out of the AF/LACF electronic system;
- Previous - This takes the user back one screen where the user continues entering information. Information entered on the current screen (before selecting the "Previous" navigation button) will not be saved; and
- Next - This saves the information entered on the current screen and takes the user to the next screen where the user continues entering information.

Figure 5 shows a picture of the computer screen when a user is at Step 1 in the procedure for entering a new process filing. The status tracking bar is at the upper right of the screen.

Figure 5: Step 1 in the Procedure for Entering a New Process Filing

The screenshot shows a web-based form titled "PRODUCT" with a red asterisk indicating required fields. At the top right, there is a status bar with step indicators: "1» 2» 3/NA 4» 5» 6» 7» confirm»" and a "Menu" link. Below the status bar are "Previous" and "Next" navigation buttons. The form contains the following fields:

- Product**: A text input field with a "Reminder: What foods are NOT covered?" tooltip.
- Processing Method**: A dropdown menu.
- Container Type**: A dropdown menu.
- Finished PH**: A dropdown menu.
- Comments to add to Filing:**: A text area with a "(max. 1000 chars)" label.

At the bottom of the form, there are "Previous" and "Next" navigation buttons. Below the form, a footer note reads: "This online form is an electronic version of the following Process Food Canning Establishment Filing Forms (OMB NO. 0910-0037):
- All Methods Except Low Acid Aseptic **FORM FDA 2541a**
- Low-Acid Aseptic Process **FORM FDA 2541c**"

E. Comment Boxes

Several data entry screens include a box to provide optional comments. The size limit for comments in these boxes is 1,000 characters, which includes blanks between words.

VI. How to Manage Access to the Electronic AF/LACF System by Authorized Representatives

A. Steps for the Facility Contact Person

The FCP may authorize one or more individuals to access the electronic AF/LACF system for a specific FCE and perform designated functions related to registration and process filing. Such individuals may be employees or agents of the establishment.² When logged into the electronic AF/LACF system through his or her FDA Account at the FIS electronic portal, the FCP authorizes an individual to access the electronic AF/LACF system for a particular FCE by assigning a role to the individual as an Authorized Representative (AR) or a Read Only Access Representative (ROAR). The assigned role determines the functions the individual can perform electronically and when contacting FDA on behalf of the FCP - e.g., by email or by telephone. For additional information about the authorized functions that can be performed by the FCP, an AR, and a ROAR, see Reference 1 and Table 1 in the Appendix of this document.

To grant access to the electronic AF/LACF system for a particular FCE, the FCP enters the electronic AF/LACF system through the FIS electronic portal and then:

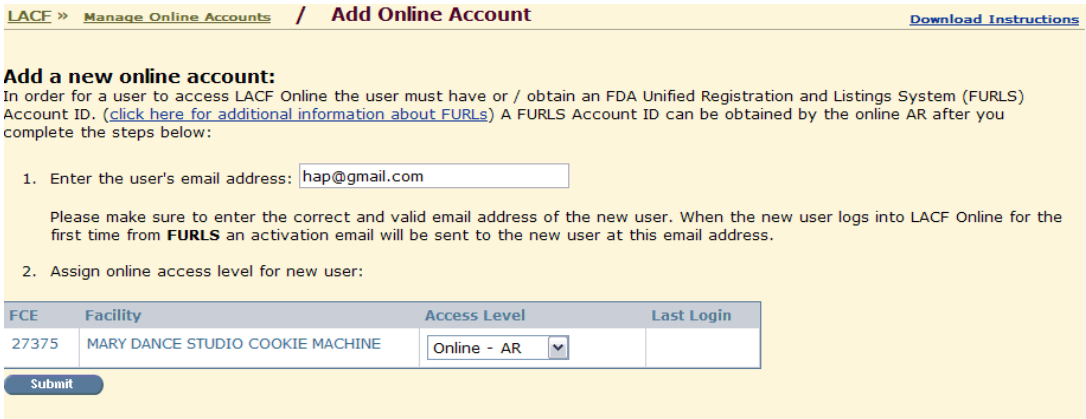
- Selects Manage Online Accounts located in the upper right corner of the FCE Account List Main Menu. See Figure 3 for a picture of an example of a computer screen showing the FCE Account List Main Menu that the FCP would see.
- Selects Add New User located in the upper right section of the Manage Online Accounts screen. Figure 6 shows a picture of an example of a computer screen displaying the menu for Managing Online Accounts.
- From the menu for Managing Online Accounts, enters the email address for the applicable individual and specifies the access rights for that individual. Figure 7 shows a picture of an example of a computer entry screen to add the new user's email address and access level as an AR or ROAR.
- Selects Submit.
- Separately notifies the individual that access has been granted - e.g., by email. The electronic AF/LACF system does not send any notification to the authorized individuals.

² Individuals who act as authorized agents may do so for more than one commercial processor.

Figure 6: Menu for Managing Online Accounts



Figure 7: Adding a New User and Assigning Access Level



B. Steps for Authorized Individuals

For initial access to the AF/LACF process filing system, the AR/ROAR obtains an FDA Account ID and password for the FIS electronic portal as described in section III of this document and then enters the electronic AF/LACF system through the FIS electronic portal as described in section IV of this document. From the AF/LACF Main Menu, the AR/ROAR selects Access AF/LACF Process Filing. The system will display a computer screen informing the user that his or her FDA Account ID has not been linked to the electronic AF/LACF system. Figure 8 shows a picture of an example of the computer screen that an AR/ROAR would see when accessing the electronic AF/LACF system for the first time. This computer screen provides an email address and telephone number where a user can obtain help. Note that this same computer screen would be seen by the FCP if the FCP tries to access the electronic AF/LACF system before the FCP’s Account ID is linked to the electronic AF/LACF System, and provides information on what the FCP would do to obtain access to the system.

Note that the bottom of the computer screen in Figure 8 provides data entry fields for FCE and SID. These are used in the search function described in section X of this document and are not relevant to the instructions in this section.

Figure 8: Example of a Data Entry Screen When an FDA Account ID Is Not Yet Linked to the Electronic AF/LACF System

**Low Acid Canned Foods
Acidified Foods ONLINE**

Your FURLS Account ID, mac77673, has not been linked to LACF Online.

- 1. If you are NOT the "FCP" for an FCE Number AND have been provided access to an FCE by the Facility Contact Person (FCP):**
Enter the same email address that you provided to the Facility Contact Person (FCP) who is giving you access to an FCE.

OR

- 2. If you are the Facility Contact Person (FCP) for an FCE Number:**
You will need to request FDA to link your FDA Industry Systems Account to your FCE Number. To view the procedures for establishing this link, view the [LACF Online Registration FAQ](#).

OR

- 3. For any additional questions or assistance:**
Contact LACF at LACF@fda.hhs.gov or 240-402-2411.

To Find out the status of the process filing, please click on the submit button::

FCE:

SID: *SID Entry should be numbers only.*

From the data entry screen, the user:

- Enters his or her email address in the data entry box.
- Selects Submit. The system informs the user that the request to link the FURLS Account ID to an FCE has been processed and instructs the user to log out of FURLS and access an email confirmation. Figure 9 shows a picture of the computer screen informing a user that a confirmation Email has been sent.

Figure 9: Computer Screen Informing User that a Confirmation Email Has Been Sent

**Low Acid Canned Foods
Acidified Foods ONLINE**

Your request to link your FURLS Account ID to an FCE has been processed.

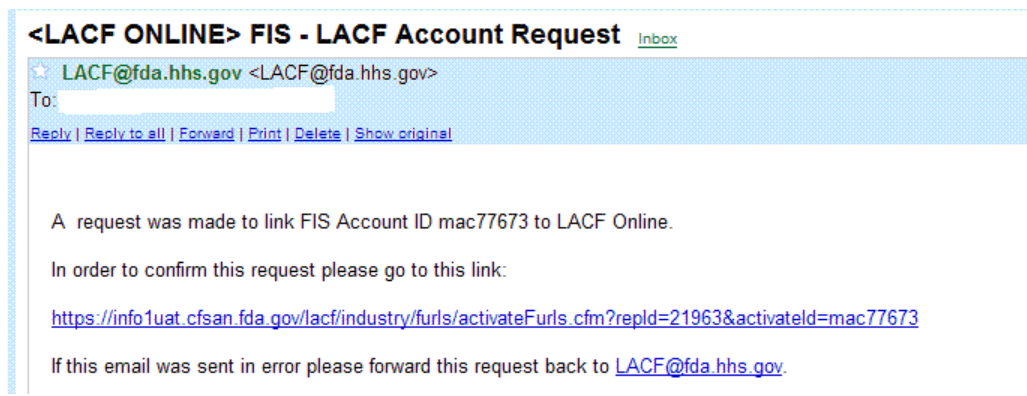
A confirmation email has just been sent to your email address. If you do not receive an email within 30 - 60 minutes please check to make sure you do not have any settings in your email account blocking this email. You can always come back to the main page and enter in your email address and click on the submit button and another email will be sent to your email address.

The next thing to do is to [log out of FURLS](#) and check your email account for an email from LACF@fda.hhs.gov. Then, once you receive the confirmation email follow the instructions in the email to access LACF Online.

For any additional questions or assistance contact LACF at LACF@fda.hhs.gov or 240-402-2411.

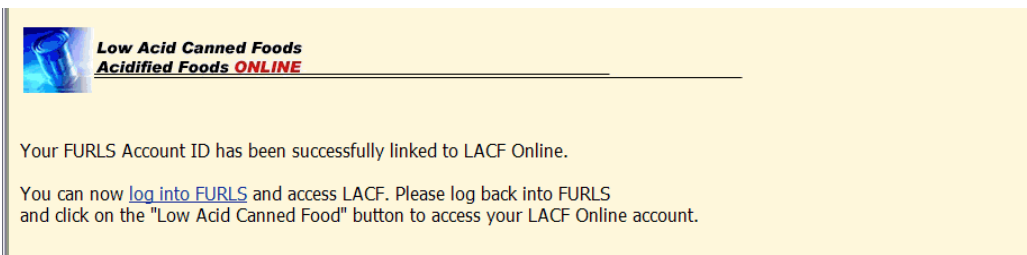
The user logs into his or her email account. Figure 10 shows a picture of an example of the computer screen confirmation email to an FDA industry user which includes a link to confirm the request to link the user's FDA Account ID to the electronic AF/LACF system.

Figure 10: Computer Screen Showing Confirmation Email to an FDA Industry User



The user selects the link in the email. The system will display a statement that FDA Account ID has been successfully linked to the electronic AF/LACF system. Figure 11 shows a picture of the computer screen informing the user that the FDA Account is successfully linked to the electronic AF/LACF system.

Figure 11: Successful Link to the Electronic AF/LACF System



To complete the procedure for accessing the electronic AF/LACF system, the user logs into the FIS electronic portal and navigates to the AF/LACF Main Menu system as described in section IV of this document. The system will display the FCE Account List Menu, with a list of FCE numbers linked to the user's account. Figure 12 shows a picture of an example of a computer screen showing the FCE Account List Main Menu for the AR or ROAR.

Figure 12: FCE Account List Main Menu for an AR or ROAR

Low Acid Canned Foods
Acidified Foods *ONLINE*

FCE ACCOUNT LIST: [View Profile](#)

Last Login: 05/18/12

(FCE) Food Canning Establishment List:
Record Count: 2

FCE	Name	City	Province	Country	Access Level
00001	MR. TESTER FESTER	COLLEGE PARK		UGANDA	Online - AR
27375	MARY DANCE STUDIO COOKIE MACHINE	DISTRICT HEIGHTS			Online - AR

For Assistance: LACF@fda.hhs.gov
[FAQs](#) - [User Guide](#) - [References](#)

» [FCE/SID Validation](#) » [FURLS Menu](#) [Log Out](#)

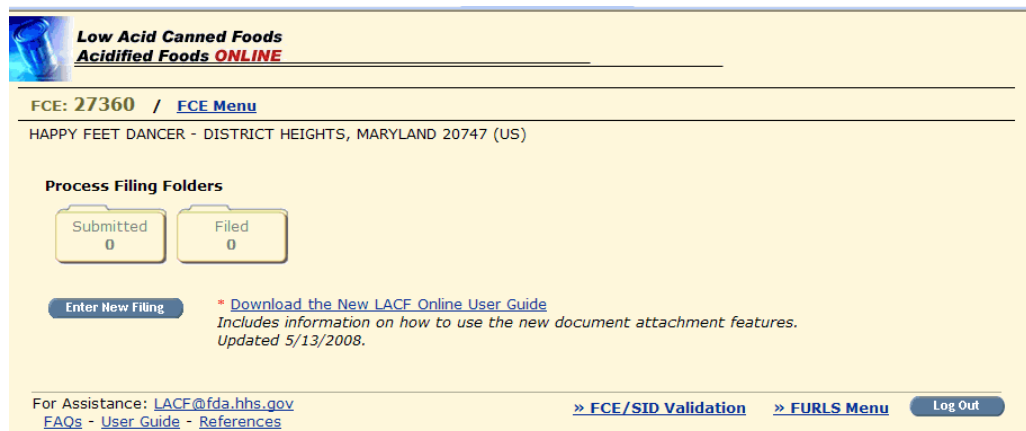
To view the contact information in the electronic AF/LACF system, the user selects View Profile from the FCE Account List Menu. The system will display contact information for the user, populated automatically from the user’s FDA Account ID at the FIS electronic portal. If any of the information is incorrect, the user should log in to the FIS electronic portal as described in section IV of this document, select Edit Account Profile under Account Management, and correct the information.

VII. General Information About the Organization of the Process Filing Section of the Electronic AF/LACF System

A. Process Filing Main Menu

Process filing forms FDA 2541a and FDA 2541c are organized in folders according to the status of the process filing form. Figure 13 shows a picture of an example of the FCE Process Filing Main Menu. Each folder accessed from the FCE Process Filing Main Menu has its own characteristics and, thus, not all process filing folders look like the example. In addition, the functions available within a particular process filing folder may vary depending on the user’s role (as FCP, AR, or ROAR).

Figure 13: FCE Process Filing Main Menu



All individuals authorized to access the electronic AF/LACF system for a particular FCE may view the process filing forms displayed in the process filing folders accessible from the FCE Process Filing Main Menu. The FCP and individuals granted access as ARs also can perform other functions, such as submitting process filings and deleting process filings. The functions available to authorized individuals depend on the folder. See the discussion of Folder Types immediately below in this section. For an overview of administrative procedures for the submission of process filing Forms FDA 2541a and 2541c process filing forms, see Reference 1. For additional information about the functions available when the user selects one of these folders, see section IX.B of this document.

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 the user is 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. Access to the Draft folder is limited to the user who creates and saves a draft process filing without submitting it to FDA. In other words, if User A creates a process filing and saves it in his or her Draft folder, Users B and C do not see that folder and cannot see or edit User A's draft process filing.

The functions available in the Draft folder are (1) Enter New Filing; (2) Edit; (3) Copy; (4) Submit; and (5) Delete.

Users can create new process filing forms and place them in the Draft folder by (1) entering a new process filing; or (2) copying a previously submitted process filing. For detailed instructions on how to enter a new process filing, see section VIII of this document.

- Option 1: Enter a new process filing.
 - Select Enter a New Filing and enter all the data as described in section VIII of this document.
 - On the Confirmation Page, select Save as Draft.
 - The form will appear in the Draft folder.
 - Select the LACF Menu link in the upper left hand corner of the screen to return to the AF/LACF Process Filing Main Menu.
 - Select the Draft folder to display a list of process filing forms in the Draft folder and see the newly entered form.

- Option 2: Copy a previously submitted process filing.
 - Select the Filed folder and locate the process filing form that will be copied.
 - Select the Submission Identifier (SID) link for the selected form.
 - Select the Copy Filing link located in the upper right corner of the form. Note: Doing so makes a copy of the form and does not remove the filed form from the Filed folder.
 - The following message will display on the copied form: “Filing Has Been Copied into Draft Folder”.
 - The copied process filing form will appear in the Draft folder.
 - Select the LACF Menu link in the upper left hand corner of the screen to return to the LACF Process Filing Main Menu.
 - Select the Draft folder to display a list of process filing forms in the Draft folder and see the newly copied form.

2. Submitted

The Submitted folder contains and displays any process filing form that has been submitted to FDA but not yet reviewed by FDA to determine whether it is complete and technically accurate. For additional information about FDA’s review of submitted process filing forms, see Reference 1.

The only available function in the Submitted folder is Copy.

3. Returned

The Returned folder contains and displays any process filing form that has been submitted to FDA, reviewed by FDA, and returned by FDA because FDA has determined that it is incomplete. For additional information about FDA’s review of submitted process filing forms, see Reference 1.

The functions available in the Returned folder are (1) Edit; (2) Submit; and (3) Delete.

4. Re-Submitted

The Re-submitted folder contains and displays any process filing form that has been submitted to FDA, reviewed by FDA, returned by FDA, and re-submitted to FDA. For additional information about FDA's review of submitted process filing forms, see Reference 1.

The only available function in the Re-Submitted folder is Copy.

5. Filed

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

The functions available in the Filed folder are (1) Copy and (2) Discontinue.

6. Discontinued

The Discontinued folder contains and displays any submitted process filing form for a product that is no longer currently used. Three years after the facility notifies FDA that a product is discontinued, the electronic AF/LACF system will archive the applicable form and the process filing will no longer be considered filed.

The only function available in the Discontinued folder is Copy.

VIII. How to Submit New Process Filing Forms to FDA

To submit process filing Forms FDA 2541a and FDA 2541c, enter the FIS electronic portal and access the AF/LACF Main Menu as described in section IV of this document. From the AF/LACF Main Menu, select Access AF/LACF Process Filing.

The system will display a list of FCE numbers the user is authorized to access. Figure 14 shows a picture of an example of a computer screen showing the FCE Account List Main Menu for the AR or ROAR. The user selects the FCE number to reach the FCE Process Filing Main Menu.

Figure 14: FCE Account List Main Menu for an AR or ROAR

**Low Acid Canned Foods
Acidified Foods **ONLINE****

FCE ACCOUNT LIST: [View Profile](#)

Last Login: 05/18/12

(FCE) Food Canning Establishment List:
Record Count: 2

FCE	Name	City	Province	Country	Access Level
00001	MR. TESTER FESTER	COLLEGE PARK		UGANDA	Online - AR
27375	MARY DANCE STUDIO COOKIE MACHINE	DISTRICT HEIGHTS			Online - AR

For Assistance: LACF@fda.hhs.gov
[FAQs](#) - [User Guide](#) - [References](#)

[» FCE/SID Validation](#) [» FURLS Menu](#) [Log Out](#)

The specific display of the AF/LACF Process Filing Main Menu depends on the information already in the electronic AF/LACF system for the FCE. For example, if there are no process filings in the Draft folder (e.g., because all process filings prepared by the user have already been submitted, or because the user is a ROAR who does not prepare process filings), the AF/LACF Process Filing Main Menu does not display a Draft folder. Figure 15 shows a picture of an example of the FCE Process Filing Main Menu.

Figure 15: FCE Process Filing Main Menu

**Low Acid Canned Foods
Acidified Foods **ONLINE****

FCE: 27360 / [FCE Menu](#)

HAPPY FEET DANCER - DISTRICT HEIGHTS, MARYLAND 20747 (US)

Process Filing Folders

Submitted 0 Filed 0

[Enter New Filing](#) * [Download the New LACF Online User Guide](#)
*Includes information on how to use the new document attachment features.
 Updated 5/13/2008.*

For Assistance: LACF@fda.hhs.gov
[FAQs](#) - [User Guide](#) - [References](#)

[» FCE/SID Validation](#) [» FURLS Menu](#) [Log Out](#)

Select Enter New Filing. The system will display Step 1. Figure 16 shows a picture of the computer screen when a user is at Step 1 in the procedure for entering a new process filing.

Figure 16: Step 1 - Enter New Filing - Data Entry Screen for Product Name, Processing Method, and Container Type

A. Step 1 - Product Name, Processing Method, and Container Type

Step 1 of the electronic process filing system has required fields for the name of the product, the processing method, the container type, and finished pH. Step 1 also provides an optional box for entry of any comments.

When entering the product name, identify each product by (1) the Food Product Name (in English), Form, or Style and (2) Packing Medium. An example of this information is “Beans, cut, green or waxed in brine”. 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. For additional instructions on entering the product name, click on the “Product” box.

To begin the process for entering a new product:

- Enter the Food Product Name (in English), Form, or Style and Packing Medium within the Product box. The system will automatically wrap the product information when it exceeds the length of the first line in the box.
- Select the Processing Method (e.g., Acidified; Still (Horizontal); Still (Vertical)) from the available List of Values in the drop-down menu.
- Select the Container Type (e.g., aluminum can, flexible pouch) from the available List of Values in the drop-down menu.
- If applicable, enter comments in the box provided.
- Select Next. The system will display Step 2.

B. Step 2 - pH, Sterilizer, Container, and Process Establishment Source

The fields in Step 2, and their designation as required or optional, depend on the processing method selected in Step 1.

If the processing method selected is anything other than “Acidified,” the required fields in Step 2 include the finished pH of the product and information about the sterilizer, the container, and the process establishment source. Optional fields include comments. Figure 17 shows a picture of the data entry screen at Step 2 for a low-acid food.

If the processing method selected is “Acidified,” the required fields in Step 2 include raw pH, container shape, and process establishment source. Optional fields for an acidified food include thermal processing equipment and comments. Figure 18 shows a picture of the data entry screen at Step 2 for an acidified food.

The process establishment source is an organization, company, individual, etc., that scientifically established the scheduled process or processes for the product being submitted. When entering information about the process establishment source, users can add attachments (e.g., lab report, publication, etc.) in optional fields. The system supports attachments of the following document types: (1) PDF; (2) JPG; and (3) GIF. The system will prompt users to provide a unique name for each attachment. Users have options to (1) add a new attachment and (2) copy an attachment that is already in the electronic AF/LACF system for the FCE. By copying an existing attachment, users can attach the same document multiple times without giving a different file name to the document each time it is attached.

Figure 17: Step 2 - Enter New Filing - Data Entry Screen for Low-Acid Food

STERILIZER & CONTAINER Menu

1» 2» 3/NA 4» 5» 6» 7» confirm»

* required fields (product) GREEN BEANS; (method) HYDROSTATIC (SINGLE)

<< Previous Next >>

Low Acid:
* Finished PH 5.4

Sterilizer:
* Manufacturer COMEWELL
Model 1.654
* Heating Medium STEAM

Container Information:
* Container Shape cylinder rectangular oval irregular
**** irregular shape requires schematic attachment**
* Pieces 2 piece 3 piece (2 or 3) piece
Side Seam Construction WELDED
**** not used for 2 piece containers**

Process Establishment Source: Add

Source	Attached Document
05/04/2012 -- PUBLICATION UMD	Lab Report -- Test file.pdf

= Edit Source
 = Remove Source (from this filing)

Comments to add to Filing:
(max. 1000 chars)

Figure 18: Step 2 - Enter New Filing - Data Entry Screen for an Acidified Food

STERILIZER & CONTAINER Menu

1» 2» 3» 4» 5» 6» 7» confirm»

* required fields (product) SALSA; (method) ACIDIFIED

<< Previous Next >>

Acidified:

* Raw pH 4.80

Thermal Processing Equipment:

(optional) Manufacturer - none -

Model

(optional) Heating Medium - none -

Container Information:

* Container Shape round square irregular

** irregular shape requires schematic attachment

Process Establishment Source: Add

Source	Attached Document
05/04/2012 -- PUBLICATION UMD	Lab Report -- Test file.pdf

= Edit Source
 = Remove Source (from this filing)

Comments to add to Filing: (max. 1000 chars)

<< Previous Next >>

1. Step 2 - Any Food Other Than an Acidified Food

- Select the Finished pH to the nearest tenth (e.g., 4.8) from the available List of Values in the drop-down menu.
- Select the Manufacturer of the Sterilizer from the available List of Values in the drop-down menu.
- Enter the Model of the Sterilizer.
- Select the Heating Medium of the Sterilizer from the available List of Values in the drop-down menu.
- Select the Container Shape from the available options (e.g., cylinder, rectangular, oval, and irregular). The available options depend on the information entered about the container in Step 1. If the container shape is irregular, the user should attach a file containing schematic of the container shape during the Confirmation Step.
- Select the Number of Pieces in the container from the available options (2 piece, 3 piece, (2 or 3) pieces). Select “2 or 3” pieces if the product is packaged in either a 2-piece can or a 3-piece can.
- Select the Side Seam Construction (e.g., welded) from the available List of Values in the drop-down menu.

- Enter the Process Establishment Source for the scheduled process by either (1) adding a new source as described in section VIII.B.3 or (2) copying a source from an existing process filing as described in section VIII.B.4.
- If applicable, enter comments on the Sterilizer in the box provided.
- After entering the Process Establishment Source, select Next. The system will display Step 4. [Note: Step 3 only applies to acidified foods.]

2. Step 2 - Acidified Foods

- Select the Raw pH to the nearest hundredth (e.g., 4.80) from the available List of Values in the drop-down menu.
- If entering optional information about Thermal Processing Equipment:
 - Select the Manufacturer of the Sterilizer from the available List of Values in the drop-down menu.
 - Enter the Model of the Sterilizer.
 - Select the Heating Medium of the Sterilizer from the available List of Values in the drop-down menu.
- Select the Container Shape from the available options (e.g., cylinder, round, rectangular, square, and irregular). The available options depend on the information entered about the container in Step 1. If the container shape is irregular, the user will attach a file containing schematic of the container shape during the Confirmation Step
- Enter the Process Establishment Source for the scheduled process by either (1) adding a new source as described in section VIII.B.3 or (2) copying a source from an existing process filing as described in section VIII.B.4.
- After entering the Process Establishment Source, select Next. The system will display Step 3, which only applies to acidified foods.

3. Step 2 - Add Source for the Process Establishment

Select Add in the field for Process Establishment Source. The system will display the Add Source Information screen. Figure 19 shows a picture of the data entry screen for adding a new process establishment source relevant to the process filing form.

Figure 19: Step 2 - Enter New Filing - Data Entry Screen to Add a Process Establishment Source

Source Information Menu


1» 2» 3/NA 4» 5» 6» 7» confirm»

* required fields (product) TEST PRODUCT; (method) AGITATING (AXIAL, CONTINUOUS)

Instructions:
Add a new Process Establishment Source. A document is optional.

* Process Establishment Source

* Source Type

* Date Last Established  (mm/dd/yyyy)

Document
(All uploaded documents in your online FCE account must have unique names.)

Type

Notes

(If applicable, add any additional notes related to Source or Document.)

- Enter information in required fields as follows:
 - Enter the name of the Process Establishment Source in the box provided.
 - Select the Source Type (e.g., letter, publication) from the available List of Values in the drop-down menu.
 - Enter the date the process was last established (i.e., the most recent document issued by the process source) in the box provided, either by selecting the date from the calendar icon or by manually entering the date in a month/day/year (mm/dd/yyyy) format.
- If desired, add electronic files containing documents relevant to the process establishment source in optional files as follows:
 - To add a document, select Browse. The system will display file folders from the user's computer system.
 - Select the folder containing the document to be attached and then select the document to be attached.
 - If applicable, enter Notes relating to the process source in the box provided.
- Complete the procedure to add a source by selecting Add Source or stop the procedure by selecting Cancel. Either way, the system returns to Step 2.

4. Step 2 - Copy Source for the Process Establishment

If the electronic AF/LACF system for a particular FCE already contains any process establishment source, the system will display a drop-down menu (Existing Process Establishment Source) containing all the existing Process Establishment Sources (and applicable attached documents, if any). Figure 20 shows a picture of the data entry screen for copying an existing process establishment source.

Figure 20: Step 2 -Enter New Filing - Data Entry Screen to Copy an Existing Process Establishment Source

To copy an existing source:

- Select the applicable Existing Process Establishment Source from the available List of Values in the drop-down menu.
- If applicable, enter Notes relating to the process source in the box provided.
- Complete the procedure to copy a source by selecting Add Source or stop the procedure by selecting Cancel. Either way, the system returns to Step 2.

C. Step 3 - Acidified Factors

Step 3 applies only when the Processing Method selected in Step 1 is Acidified. Step 3 has required fields for maximum equilibrium pH, method of acidification, acidifying agent, and thermal processing method and has optional fields for preservative used and comments. Figure 21 shows a picture of the data entry screen for acidified factors in Step 3.

Figure 21: Step 3 - Enter New Filing - Acidified Factors

- Enter information in required fields as follows:

- Select the Maximum Equilibrium pH to the nearest tenth (e.g., 3.0) from the available List of Values in the drop-down menu.
- Select the Method of Acidification (e.g., batch, direct, indirect) from the available List of Values in the drop-down menu.
- Select the Acidifying Agent (e.g. acetic, lactic) from the available List of Values in the drop-down menu.
- Select the Thermal Processing Method (e.g., atmospheric cooker, batch rotary retort, cascading water) from the available List of Values in the drop-down menu.
- Enter information in optional fields as follows:
 - Select the Preservative(s) Used (e.g., ascorbic or citric) from the available List of Values in the drop-down menu.
 - If applicable, enter comments on the acidified factors in the box provided.
- Select Next. The system will display Step 4.

D. Step 4 - Critical Factors

Both Step 4 and Step 6 have data entry screens for information about the critical factors associated with the scheduled process. The critical factors depend on the product. Figure 22 shows an example of a data entry screen at Step 4 for the following critical factors: matting tendency, consistency/viscosity, starch added, nesting of containers, fill method, container position in retort, maximum pH, and maximum percent solids. The system distinguishes between critical factors that the user merely checks and critical factor information that the user provides in data entry boxes or selects from the available List of Values in pull-down menus. The system also provides for entry of “other” critical factors as well. Help screens are available.

Figure 22: Step 4 - Enter New Filing - Example of Data Entry Screen for Critical Factors

CRITICAL FACTORS
enter data for factors that are critical

Menu
1> 2> 3> 4> 5> 6> 7> confirm>

(product) TEST PRODUCT; (method) ACIDIFIED

<< Previous Next >>

- Check any critical factors to your process:
(matting tendency)
- Enter critical factor information:
 - ① (consistency/viscosity)
Value Units
Method name
Temperature °F
 - ① (starch_added)
Type MAX %
 - ① (nesting_of_containers) - none -
 - ① (fill_method) - none -
*Choose worst case scenario
 - ① (container_position_in_retort)
 - ① (maximum pH) 4.5
 - ① (solids) MAX %
 - ① (other_factor)

<< Previous Next >>

To complete Step 4 for the example shown in Figure 22:

- Check the applicable boxes for critical factors such as Matting Tendency.
- Provide applicable critical factor information for Consistency/Viscosity, Starch Added, Nesting of Containers, Fill Method, Container Position in Retort, Maximum pH, Maximum Percent Solids, and any Other critical factors, either by entering information in the boxes provided or by selecting entries from the available List of Values in drop-down menus, as applicable.
- Select Next. The system will display Step 5.

E. Step 5 - Container Dimensions, Number of Scheduled Processes, and the Number of Steps in the Scheduled Process

Step 5 has data entry screens for information about the container dimensions, the number of scheduled processes for the product, and the steps to each process. Step 5 includes an optional field for entry of comments. The data entry screens in Step 5 depend on information entered in Step 1. Figure 23 shows a picture of an example of the data entry screen at Step 5 for the container dimensions, the number of scheduled processes for the product, and the steps to each process.

Depending on the shape of container entered in Step 1, the system has data entry screens for dimensions such as diameter, length, width, height, thickness, and volume of the container. Volume is always optional. For example:

- If the container is cylindrical, the system has data entry screens for the diameter and height.
- If the container is round, the system has data entry screens for diameter, height, and volume.
- If the container is rectangular, the system has data entry screens for length, width, and height.
- If the container is a flexible pouch, the system has data entry screens for length, width, and thickness.
- If the container is semi-rigid with an irregular shape, the system has data entry screens for diameter, width, height and volume.

When entering dimensions for diameter, length, width, height, and thickness, express the dimensions by creating a round number that is a code reflecting the dimensions in inches. The first part of the code represents the whole number of inches and the second part of the code represents the fraction of inches in sixteenths. For example:

- If the dimension is 5 and 15/16 inches, create the code from 5 and 15 - i.e., 515.
- If the dimension is 3 and $\frac{3}{4}$ inches, first express the $\frac{3}{4}$ inches in sixteenths - i.e., 12/16. Then create the code from 3 and 12 - i.e., 312,
- If the dimension is 4 inches, create the code from 4 and 00 - i.e., 400.
- If the dimension is 4 and 1/8 inches, first express the 1/8 inches in sixteenths - i.e., 2/16. Then create the code from 4 and 2 - i.e., 402.

Users can report more than one scheduled process for a particular product. The information entered about the number of scheduled processes for the product and the steps to each process will affect the display of Step 7, which has data entry screens for specific information about each step of each scheduled process. If more than one process is entered in Step 5, the system assumes that each process has the same number of steps. The majority of processes are single step.

Figure 23: Step 5 - Enter New Filing - Example of Data Entry Screen for Container Dimensions, Number of Scheduled Processes, and Number of Steps

CONTAINER DIMENSIONS Menu

1» 2» 3» 4» 5» 6» 7» confirm»

* Volume AND/OR Dimension information is required. (product) TEST PRODUCT; (method) ACIDIFIED

<< Previous Next >>

Container Type: CAN - ALUMINUM

Instructions: Enter dimensions in inches and sixteenths for all fields.
 Example: LENGTH = 515 is 5 15/16 inch; WIDTH = 312 is 3 12/16 inch; HEIGHT = 400 is 4 inches
 VOLUME is entered in fluid ounces (FL OZ) or gallons (GA).

LENGTH	WIDTH	HEIGHT	VOLUME	# of PROCESSES	# of STEPS
200	100	100	4 FL OZ	1	1

Comments to add to Filing: (max. 1000 chars)

<< Previous Next >>

To complete step 5:

- Enter dimensions such as diameter, length, width, height, and thickness using the whole number code described above.
- Enter Volume to the nearest whole number and select the units (i.e., fluid ounces, gallons, or milliliters) by selecting the available List of Values from the drop-down menu.
- Enter the number of Processes from the available List of Values in the drop-down menu.
- Enter the number of Steps to each process from the available List of Values in the drop-down menu.
- If applicable, enter comments on the container, number of processes, or steps in the box provided.
- Select Next. The system will display Step 6.

F. Step 6 - Scheduled Process Options and Related Critical Factors

Step 6 has data entry screens for additional information about the scheduled process options and related critical factors and includes an optional field for entry of comments. The scheduled process options and related critical factors depend on the product and processing method identified in the prior steps. Figure 24 shows a picture of an example of the data entry screen listing scheduled process options relating to the Least Sterilizing Value and Related Critical Factors.

Figure 24: Step 6 - Enter New Filing - Example of Scheduled Process Options and Related Critical Factors

To complete Step 6:

- Enter information for scheduled process options by selecting the appropriate radio buttons and, when applicable, selecting values from the available List of Values in the drop-down menu.
- Enter information about related critical factors by selecting the appropriate radio buttons.
- If applicable, enter comments on the scheduled process options and related critical factors in the box provided.
- Select Next.

G. Step 7 - Critical Factors for Scheduled Process

Step 7 has data entry screens for additional information about the critical factors associated with the scheduled process and includes an optional field for entry of comments. The critical factors for a scheduled process and the required fields displayed depend on the product and processing method identified in the prior steps. If Step 4 specifies more than one scheduled process, Step 7 displays the applicable list of critical factors for each process so that the user can enter the information for each scheduled process. Figure 25 shows a picture of the data entry screen at Step 7 for an example of critical factors for the scheduled process for an acidified product. For this example, the system lists the product, processing method, container time and dimensions, center temperature, least sterilizing value, maximum drained weight, minimum weight, minimum free liquid, minimum container closing machine gauge vacuum temperature and an optional comment field.

Figure 25: Step 7 - Enter New Filing - Example of Critical Factors for Scheduled Process

SCHEDULED PROCESS
 enter processes information
 * every column requires data
 (product) TEST PRODUCT; (method) ACIDIFIED

1» 2» 3» 4» 5» 6» 7» confirm»
 Menu

<< Previous Next >>

(container description) rectangular; 2-PIECES
 CAN - ALUMINUM DIAMETER: 200 WIDTH: 100 HEIGHT: 100 VOLUME: 004 FL OZ

PROCESS #1	
Start Temp (CENTER TEMP) °F	80
Least Sterilizing Value F ₀	15
Max Weight (DRAINED) ounce	5
Min Weight ounce	31
Min Free Liq ounce	53
Min Container Closing Mach Gauge Vac Temp IN HG	4

Comments to add to Filing: (max. 1000 chars)

<< Previous Next >>

To complete Step 7:

- Enter all information that is applicable to the scheduled process, using the available List of Values in a drop-down menu when applicable.
- If applicable, enter comments on the scheduled process in the box provided.
- Select Next. The system will display a confirmation.

H. Confirmation Step

The confirmation step provides an opportunity for the user to review all the information supplied for the process filing and to add attachments (such as schematics of irregular shaped containers) that were not attached in Steps 1 through 7. Figure 26 shows a picture of an example of the confirmation page.

Users should return to Step 2 to attach documents associated with the Process Establishment Source. Users can return to any previous Step to edit information in that step by selecting the applicable Step in the status bar at the upper right of the confirmation screen.

After reviewing the information and adding attachments, the user can (1) Submit for Processing; (2) Save to Draft; or (3) Cancel the process filing.

Figure 26: Enter New Filing - Confirmation Page

CONFIRMATION PAGE Menu
review information below before submitting 1> 2> 3> 4> 5> 6> 7> confirm>>

PRODUCT INFORMATION - [edit](#)

TEST PRODUCT

(raw pH) 5.2
 (processing method) ACIDIFIED
 (finished pH) 2.6
 (sterilizer) ANDERSON BARNGROVER
 (heating medium) STEAM AND AIR
 (process source)

Source	Attached Document
04/03/2008 -- LAB REPORT Testing PROD Source1	

ACIDIFIED OR CONTROLLED FACTORS - [edit](#)

(maximum equilibrium pH) 4.5
 (method of acidification) DIRECT
 (acidifying agent) ACETIC AND LACTIC ACID
 (thermal processing method) CENTER TEMPERATURE

SCHEDULED PROCESS - [edit: container](#) [edit: factors](#) [edit: process](#)

(container description) rectangular; 2-PIECES
 CAN - ALUMINUM / DIAMETER: 200 WIDTH: 100 HEIGHT: 100 VOLUME: 004 FL OZ

PROCESS #	1
Start Temp (CENTER TEMP) °F	80
Least Sterilizing Value F ₀	1.5

1. Confirmation Step - Attach Document

The system supports attachments of the following document types: (1) PDF; (2) JPG; and (3) GIF. The system will prompt users to enter a unique file name for each attachment. Users have options to (1) add a new attachment and (2) copy an attachment that is already in the electronic AF/LACF system for the FCE. By copying an existing attachment, users can attach the same document multiple times without giving a different file name to the document each time it is attached.

2. Confirmation Step - Attach New Document

To attach a new document, select Attach Document on the Confirmation Step screen. A new screen for Attach Document will appear with two tabs:

- Copy document
- Add document..

Figure 27 shows a picture of an example of the Attach Document screen with tabs for Copy Document and Add Document. The “Add Document” tab is selected.

Figure 27: Attach Documents - Add Document

Attach Documents [Menu](#)

1> 2> 3> 4> 5> 6> 7> [confirm>](#)

* required fields (product) TEST PRODUCT; (method) ACIDIFIED

Instructions:
If your document has already been uploaded to another filing use the *Copy Document* tab, otherwise, attach all new documents through the *Add Document* tab. [Return to Confirmation Page](#)

[Copy Document](#) | **[Add Document](#)**

* Document

* All uploaded documents in your FCE online account must have unique names.

* Type

Notes

Once you have filled out form click on **Submit** button to copy or add selected document to this filing.

To add a new document from the Attach Documents screen:

- Select the Add Document tab.
- Select Browse. The system will display file folders from the user's computer system.
- Select the folder containing the document to be attached and then select the document to be attached.
- Select the Type of document (e.g., container schematic, supplementary SID, memo, and return letter) from the available List of Values in the drop-down menu.
- If applicable, enter Notes relating to the document in the box provided.
- Select Submit to complete the attachment procedure or Cancel to stop the attachment procedure. Either way, the system returns to the Confirmation Step.

3. Confirmation Step - Copy an Existing Document

To copy an existing document, select Attach Document on the Confirmation Step screen. A new screen for Attach Document will appear with two tabs:

- Copy document;
- Add document.

Figure 28 shows a picture of an example of the Attach Document screen with tabs for Copy Document and Add Document. The Copy Document tab is selected.

Figure 28: Attach Documents - Copy Document

The screenshot shows the 'Attach Documents' screen. At the top right, there is a 'Menu' link and a breadcrumb trail: '1» 2» 3» 4» 5» 6» 7» confirm»'. Below this, the text '(product) TEST PRODUCT; (method) ACIDIFIED' is displayed. A 'Return to Confirmation Page' link is also present. The main content area has two tabs: 'Copy Document' (selected) and 'Add Document'. Below the tabs, there is a required field: '* Select an already uploaded document to copy to this filing:'. This field is a dropdown menu. Below the dropdown is a text area labeled 'Notes'. At the bottom of the form are 'Submit' and 'Cancel' buttons. A footer note states: 'Once you have filled out form click on **SUBMIT** button to copy or add selected document to this filing.'

To copy a document from the Attach Documents screen:

- Select the Copy Document tab.
- Select a document to copy from the available documents in the List of Values in the drop-down menu.
- If applicable, enter Notes relating to the document in the box provided.
- Select Submit to complete the attachment procedure or Cancel to stop the attachment procedure. Either way, the system returns to the Confirmation Step screen.

4. Confirmation Step - Complete the Confirmation Step

After reviewing the information on the confirmation screen, editing information if appropriate, and adding any applicable attachments, users select one of the following options:

- Select Submit for Processing to send the process filing form to FDA; or
- Select Save to Draft to save the process filing form to the Draft folder without sending it to FDA. Process filings in the Draft folder remain available to the user who creates them and cannot be viewed by FDA or by other authorized users of the electronic AF/LACF system; or
- Select the Menu link located in the upper right hand corner of the screen to cancel the process filing form without saving any of the information.

I. Confirmation of Submitted Process Filing Form

After the user selects Submit for Processing, the system will provide a confirmation screen. Figure 29 shows a picture of an example of the confirmation page informing the user that a process filing has been submitted for a particular FCE and providing the user with the SID assigned to the process filing form.

Figure 29: Confirmation of Submitted Process Filing Form



Select Menu to return to the FCE Process Filing Main Menu. From the FCE Process Main folder, select the Submitted Folder to view the submitted process filing.

IX. How to Manage Process Filings

A. Filter and Sort Process Filings in a Folder

A folder contains a list of process filing forms. See section VII of this document for a description of the folders in the electronic AF/LACF system and a list of the functions available in each folder.

Figure 30 shows a picture of an example of the Filed folder displaying the SID, product name, processing method, type of container and container size for several process filings.

Figure 30: Example of List of Process Filings in the Filed Folder

SID	PRODUCT	PROCESS	CONT	SIZE
<input type="checkbox"/> 2012-05-21/010	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/009	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/008	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/007	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/006	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/005	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108

Selecting a folder will show a list of process filing forms. For each process filing form, the system displays the:

- SID;
- Product name;
- Processing method;
- Container type; and
- Size(s).

The user can navigate to other available folders using links at the top of the screen.

1. Filtering Process Filing Forms

If there are more than 20 process filing forms in a particular folder, the user can filter the process filing forms by process method, container type, or both process method and container type. Figure 31 shows an example of a process filing folder containing more than 20 process filing forms and the two available filter options: 1) View All Process Methods; and 2) View All Containers. The screen displays the SID, product name, processing method, type of container and container size. Because the folder contains more than 20 process filings forms, the screen has pull-down menus for filtering the process filings using one or both filter options. In the example, the available List of Values in the pull-down menus will identify processes and containers associated with the process filings in the folder, rather than all process types and container types available in the electronic AF/LACF system. For example, if none of the process filings are for an agitating process method, “Agitating” would not be in the available List of Values under “View All Process Methods.”

Figure 31: Process Filing Folder Showing List of SIDS and Filter Options

SID	PRODUCT	PROCESS	CONT	SIZE
<input type="checkbox"/> 2012-05-21/010	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/009	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/008	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/007	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/006	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/005	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/004	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/003	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/002	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/001	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-01/003	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-01/002	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-01/001	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-04-26/001	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-04-25/001	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108

To apply a filter - e.g., for Process Methods:

- Click on “View All Process Methods.”

- Select the Processing Method (e.g., Acidified) from the available List of Values in the drop-down menu and Click on “Filter.”
- The system will display only those process filings that are contained in the folder and are processed using an “Acidified” process method.

2. Sorting Process Filing Forms

Within a folder, users can sort the list by SID, product, process, or container columns by selecting a link in the applicable column heading. The user can sort forms in either ascending or descending order.

To sort a list of process filings:

- Select the link in the applicable column heading (e.g., Process).
- The display of the list of process filing forms changes to reflect the sorting of the forms in ascending alphabetical for the selected column heading (in this case, Process). A down arrow appears near the right end of the sorting column heading. Figure 32 shows a picture of an example of a list of process filings in the Submitted folder sorted in ascending order by Process.
- To re-sort the items in descending order, select the down arrow. The list of process filings will re-sort in descending order and the down arrows will be replaced with an up arrow.
- To sort on another column heading, select that column heading.

Figure 32: Example of List of Process Filings in the Submitted Folder Sorted by Process

The screenshot shows a web application interface for managing process filings. At the top, there is a breadcrumb trail: » LACF MENU (FCE: 00001) » Draft » Submitted » Filed » Discontinued. Below this, there are two dropdown menus: « - VIEW ALL PROCESS METHODS - » and « - VIEW ALL CONTAINERS - ». A blue 'Filter' button is positioned to the right of the second dropdown. Below the dropdowns, the text 'deleted online.' is visible. A 'Delete Filing' button is located on the right side of the interface. The main content is a table with the following columns: SID, PRODUCT, PROCESS, CONT, and SIZE. The table contains 10 rows of data, all with 'AC' in the PROCESS column.

SID	PRODUCT	PROCESS	CONT	SIZE
<input type="checkbox"/> 2012-05-21/010	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/009	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/008	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/007	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/006	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/005	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/004	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/003	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/002	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108
<input type="checkbox"/> 2012-05-21/001	SALMON, COLD SMOKED	AC	POU	1708 * 704 * 108

B. Available Functions

The functions available to the FCP and ARs are:

- Edit;
- Copy;
- Submit;
- Delete; and
- Discontinue.

1. Edit Function

The Edit function is only available for process filings in the Draft folder and the Returned folder. To edit a process filing:

- Select the Folder containing the SID to be edited.
- Select the SID link for the applicable process filing.
- Select Edit Filing.
- Edit the information at various Steps in the process as described in section VIII of this document.

2. Copy Function

The Copy function is available in the Draft, Submitted, Returned, Re-submitted, Filed, and Discontinued Folders. To copy a process filing:

- Select the Folder containing the process filing to be copied.
- Select the SID link for the applicable process filing.
- Select Copy Filing.
- The system will display the following message. “Filing has been copied into Draft Folder”.
- Select Menu to return to the AF/LACF Process Filing Main Menu.
- Select the Draft folder to see the copied process filing.

3. Submit Function

The Submit function is only available in the Draft folder and the Returned folder. To submit a process filing:

- Select the Folder containing the SID to be submitted.
- Select the checkbox to the left of the SID to be submitted.
- Select Submit Filing.

4. Delete Function

The Delete function is only available in the Draft folder and the Returned folder. To delete a process filing:

- Select the Folder containing the SID to be deleted.
- Select the checkbox to the left of the SID to be deleted.
- Select Delete Filing.

5. Discontinue Function

The Discontinue function is only available in the Filed folder. To discontinue a process filing:

- Select the Filed Folder.
- Select the checkbox to the left of the SID to be discontinued
- Select Discontinued Form.

C. View a Process Filing Form

Users can view process filing forms in any folders that are available to them when logged into the electronic AF/LACF system. Figure 33 shows a picture of an example of a view of product information and critical factors for a product in the Filed folder.

Figure 33: View Product Information and Critical Factors Entered on a Process Filing Form

LACF MENU » Filed List / FCE: 00001, FILING - 2008-04-07/004		» Copy Filing
Record 1 of 25		Next >>
PRODUCT INFORMATION		
YUMMY MUSTARD BALLS		
(processing method)	HYDROSTATIC (INNER & OUTER)	
(sterilizer)	ATM	
(heating medium)	WATER SHOWER (CASCADE)	
(process source)	MEMORANDUM -- Happy Sources; 04/07/2008	
(date filed)	04/16/2008	
(maximum equilibrium pH)	6	
CRITICAL FACTORS		
(applicable factors)	Matting Tendency, Preparation Method, Product Quality, Formulation Changes, Layer Pack	
(starch added)	Type=AMIOCA; CORN,Max %=56	
(consistency/viscosity)	Value=65 CEN ; Method=B TYPE KEIKIMET; Temp=44 °F	
(maximum equilibrium pH)	6	
(nesting of containers)	STACKING IN SPIRAL FORM	

To view a process filing:

- Select the Folder containing a listing of process filing forms.
- Select the SID link for the applicable process filing. The system will display the information entered for that SID. The display of information is similar to the display during the Confirmation Step.
- View the information displayed on the screen form.
- If the information covers more than a single screen, use the Page Down, Page Up, or scroll bar to the right of the browser screen to view the information on multiple screens.
- To view the next process filing form in the list of process filings in the selected folder, select Next. To return to the list of process filings in the selected folder, select Folder.

X. How to Search Process Filings

Users can search the electronic AF/LACF system for process filings that are in the Filed folder. Any authorized user for a particular FCE (FCP, AR, and ROAR) can use the search function. In addition, any person with an FDA Account ID and password for the FIS electronic portal may use the search function. 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 search the electronic AF/LACF system for that process filing.

At this time, the electronic AF/LACF system only reports that a process filing is “on file” if it is in the Filed folder. The search engine does not report process filings in the Submitted folder as “on file.” If the search function does not report that a process filing is “on file,” a user who wants to check on the status of that process filing may contact FDA as described in section XI of this document and ask FDA to check the status.

To search the electronic AF/LACF system:

- Enter the FIS electronic portal as described in section IV of this document and access the AF/LACF Main Menu.
- Select Access AF/LACF Process Filings.
- The system display will depend on whether the user is an authorized user for one or more FCEs.

A. Search Function When the User is Not Linked to the Electronic AF/LACF System

A user (such as an importer) who has an FDA Account ID, but is not linked to the electronic AF/LACF system through authorized by an FCP, would see a screen similar to the screen that an AR would see before the AR's FDA Account ID is linked to the electronic AF/LACF system. (See Figure 8 in section VI.B of this document.) For the convenience of the reader, we reproduce Figure 8 below as Figure 34. Figure 34 shows a picture of an example of the computer screen that a user who has an FDA Account ID that is not linked to the electronic AF/LACF system will see after selecting Access AF/LACF Process Filings from the AF/LACF Main Menu. The bottom of the screen has data entry boxes, for FCE and SID, that are used to search the electronic AF/LACF system to determine the status of a process filing

To search for the status of a process filing:

- Scroll down to the bottom of the computer screen and 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.
- The system display will depend on whether the FCE and SID combination is found on file.
 - If the specified SID is in the Filed folder for the specified FCE, the system will display a message that the FCE/SID is on file. Figure 35 shows a picture of an example of the computer screen when the specified FCE/SID is on file.
 - If the specified SID is not in the Filed folder for the specified FCE, the system will display a message that the FCE/SID is not on file. Figure 36 shows a picture of an example of the computer screen when the specified FCE/SID is not on file. Users may contact FDA as described in section XI of this document to check on the status of process filings reported as “not on file.”

Figure 34: Search Screen for Users Not Linked to the Electronic AF/LACF System

**Low Acid Canned Foods
Acidified Foods ONLINE**

Your FURLS Account ID, mac77673, has not been linked to LACF Online.

- 1. If you are NOT the "FCP" for an FCE Number AND have been provided access to an FCE by the Facility Contact Person (FCP):**
Enter the same email address that you provided to the Facility Contact Person (FCP) who is giving you access to an FCE.

OR

- 2. If you are the Facility Contact Person (FCP) for an FCE Number:**
You will need to request FDA to link your FDA Industry Systems Account to your FCE Number. To view the procedures for establishing this link, view the [LACF Online Registration FAQ](#).

OR

- 3. For any additional questions or assistance:**
Contact LACF at LACF@fda.hhs.gov or 240-402-2411.

To Find out the status of the process filing, please click on the submit button::

FCE:
SID: *SID Entry should be numbers only.*

Figure 35: Example of Search Results When a Specified FCE/SID is on File

**Low Acid Canned Foods
Acidified Foods ONLINE**

Your FURLS Account ID, mac77673, has not been linked to LACF Online.

- 1. If you are NOT the "FCP" for an FCE Number AND have been provided access to an FCE by the Facility Contact Person (FCP):**
Enter the same email address that you provided to the Facility Contact Person (FCP) who is giving you access to an FCE.

OR

- 2. If you are the Facility Contact Person (FCP) for an FCE Number:**
You will need to request FDA to link your FDA Industry Systems Account to your FCE Number. To view the procedures for establishing this link, view the [LACF Online Registration FAQ](#).

OR

- 3. For any additional questions or assistance:**
Contact LACF at LACF@fda.hhs.gov or 240-402-2411.

To Find out the status of the process filing, please click on the submit button::

FCE:
SID: *SID Entry should be numbers only.*

FCE: 00001 / SID:20110509004 is On File!

Figure 36: Example of Search Results When a Specified FCE/SID is Not on File

**Low Acid Canned Foods
Acidified Foods ONLINE**

Your FURLS Account ID, mac77673, has not been linked to LACF Online.

- If you are NOT the "FCP" for an FCE Number AND have been provided access to an FCE by the Facility Contact Person (FCP):**
Enter the same email address that you provided to the Facility Contact Person (FCP) who is giving you access to an FCE.

OR

- If you are the Facility Contact Person (FCP) for an FCE Number:**
You will need to request FDA to link your FDA Industry Systems Account to your FCE Number. To view the procedures for establishing this link, view the [LACF Online Registration FAQ](#).

OR

- For any additional questions or assistance:**
Contact LACF at LACF@fda.hhs.gov or 240-402-2411.

To Find out the status of the process filing, please click on the submit button::

FCE:
SID: *SID Entry should be numbers only.*

FCE: 00001 / SID:20120101001 is **Not on File!**
Please search again.

B. Search Function When the User is Linked to the Electronic AF/LACF System as a Facility Contact Person, Authorized Representative, or Read Only Access Representative

An FCP, AR, or ROAR who selects Access AF/LACF Process Filings from the AF/LACF Main Menu would see the FCE Account List Menu, with a list of FCE numbers linked to the user's account. Users access the search function from the FCE/SID Validation link at the bottom of the screen. Figure 37 shows a picture of an example of the FCE Account List Main Menu that the FCP would see, including the FCE/SID Validation link.

Figure 37: Example of the FCE Account List Main Menu that the FCP Would See

**Low Acid Canned Foods
Acidified Foods ONLINE**

FCE ACCOUNT LIST: [View Profile](#) | [Manage Online Accounts](#)

Last Login: 05/08/12

(FCE) Food Canning Establishment List:
Record Count: 5

FCE	Name	City	Province	Country	Access Level
00001	MR. TESTER FESTER	COLLEGE PARK		UGANDA	Online - FCP
27375	MARY DANCE STUDIO COOKIE MACHINE	DISTRICT HEIGHTS			Online - FCP
27391	NEW REGISTRATION FROM OLD	BYSUA			Online - FCP
27417	TESTING FOR FOREIGN LACF	MAHAJANGA			Online - FCP
27428	HAPPY FEET DANCER	DISTRICT HEIGHTS			Online - FCP

For Assistance: LACF@fda.hhs.gov
FAQs - [User Guide](#) - [References](#)

[» FCE/SID Validation](#) [» FURLS Menu](#) [Log Out](#)

To search for the status of a process filing:

- Select FCE/SID Validation.
- 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.
- The system display will depend on whether the FCE and SID combination is found on file.
 - If the specified SID is in the Filed folder for the specified FCE, the system will display a message that the FCE/SID is on file. Figure 38 shows a picture of an example of the computer screen when the specified FCE/SID is on file.
 - If the specified SID is not in the Filed folder for the specified FCE, the system will display a message that the FCE/SID is not on file. Figure 39 shows a picture of an example of the computer screen when the specified FCE/SID is not on file. Users may contact FDA as described in section XI of this document to check on the status of process filings reported as “not on file.”

Figure 38: FCE and SID Validation of Form on File

LACF > FCE/SID Validation

To Find out the status of the process filing, please click on the submit button::

FCE:

SID: SID Entry should be numbers only.

FCE: 16171 / SID:20110720001 is On File!

Figure 39: FCE and SID Validation of Form Not on File

LACF > FCE/SID Validation

To Find out the status of the process filing, please click on the submit button::

FCE:

SID: SID Entry should be numbers only.

FCE: 00001 / SID:200100101001 is Not on File!
Please search again.

XI. 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

XII. References

1. [Guidance for Industry: Submitting FDA Form 2541 \(Food Canning Establishment Registration\) and FDA Forms 2541a and 2541c \(Food Process Filing Forms\) to FDA in Electronic or Paper Format](#)

XIII. Appendix

Table 1: Authorized Functions Associated with Assigned Roles

Authorized Functions	Facility Contact Person (FCP)	Authorized Representative (AR)	Read-Only Authorized Representative
Submit initial FCE Registration Form 2541	Yes	No	No
Access the FCE's electronic AF/LACF Online Account	Yes	Yes	Yes
Assign roles	Yes	No	No
Update FCE registration information	Yes	Yes*	No
Discuss FCE registration information with FDA	Yes	Yes*	No
Submit process filings	Yes	Yes	No
Discuss process filings with FDA	Yes	Yes	Yes
View process filings in the FCE's electronic AF/LACF Online Account	Yes	Yes	Yes
Provide additional information to FDA (e.g., upon request) by mail, E-mail, or fax	Yes	Yes	No

*At this time, the only mechanism available for the FCP to authorize another individual to update registration information or to discuss registration information with FDA is to contact us as described in section XI of this guidance to ask us to add the authorization to your account. After initial registration is complete, the FCP may contact FDA as described in section XI of this document to authorize additional individuals to update registration information. We expect that future enhancements to the electronic AF/LACF system will enable the FCP to electronically authorize other individuals to perform functions related to registration.