

# **Instructions for Electronic Submission of Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)**

**U.S. Department of Health and Human Services**

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**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 thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as “low-acid canned foods” or “LACF”)<sup>1</sup>; and
- Persons who are authorized to act on behalf of such commercial processors<sup>2</sup>.

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

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

This document provides detailed instructions on how to submit process filings by using an *electronic* Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method). Form FDA 2541d is intended for low-acid food products where the growth of microorganisms is controlled through the application of heat to foods.

This document does not provide:

- Process filing instructions for low-acid food products where the growth of microorganisms is controlled through the amount of water available for microbiological growth (i.e. “water control” products), and for low-acid food products where the growth of microorganisms is controlled through multiple physical and/or physicochemical hurdles (i.e. “formulation

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<sup>1</sup> 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.

<sup>2</sup> Individuals who are authorized to act on behalf of commercial processors may do so for more than one commercial processor. Reference 1 addresses our electronic system for submitting process filing and identifies the responsibilities of each type of authorized user for that system.

control” products). The process filing for such products is instead covered by Form FDA 2541f.

- Instructions for *paper* submission of Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method);
- Instructions for submitting process filing Forms FDA 2541f, and FDA 2541g in either electronic or paper format;
- Instructions for submitting Form FDA 2541e (Acidified Foods) in either electronic or paper format;
- Instructions for submitting plant registration Form FDA 2541 in either electronic or paper format; or
- Instructions on how to use the *electronic* system for acidified foods (AF) and LACF (which we call the AF LACF Online System).

## 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 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.)

See instructions entitled “How to Use AF/LACF Electronic System” (Ref. 2 and the appendices in Reference 2) which cover:

- 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 Electronic AF/LACF System;
- How the Establishment Contact Person for an Establishment Manages Access to the Establishment’s Electronic AF/LACF System;
- General Information About the Organization of the Process Filing Folders;
- How to Manage Process Filings; and
- How to Search Process Filings.

## **II. How to Submit Electronic Process Filing Form FDA 2541d**

### **A. General Information**

The electronic Form FDA 2541d contains 11 Steps (Sections A through K).

- All mandatory fields on the electronic Form FDA 2541d must be completed. Only three sections include optional information:
  - In Step 1 (Section A), Question 1 (Food Product Group) is optional.
  - In Step 4 (Section D), Question 2 (Net Weight (Optional)) is optional.
  - Section K, Additional Information (Optional) is optional.
- When you manufacture, process, or pack a product in more than one container size or type, you are required to submit a separate Form FDA 2541d for each container size and type.

- You may report multiple forms of the product (e.g., diced, chunks, cut, fillet) on the same Form FDA 2541d, provided that:
  - Other factors (e.g., container type or size) do not require separate filing; and
  - The process information you provide in Step 10 (Section J) of Form FDA 2541d applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation of the product form must be filed. The comment section of the filing form should state which formulation product form heats the slowest.
- You may report multiple product packing mediums on the same Form FDA 2541d provided that:
  - Factors other than “product packing medium” (e.g., container type or size) do not require separate filing; and
  - The process information you provide in Step 10 (Section J) of Form FDA 2541d applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation of the product packing medium must be filed. The comment section of the filing form should state which formulation packing medium heats the slowest.
- You may report multiple products with minor formulation changes (e.g., a shake base that you produce to have a strawberry-flavored version, and a shake base that you produce to have a vanilla-flavored version) on the same Form FDA 2541d provided that:
  - Other factors (e.g., container type or size) do not require separate filing; and
  - The process information you provide in Step 10 (Section J) of Form FDA 2541d applies to each formulation of the product. If the heat transfer rates are different for each product formulation variation, the process for the slowest heating formulation of the product must be filed. The comment section of the filing form should state which formulation heats the slowest.
- Brand names of products generally should not be part of the Product Name. However, you may need to include the brand name as part of the Product Name if it is necessary to distinguish products that are produced using different scheduled processes. You need not submit a separate Form FDA 2541d for each brand name of a product that is manufactured, processed, or packed under more than one brand name if the scheduled process for each brand is exactly the same.

## **B. What You Need to Know About Saving Preliminary Drafts of Form FDA 2541d**

In general, you can save information you enter into Form FDA 2541d after each step in the data entry process, exit the system, and return later to continue data entry into subsequent sections of the form. Importantly, the electronic system distinguishes required information from optional information. After you begin data entry for a section of the form, the “Save and Exit” function is not available until you complete data entry for all the required information in that section. Therefore, we recommend that you only begin data entry in a new section of the form if you expect to complete data entry in that section.

Likewise, when you will be submitting separate forms for related products (such as for a product that you manufacture, process, or pack in multiple container sizes), and much of the information about each of these products will be the same, the electronic system enables you to copy a previously submitted form to your Draft folder and then edit that form (e.g., to change the container size) for subsequent submission to FDA. (See Ref. 2 for instructions on how to copy a form.) As you edit a previously submitted form, you may save the edited information in your draft folder and continue editing the form later. However, you should be aware that deleting some required information from the form, without replacing that required information with new information before you try to save the form, may cause the system to prompt you to add that required information before you can save the form.

## **C. What You Need to Know About Adding Attachments to Form FDA 2541d**

### **1. Types of Documents That You Can Attach**

Some sections of Form FDA 2541d require that you provide documentation by attaching an electronic file to the form (see Figure 1). In addition, a “Review” screen allows you to add optional documentation (see Figure 2) that you consider would help FDA review the form. Examples of such documentation include pictures, schematics, or other supporting information. The electronic AF/LACF system supports attachments of the following document types: (1) PDF; (2) JPG; (3) GIF; (4) XLS; (5) XLSX; (6) DOC; (7) DOCX; (8) RTF; and (9) TXT. Within an FCE’s AF/LACF Online System, the file name for an attachment must be unique.

### **2. The Two Procedures That You Can Use to Attach a Document**

There are two procedures that you can use to attach a document:

- Use the “Browse” function to attach a document from your personal computer or network. When you use the “Browse” function, you will be adding a new document to the “Document Library” already in the FCE’s AF/LACF Online System. The file name for this new document cannot be the same as the file name for any document already in that Document Library.
- Use the “Document Library” function to attach a document previously submitted to the FCE’s AF/LACF Online System. When you use the “Document Library” function, you will attach a document that already has a unique file name for the purpose of the FCE’s AF/LACF Online System, and you will not need to rename the file. In other words, attaching a document from within the FCE’s “Document Library” allows you to attach the same document to several SIDs without giving that document a different file name each time you attach it to a new SID.

Figure 1 is an example of a computer screen that provides buttons to select either the “Browse” or “Document Library” functions when the AF/LACF Online System prompts you to attach a required document during data entry. Later in this document (see section II.C.3), we describe how to add a required attachment during data entry.

**Figure 1 - AF/LACF Online System Prompts You to Attach a Required Document During Data Entry**

The screenshot shows the AF/LACF Online System interface. At the top, there is a progress bar with steps 01 through 09. Step 03 is highlighted in orange. The header includes the AF/LACF logo, the text "Acidified/Low Acid Canned Foods", and the FDA logo. On the right, there are links for "FURLS HOME" and "AF/LACF HOME". Below the progress bar, the section is titled "SECTION C CONTAINER TYPE" with a "Clear" button. The main content area prompts the user to "Select one" container type. A note states: "Note: If the product is not packaged in one of the container types identified below, select Other option." There are seven radio button options:
 

- Aluminum/Tinplate/Steel Can
  - a) What is the shape of the container? Other [dropdown]
  - Attach a picture or schematic: [text input] [Browse] [Upload]
  - Document Library [button] Upload Selected Document Library [button]
  - b) How many pieces are used to construct the container? [Select one dropdown]
  - Do you use perforated divider plates?  Yes  No
- Ceramic/Glass
- Flexible Pouch
- Retortable Paperboard Carton
- Rigid (Commercial)
- Semi-Rigid
- Other

 At the bottom, there are navigation buttons: << Back, >> Save & Edit, >> Continue, and << Cancel & Start Again.

After you have entered required information into all sections of the form, the AF/LACF Online System will display a “Review” screen. The review screen displays the entire process filing form before submission and provides you an opportunity to attach optional documents that will help FDA review your form. See section II.Q of this document for more information about the Review screen. Figure 2 shows an example of the “Additional Info” section that you will see on the “Review” screen. The “Additional Info” screen provides buttons to select either the “Browse” or “Document Library” functions. Later in this document (see section II.C.4), we describe how to add an attachment at the “Review” screen.

**Figure 2 – Additional Information - Attach Document from the Review Screen**

The screenshot shows the "SECTION K ADDITIONAL INFORMATION" section of the review screen. It includes a "Heat Penetration Data (optional)" section with fields for 1. j value, 2. f0 value, 3. f2 value, 4. j0 value, 5. f0 value, and 6. n (DGR) value. Below this is a note: "If you consider any additional information pertinent to the product and/or the scheduled process critical factors, enter that information in the comment box and/or attach one or more documents containing the additional information. The size is limited to 50MB. Acceptable file types are .jpg, .doc, .docx, .xls, .xlsx, .pdf, .gif, .png". There is an "Attachment Type: Please Select" dropdown and an "Attach document:" field with "Browse" and "Upload" buttons. A "Document Library" button is also present. A note states: "Note: You may enter up to 4000 characters in the comment field. If your comment exceeds 4000 characters, you can upload a file with your comment." Below this is a "Comments:" text area with a character count: "(Maximum characters: 4000) You have 4000 characters left." At the bottom, there are fields for "Full Name", "Establishment Name", "State or Province", "Country (other than U.S.)", "Date", and "Telephone No.", followed by navigation buttons: << Cancel & Start Again, >> Save & Edit, and >> Submit.

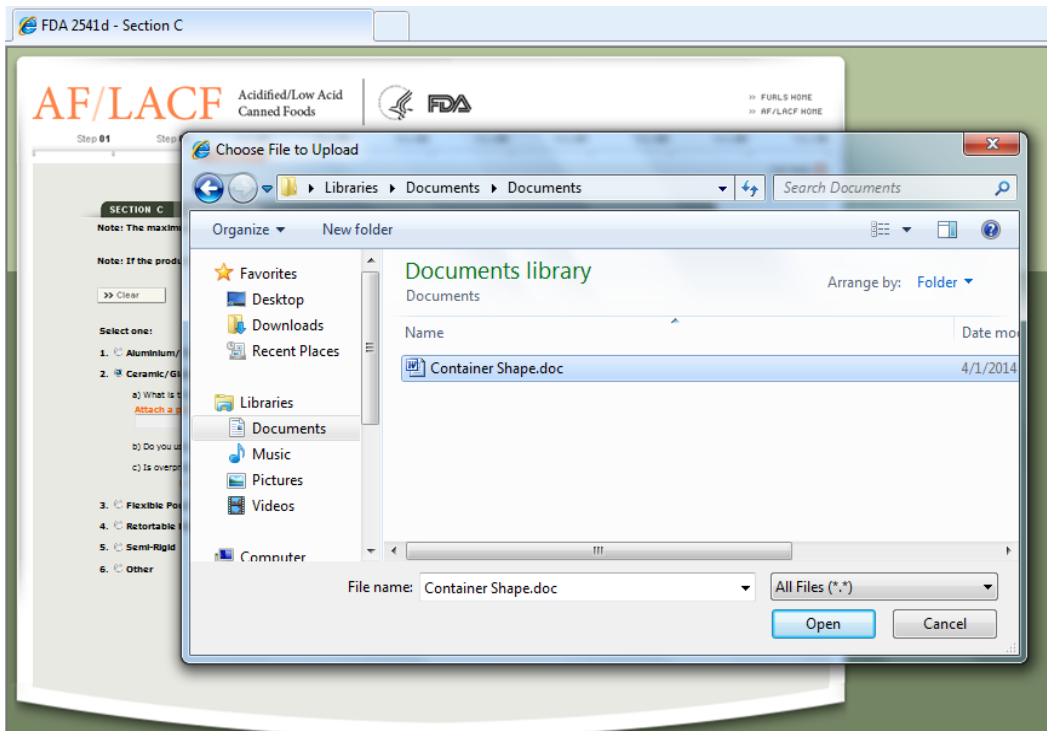
### 3. How to Add Required Attachments During Data Entry

#### a) How to Attach a Document Using the “Browse” Function

Follow the steps below using the “Browse” function to add a document from your personal computer or network.

- Select “Browse” to display file folders from your personal computer system or network (See Figure 3)
- Select the folder containing the document to be attached and then select the document from within that folder.
- Click Open. The system will enter the folder path and file name on the screen (see Figure 4).
- Select “Upload.” The system will display the uploaded file’s name and size (see Figure 5). The system also will provide an opportunity to either (1) select a link to view the content of the file or (2) remove the file as an attachment.

Figure 3 – System Display After You Select the “Browse” Function



**Figure 4 – System Display After You Select the Folder and File Using the “Browse” Function**

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09 Step 10

SECTION I PROCESS SOURCE

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls,xlsx, pdf, gif and rtf.

\*Note: If you selected "Still" as the mode in Section F.1, and "Steam" as the heating medium in Section E.1, you may select "Unknown" or "Locally Made" for sterilizer if applicable.

>> Clear

1. Process Source :

a) What is the Process Source?

Attach support documentation: C:\Users\SMACUCI\Des  >> Upload

b) What is the date of the Process Source Document (mm/dd/yyyy)?

2. What is the Manufacturer's Name and the Sterilizer Model :

<< Back >> Save & Exit >> Continue  
 << Cancel & Start Again

**Figure 5 – System Display After You Upload a Document Using the “Browse” Function**

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09 Step 10

SECTION G PROCESS SYSTEM CRITICAL FACTORS

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf.

>> Clear

1) What is the filling method(s) used to fill the product into the container?  
 Hand filling  Piston filling  Pocket filler  Vibrating/Tumble filling  Volumetric filling

2) How many phases are used to fill the container with the product?

3) Is the product vacuum packed?  Yes  No

4) What is the container position in retort?

5) Minimum Come-Up-Time:  .  (enter in minutes)

Attach a temperature distribution study:

	File Name	File Size (MB)	
1	Temperature Distribution for Mushrooms_20140409062905771.doc	0.0215	<a href="#">Remove</a>
Total Size:		0.0215	

6) Minimum Water Flow Rate:  .  (enter using gallons per minute (gpm))

<< Back >> Save & Exit >> Continue  
 << Cancel & Start Again

b) How to Attach a Document Using the “Document Library” Function

Follow the steps below to attach a document from the Document Library in the FCE’s AF/LACF Online System.

- Select “Document Library” to display the document library for the FCE’s filed SIDs (see Figure 6).
- Select the check box next to the document name to be attached.
- Select “Upload Selected Document Library.” The system will display the uploaded file’s name and size (see Figure 7). The system also will provide an opportunity to either (1) select the link on the file name to view the content of the file or (2) remove the file as an attachment.

Figure 6 – System Display When You Select a Document from the Document Library

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09 Step 10

SECTION E PROCESSING METHOD: THERMALLY PROCESSED NON-ASEPTIC SYSTEMS

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls,xlsx, pdf, gif and rtf.

>> Clear

1. What is the finished equilibrium pH of the product after processing? 4 . 8

2. Heating Medium Steam-air

Please select the document:

	File Name	File Size (MB)
<input type="checkbox"/>	<a href="#">source_20140627075744299.doc</a>	0.0215
<input checked="" type="checkbox"/>	<a href="#">Heat Distribution Study_20140714164521827.doc</a>	4.874
<input type="checkbox"/>	<a href="#">source_20140627075744299.doc</a>	0.0215
<input type="checkbox"/>	<a href="#">Heat Distribution Study_20140714164521827.doc</a>	4.874

Attach a heat distribution study:

Figure 7 – System Display after Document Attached from Document Library and File Size

AF/LACF Acidified/Low Acid Canned Foods

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09 Step 10

Get Help

SECTION E PROCESSING METHOD: THERMALLY PROCESSED NON-ASEPTIC SYSTEMS

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls,xlsx, pdf, gif and rtf.

>> Clear

1. What is the finished equilibrium pH of the product after processing? 4 . 8

2. Heating Medium Steam-air

Attach a heat distribution study:

	File Name	File Size (MB)	
1	<a href="#">Heat Distribution Study_20140715080810713.doc</a>	4.874	<a href="#">Remove</a>
Total Size:		4.874	

<< Back >> Save & Exit >> Continue

<< Cancel & Start Again

#### 4. How to Add Optional Attachments from the Review Screen

You may add optional attachments during the final review of the process filing form under the “Additional Info” section of the “Review” screen.

Follow the steps below to attach a document from the “Additional Info.” section of “Review” screen using either the “Browse” or “Document Library” function.

- Select the down arrow next to “Type of Attachment” to display a List of Values. Figure 8 shows an example of the computer screen displaying Memo/Letter, Study, Lab Report, Container Schematic, Retort Schematic, and Other Supporting Documentation within the List of Values.
- Select the “Browse” function and follow the steps in section II.c.3.a or “Document Library” function and follow the steps in section II.c.3.b.
- Repeat the above steps until all attachments are added.



**Figure 8 - Attach Document –List of Values for the Type of Attachment**

**SECTION K ADDITIONAL INFORMATION**

**Heat Penetration Data (optional):** Enter applicable values:  
 1. j value  2. fh value  3. f2 value   
 4. jv value  5. fv value  6. x (XBR) value

If you consider any additional information pertinent to the product and/or the scheduled process critical factor(s), enter that information in the comment box and/or attach one or more documents containing the additional information. File size is limited to 50MB. Acceptable file types are: .jpg, .doc, .docx, .bit, .xls, .xlsx, .pdf, .gif, .tif.

**Attachment Type:** **Pass Select:**  
 Heat Penetration Study  
 Temperature Distribution Study  
 Other

**Attach document:**

	Attachment Type	File Name	File Size (MB)	
1	Other	Example 20130523_20140714132554334.doc	0.5505	<a href="#">Remove</a>
Total Size:			0.5505	

**Note:** You may enter up to 4000 characters in the comment field. If your comment exceeds 4000 characters, you can upload a file with your comment.

**Comments:**

(Maximum characters: 4000)  
 You have 4000 characters left.

**Full Name:** Testor Test  
**Establishment Name:** Test Company  
**State or Province:** Maryland  
**Country (other than U.S.):** UNITED STATES  
**Date:** 07/14/2014  
**Telephone No.:** 3011212121

**Note:** If there are any attachments in addition to those that are required, they need to be added prior to submitting the filing.

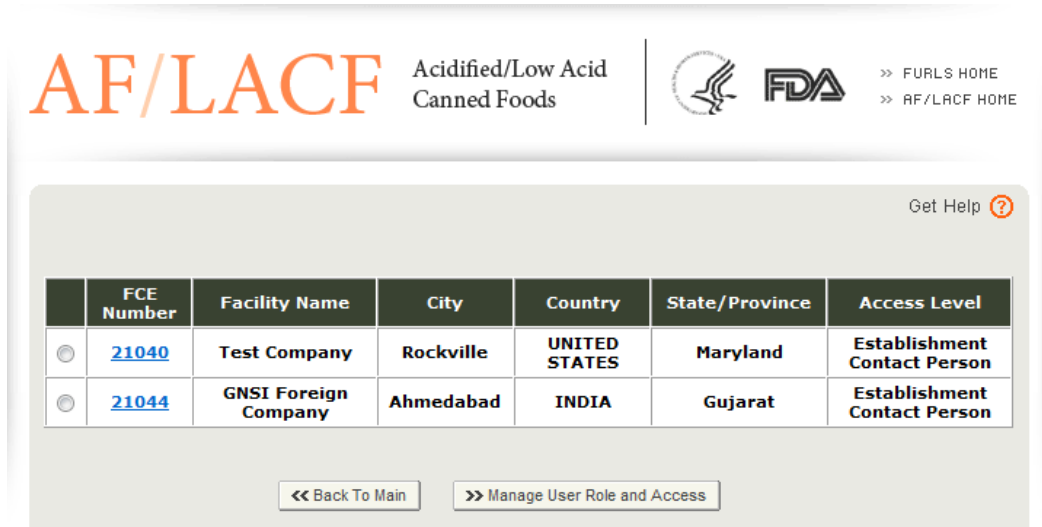
## D. How to Access the Process Filing Folders for a Specific Establishment

To access the Process Filing folders for a specific establishment, enter the FIS electronic portal using your FIS Account and then select the AF/LACF Main Menu. See Ref. 2 for instructions on how to enter the FIS electronic portal. From the AF/LACF Main Menu, select Access AF/LACF Process Filing.

The system will display a list of Food Canning Establishment (FCE) numbers you are authorized to access (Figure 9). If you are only authorized to access one FCE number, the system will display the FCE Process Filing Folder Main Menu for that FCE (Figure 10).

Figure 9 shows a picture of an example of a computer screen showing the FCE List Main Menu that you would see if you are the Establishment Contact Person (ECP) for an establishment. The “Manage User Role and Access” function on this screen only displays when the user is authorized as the ECP.

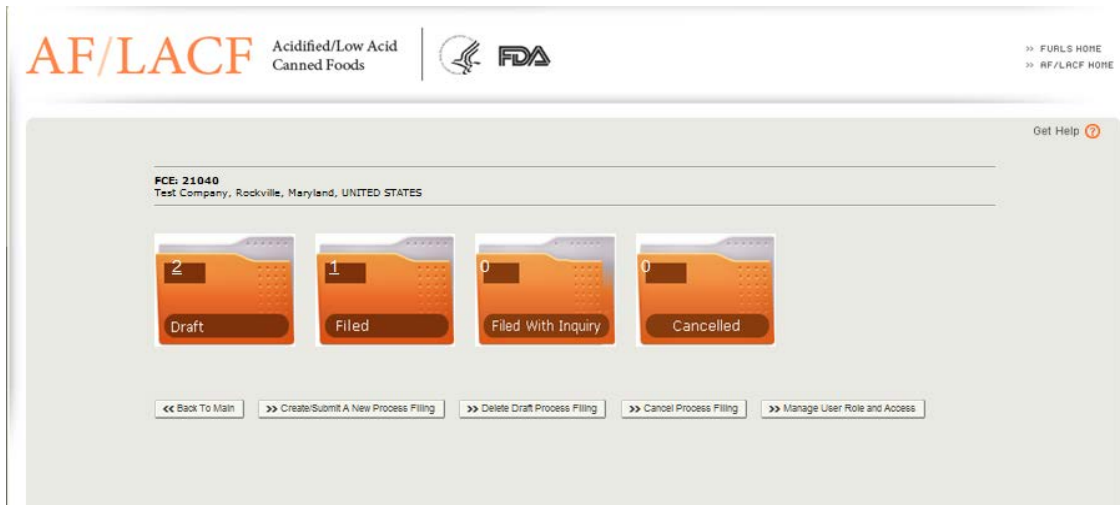
Figure 9 – Example of the FCE List Main Menu



Select the applicable FCE number to reach the FCE Process Filing Folder Main Menu for that establishment. The specific display of the AF/LACF Process Filing Folder Main Menu depends on the information already in the FCE’s AF/LACF Online System. 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) the AF/LACF Process Filing Folder Main Menu will display the Draft Folder with a zero (0) count to indicate that there are no process filing forms in the folder.

Figure 10 shows a picture of an example of the FCE Process Filing Folder Main Menu that you would see if you are the Establishment Contact Person (ECP) for an establishment. The system display would be the same for all other authorized users, except that users other than the ECP will not see the “Manage User Role and Access” function.

**Figure 10 - FCE Process Filing Folder Main Menu**



Select Create/Submit a New Process Filing. The system will display the Process Methods and Forms screen. See section II.E of this document for instructions on selecting the process method and form.

## **E. Process Methods and FDA Forms**

Figure 11 shows a picture of the computer screen displaying the available process methods and forms. Select Form 2541d – Low-Acid Retorted Method and then select the “Continue” button to start the submission process.

**Figure 11 - Process Methods and FDA Forms Screen**



## F. Top of Form – Food Canning Establishment Number and Submission Identifier

The system automatically enters the FCE number and a Submission Identifier (SID) at the top of Form FDA 2541d, before Section A, based on your selection of the FCE and process method/ FDA form (Figure 12).. The “Date Received by FDA” will reflect the date you submit the form to FDA electronically and will appear on the completed submission. See section II.F.2 of these instructions for detailed information about what a SID is and how it is assigned.

Figure 12 - Screen Display After You Select the Process Method and Form

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

Get Help ?

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d)

Note: There are separate process filing forms for each of the following: Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d); Food Process Filing for Acidified Method (Form FDA 2541e); Food Process Filing for Water Activity/Formulation Control Method (Form FDA 2541f); and Food Process Filing for Low-Acid Aseptic Systems (Form FDA 2541g).

USE FDA INSTRUCTIONS ENTITLED "[Instructions for Electronic Submission of Form FDA 2541d \(Food Process Filing for Low-Acid Retorted Method\)](#)"

Food Canning Establishment (FCE) Number:

Submission Identifier (SID)  (YYYYMMDD###)

<< Back >> Continue

### 1. Food Canning Establishment (FCE) Number:

The system automatically enters the FCE number.

### 2. Submission Identifier (SID):

The SID is a unique number associated with each new process filing. The system will assign the SID. The combination of the FCE number and the SID identifies a specific process filing form.

The SID is a combination of:

- (1) The date (i.e., year, month, and day of the month) that a process filing form is created; and

- (2) A sequence number that would distinguish multiple forms created on the same date. The sequence number starts with 001 and continues (002, 003) for as long as necessary to uniquely identify all forms created on the same date.

If you create multiple types of process filing forms on the same date (e.g., if you create three Forms FDA 2541d and three Forms FDA 2541f on the same date), the sequence number would increase by 001 for each created form rather than begin again at 001 for each type of form (see examples immediately below).

When you create multiple *electronic* forms, the system will assign the SID and automatically enter the SID on the form using the following format:

YYYY-MM-DD/SSS

Where:

YYYY represents the calendar year (e.g., 2013, 2014)

MM represents the month (e.g., 02 for February, 10 for October)

DD represents the day of the month (e.g., 02, 19, 30)

SSS represents the assigned sequence number (e.g., 001, 002, 003).

Examples of SIDs include:

2013-02-22/001: The first Form FDA 2541d created on February 22, 2013

2013-02-22/002: The second Form FDA 2541d created on February 22, 2013

2013-02-22/003: The third Form FDA 2541d created on February 22, 2013

2013-02-22/004: The fourth process filing form, this one a Form FDA 2541f, created on February 22, 2013

2013-02-22/005: The fifth process filing form, this one a Form FDA 2541f, created on February 22, 2013

2013-02-22/006: The sixth process filing form, this one a Form FDA 2541f, created on February 22, 2013

## **G. Step 1 – Section A. Product Information**

From the display screen for the Top of Form FDA 2541d as shown in Figure 12 above, select the “Continue” button. The system will display Step 1 (Section A).

Figure 13 shows a picture of the computer screen when a user is at Step 1 (Section A) in the procedure for creating a new process filing.

**Figure 13 - Step 1 (Section A) Product Information**

Step 1 (Section A) of the electronic process filing system has required fields for the name of the product, the form of the product (e.g., whole, cut), and product packing medium (e.g., brine, all liquid). Step 1 (Section A) also includes optional information for the food product group (e.g., vegetables, baby food).

### **1. Food Product Group (Optional):**

We request information about “Food Product Groups” to help us understand the nature of your products. The information you provide helps FDA prioritize which commercial processing facilities to inspect. The Food Product Group is optional information (i.e., you are not required to identify the Food Product Group.) If you choose to fill in this information and there is no single best Food Product Group applicable to the product, select “Other.”

### **2. Enter Product Name.**

Describe the actual food commodity or formulated food in the container (e.g., beans, green; mushrooms (button); tuna (light); sardines (sild)).

- If the product is named in a foreign language, provide its English equivalent first and then provide the foreign language name in parentheses (e.g., green kidney beans (flageolets) in brine).

The product name may include scientific names. When a scientific name is in Latin, the product name should also include the common English translation or description of the scientific name (e.g., mushrooms (*Agaricus bisporus*) pieces and stems, in brine; Beans (*Phaseolus vulgaris*) in brine)

- Brand names should not be part of the product name unless a brand name is necessary to distinguish products that are produced using different scheduled processes.

Some product names may include qualifying terms that identify unique species, processing methods, or organoleptic or visual properties. Some products may be compartmentalized, and include multiple types of foods. For such products, specify these unique properties. If, however, you are submitting the same Form FDA 2541d for multiple products with minor formulation differences indicate those minor formulation differences with the product name. (See section II.A of these instructions.) For example, if you are submitting the same Form FDA 2541d for beans that you make using green or wax varieties, indicate those varieties as part of the product name. Some examples of product names:

- Enter “Sardines (Sild),” not “Sardines”
- Enter “Radishes, pickled (Szechuan),” not “Radishes”
- Enter “Tuna (light),” not “Tuna”
- Enter “Mixed vegetables, pickled (matsutake meshi-no-moto),” not “Mixed vegetables”
- Enter “Macaroni and cheese entrée with green beans and apple pie,” not “Macaroni and cheese” (This is an example of a compartmentalized shelf stable product).
- Enter “Beans (green or wax),” not “Beans”
- Enter “Mushrooms (button),” not “Mushrooms”
- Enter “Sugar snap peas”, not “Peas”
- Enter “Refried Beans”, not “Beans”

### **3. What is the form of the product?**

The product form relates to the shape or appearance of the product itself (e.g., cut, pieces and stems, whole) rather than the characteristics of the container.

Select one or more product forms listed on the filing form. You may report multiple forms of the product on the same Form FDA 2541d with the caveats discussed in section II.A of this document. If none of the product forms listed on the form apply, select “Other” and enter the product form in the space provided.

#### 4. What is the packing medium?

In general, “packing medium” refers to the liquid portion(s) of a product when the liquid is added over, or added to, the solid portion(s) of a product. You may report multiple product packing mediums on the same Form FDA2541d with the caveats discussed in section II.A of this document.

Select one or more packing mediums listed on the form. If a product is all liquid, select “None.” If there is no packing medium, select “Solid (no packing medium).”

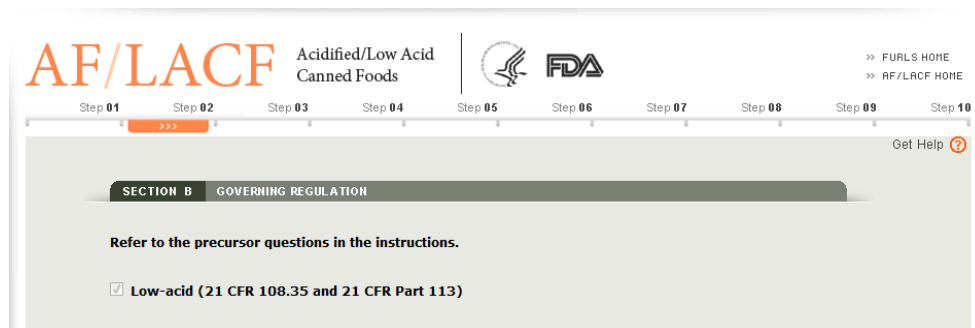
After you complete this section, select “Continue.”

#### H. Step 2 – Section B. Governing Regulation

Form FDA 2541d only applies to Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, which are regulated pursuant to 21 CFR 108.35 and 21 CFR Part 113. Refer to Ref. 3 of this document. The electronic system automatically enters this “Governing Regulation” in Section B of the form and, therefore, you do not have to enter this information yourself. Because the electronic system automatically enters the correct governing regulation in the form, the system will skip Step 2 (Section B) and display Step 3 (Section C). For your convenience, Figure 14 shows a picture of the computer screen showing Step 2 (Section B) with the governing regulation automatically entered.

At this stage in the data entry process, you can select “Save and Exit.” Doing so saves all the information you entered so far in the Draft Folder. Alternatively, you can select “Continue” to enter information for Step 3.

Figure 14 - Step 2 (Section B) Governing Regulation



The screenshot displays the AF/LACF (Acidified/Low Acid Canned Foods) web application interface. At the top, the logo "AF/LACF" is shown next to the text "Acidified/Low Acid Canned Foods". To the right is the FDA logo. A navigation bar at the top contains steps from Step 01 to Step 10, with Step 02 highlighted in orange and containing a right-pointing arrow. In the top right corner, there are links for "FURLS HOME" and "AF/LACF HOME", and a "Get Help" button with a question mark icon. The main content area is titled "SECTION B GOVERNING REGULATION" and contains the instruction "Refer to the precursor questions in the instructions." Below this, there is a checked checkbox labeled "Low-acid (21 CFR 108.35 and 21 CFR Part 113)".

#### I. Step 3 – Section C. Container Type

Each different container type and each different size of the same container type should be filed as a separate Form FDA 2541d. Therefore, for any Form FDA 2541d that you submit, select a single container type. To submit additional container types and/or different container sizes for the same product, you may copy the form for the product in



one container type and size and then edit the information on that form to reflect a different container type and/or size. (See Ref. 2 for instructions on how to copy a form.) For technical information about container types, refer to Appendix – A, Container Types and Shapes.

Figure 15 shows a picture of an example of a computer screen displaying container types available in Step 3 (Section C).

**Figure 15 – Step 3 (Section C) Container Type**

The screenshot displays the AF/LACF web application interface. At the top, there is a header with the AF/LACF logo, the text 'Acidified/Low Acid Canned Foods', and the FDA logo. A progress bar below the header shows steps 01 through 10, with Step 03 highlighted. The main content area is titled 'SECTION C CONTAINER TYPE'. It includes a note about file size and types, a 'Clear' button, and a 'Select one:' section with radio buttons for container types: 1. Aluminium/Tinplate/Steel Can, 2. Ceramic/Glass, 3. Flexible Pouch, 4. Retortable Paperboard Carton, 5. Semi-Rigid, and 6. Other. Under the first option, there are several questions with radio buttons for Yes/No and text input fields for specific details like shape, number of pieces, perforated divider plates, and side seam sealing. At the bottom, there are navigation buttons: '<< Back', '>> Save & Exit', '>> Continue', and '<< Cancel & Start Again'.

## 1. Aluminum/Tinplate/Steel Can

The first container type listed on Form FDA 2541d is for a container of all non-flexible metal (i.e., aluminum,<sup>3</sup> tinplate, or steel can). Do not select Aluminum/Tinplate/Steel Can if the container combines metal in one layer with other materials (e.g., paperboard or a polymer) in other layers.<sup>4</sup>

*a) What is the shape of the container?*

<sup>3</sup> Note that we consider an aluminum can to be a non-flexible metal container rather than a semi-rigid container.

<sup>4</sup> Note that we consider a combination of metal and other material containers to be a retortable paperboard or semi-rigid container.

Select the shape that best applies to the container. If the container is asymmetrical in shape, select “Irregular” and attach a picture or schematic. If none of the shapes apply, select “Other” and attach a picture or schematic. See section II.C of this document for instructions on how to attach a document.

*b) How many pieces are used to construct the container?*

A 2-piece container is a container where one end is made as part of the can body. There is no side seam and only one end is attached through the formation of a double seam.

A 3-piece container consists of a can body and two attached ends. A 3-piece container can be identified by the presence of a side seam. The side seam runs the length of the cylinder from one end to the other. Side seams are either cemented or welded.

You may select “2-piece container”, “3-piece container” or both, as applicable. Divider plates are any material used to separate layers of containers. If divider plates are used, select “Yes.” Otherwise, select “No.” For 3-piece containers, select “cemented” or “welded” to indicate how the side seam is sealed.

*c) Is the container a low-profile container?*

A low-profile container is a container where the width/diameter of the container is greater than the height (e.g., sardine can).

Select “Yes” or “No.” If yes, answer either question c.i or c.ii. If no, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

Question c.i: If a heat penetration (HP) test was conducted on nested containers, select “c.i” and attach the heat penetration study along with a picture or diagram of the nested containers. Then either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

Question c.ii: If a heat penetration (HP) test was conducted on non-nested containers, select one of the following that prevents nesting of containers: brick stacked, lid to lid/bottom to bottom, perforated divider plates, racks, or spiral. Then either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

## **2. Ceramic/Glass**

The second container type listed on Form FDA 2541d is for a container of ceramic or glass.

*a) What is the shape of the container?*

Select the shape that best applies to the container. If the container is asymmetrical in shape (e.g., boot, hat, tree), select “Irregular” and attach a picture or schematic. If the shape choices listed on the form are not applicable, select “Other” and attach a picture or

schematic. See section II.C of this document for instructions on how to attach a document.

*b) Do you use perforated divider plates?*

Select “Yes” or “No.” Divider plates are any material used to separate layers of containers.

*c) Is overpressure used during processing of the product to maintain container integrity?*

Overpressure is the additional external pressure often used to maintain the hermetic seal during the processing cycle (heating and cooling). This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

Select “Yes” or “No.” If yes, continue to question c.i. If no, continue to c.ii through c.iv. After completing question c.i or questions c.ii through c.iv, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point.

Question c.ii: What is the percent (%) headspace?

Percent headspace is the fraction of volume of the void (where there is no food product) in the container divided by the volume of the entire container multiplied by 100. Enter the headspace using a maximum of two digits before the decimal point and one digit after the decimal point and continue to the next question.

Question c.iii: What is the minimum initial temperature?

Minimum initial temperature (IT) is the average temperature of the contents of the coldest container to be processed at the time the thermal process cycle begins. Enter the minimum initial temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point and continue to the next question.

Question c.iv: What is the vacuum?

Control of the internal pressure depends upon the vacuum in the container. Enter the vacuum in inches of mercury (Hg) using a maximum of two digits before the decimal point and one digit after the decimal point.

### 3. Flexible Pouch

The third container type listed on Form FDA 2541d is for a container of flexible material.

A flexible pouch is a food container that has no fixed shape. Its final shape is defined by the product placed inside it during the filling and sealing process. It is constructed of flexible panels composed of laminated polymers. The composition of laminated polymers varies depending on the food product, the processing method, and the intended use. Some flexible pouches contain a foil layer.

*a) What is the shape of the container?*

Select the shape that applies to the container. For “Irregular” or “Other” shapes, attach a picture or schematic of the pouch. See section II.C of this document for instructions on how to attach a document.

*b) Is the container physically restricted during the processing of the product to control the container thickness?*

During processing, the pressure inside the pouch often exceeds the pressure inside the processing vessel. In this instance, the pouch can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the pouch from expanding.

Select “Yes” or “No.” If yes, continue to question b.i to indicate how the container is restricted. If no, continue to question c.

Question b.i: Racks: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Pouches can be restrained by closely placed flat racks or racks that have indentations.

Other: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, select “Other” and attach a picture of the restraint used. See section II.C of this document for instructions on how to attach a document.

*c) Is overpressure used during the processing of the product to control container thickness?*

With flexible pouches, some additional external pressure may be required to conform the container to its maximum dimensions for proper heat penetration and to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

Select “Yes” or “No.” If yes, continue to question c.i. If no, continue to question d.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point.

*d) What is the maximum thickness during retort processing?*

Pouches can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. Enter the maximum thickness in inches using a maximum of two digits before the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and ¼ of an inch, 10.00 is a representation of exactly 10 inches).

*e) What is the maximum residual air?*

Residual air trapped inside a flexible pouch can cause significant package expansion during processing. If the package position (e.g., vertical, on edge, etc.) or physical restraint in the retort does not allow residual air to affect the heating rate, select “Not Applicable.” Otherwise, enter the maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

#### **4. Retortable Paperboard Carton**

The fourth container type listed on Form FDA 2541d is for a container of retortable paperboard material.

Paperboard is a thick, paper-based material. While there is no rigid differentiation between paper and paperboard, paperboard is generally thicker than paper (usually more than 0.25 mm thicker (equal to 0.010 inches or 10 points)). A paperboard container is a container where the structure of the container is based on a wood pulp-based core which has the consistency of thick paper or cardboard.

*a) What is the shape of the container?*

Select the shape that best applies to the container. If the container is rectangular (e.g., juice box, soup box) in shape, select “Rectangular.” Otherwise, select “Other” and attach a picture or schematic. See section II.C of this document for instructions on how to attach a document.

*b) Is the container physically restricted during the processing of the product to control the container thickness?*

During processing, the pressure inside the retortable paperboard carton often exceeds the pressure inside the processing vessel. In this instance, the retortable paperboard carton can expand---resulting in under processing from poor heat penetration or rupturing from

structural stresses. In place of overpressure, physical restraints can be used to inhibit the retortable paperboard carton from expanding.

Select “Yes” or “No.” If yes, continue to question b.i to indicate how the container is restricted. If no, continue to question c.

Question b.i: Racks - For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Retortable paperboard cartons can be restrained by closely placed flat racks or racks that have indentations.

Other: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, then select “Other” and attach a picture of the restraint that is used. See section II.C of this document for instructions on how to attach a document.

*c) Is overpressure used during the processing of the product to control container thickness?*

Overpressure is extra external pressure to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

Select “Yes” or “No.” If yes, continue to question c.i. If no, continue to question d.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point

*d) What is the maximum thickness during retort processing?*

Retortable paperboard carton can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. Enter the maximum thickness in inches using a maximum of two digits before the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and  $\frac{1}{4}$  of an inch, 10.00 is a representation of exactly 10 inches).

*e) What is the maximum residual air?*

Residual air trapped inside a retortable paperboard carton can cause significant package expansion during processing. If the package position (e.g., vertical, on edge, etc.) or physical restraint in the retort does not allow residual air to affect the heating rate, select

“Not Applicable.” Otherwise, enter the maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

## **5. Semi-Rigid**

The fifth container type listed on Form FDA 2541d is for a container of semi-rigid material.

A semi-rigid container is a container where the shape of the container is not altered by filling of product at atmospheric pressures---but can be altered by additional external pressure.

*a) What is the shape of the container?*

Select the shape that best fits the container. For “Irregular” or “Other” shapes, attach a picture or schematic. See section II.C for instructions on how to attach a document.

*b) Is this a compartmentalized container?*

Compartmentalized containers are containers that hold more than one food product (e.g., corn and green beans where corn and green beans are held in separate sections within a single container) and the food is processed in the single container.

If the container consists of more than one compartment and the compartments contain different food products, select “Yes” and identify the number of compartments. Otherwise, select “No.”

*c) What is the predominant material used to make the body of the container?*

Select the material that, based on weight, is the predominant material used to make the container stock. If you select “Other,” enter the information next to “Other.”

*d) What is the predominant material used to make the lid of the container?*

Select the material that, based on weight, is the predominant material used to make the lid stock. If you select “Other,” enter the information next to “Other.” If the container is a web fed paperboard brick pack, without a lid, select “Not Applicable.”

*e) How is the lid sealed to the body of the container?*

Select the appropriate mechanism for how the lid is sealed to the body of the container. If you select “Other,” enter the information next to “Other.” If the container is a web fed paperboard brick pack, without a lid, select “Not Applicable.”

*f) Is the container physically restricted during the processing of the product to control container thickness?*

During processing, the pressure inside the semi-rigid container often exceeds the pressure inside the processing vessel. In this instance, the semi-rigid container can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the semi-rigid container from expanding.

Select “Yes” or “No.” If yes, continue to question f.i to indicate how the container is restricted. If no, continue to question g.

Question f.i: Racks – For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Semi-rigid containers can be restrained by closely placed flat racks or racks that have indentations.

Other: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, then select other and attach a picture of the restraint that is used.

*g) Is overpressure used during the processing of the product to control container thickness?*

Overpressure is additional external pressure required to conform the semi-rigid container to its maximum dimensions for proper heat penetration and to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

Select “Yes” or “No.” If yes, continue to question g.i. If no, continue to question h.

Question g.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point.

*h) What is the maximum thickness during retort processing?*

Semi-rigid containers can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. Enter the maximum thickness in inches using a maximum of two digits before the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and ¼ of an inch, 10.00 is a representation of exactly 10 inches).

*i) What is the maximum residual air?*

Residual air trapped inside a semi-rigid container can cause significant package expansion during processing. If the package position (e.g., vertical, on edge, etc.) or



physical restraint in the retort does not allow residual air to affect the heating rate, select “Not Applicable.” Otherwise, enter maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

## **6. Other Container**

The sixth container type listed on Form FDA 2541d is for a container of a type other than the ones listed above.

Select “Other” when none of the container types listed on the form applies and enter the container type.

*a) Attach a schematic or picture of the container. See section II.C of this document for instructions on how to attach a document.*

*b) Specify the material that, based on weight, is the predominant material used to make the container stock. This is the material that constitutes the highest weight value of the container stock.*

*c) Specify the material that, based on weight, is the predominant material used to make the lid stock. This is the material that constitutes the highest weight value of the lid stock. If the container does not have a lid, specify Not Applicable.*

*d) Specify the method used to seal the lid to the body. If the container does not have a lid, specify Not Applicable.*

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

## **J. Step 4 – Section D. Container Size**

Step 4 (Section D) includes one required field (D.1 – Dimensions) and one optional field (D.2 –Net Weight). Products come in a variety of container shapes (see section II.I of these instructions for information about container shapes). For cylindrical (including bowl and oval) shapes, select “a” to report the container size. For rectangular (including trays) shapes, irregular shapes, or pouches, select “b” to report the container size. Report container dimensions in English units (number of whole inches and sixteenths of an inch). Figure 16 displays a picture of a computer screen for data entry of the container dimensions.

Refer to Appendix – B, Container Dimension Measurements for examples.

**Figure 16 – Step 4 (Section D) Container Size**

**1. Dimensions:**

*a) Diameter and Height.*

*Enter information for Diameter and Height only for cylindrical (including bowl and oval) shaped containers.*

*b) Length, Width and Height/Thickness.*

*Enter information for Length, Width, and Height/Thickness for container shapes other than cylindrical.*

When entering dimensions for diameter, length, width, and height/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 last two digits represent the fraction of an inch in sixteenths. For example:

- If the dimension is 12 and 8/16 inches, create the code from 12 and 08 – i.e., 1208.
- 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 ¾ inches, first express the ¾ 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.

Rounding may be necessary for sizes that are less than one sixteenth of an inch. Rounding can be up or down depending on the measurement. If the measurement is

closer to the “higher” sixteenth, round up; if the measurement is closer to the “lower” sixteenth, round down. For example:

- If the diameter is 3 and 7/16 inches and the width is 2 inches and 1/4 of one 16th inches, the rounded dimensions will be 307 x 200
- If the diameter is 4 5/16 inches, the width 3 and 1/16 inches, and height is 0.906 (14/16ths and 1/2 of one 16th of an inch), the rounded dimensions will be 405 x 301 x 015

## **2. Net Weight (Optional):**

This question provides the opportunity for you to include the net weight of your product. Although you are not required to enter this information on this filing form, entering the information can help FDA inspectors examining product in matching a product under examination to the product described in this filing form.

Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food.

Enter the net weight in ounces if you choose to provide this optional information using a maximum of three digits before the decimal point and two digits after the decimal point.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 5 (Section E).

## **K. Step 5 – Section E. Processing Method: Thermally Processed Non-Aseptic System**

Processing method is a general description of how the product in the container is treated during the heating process (e.g., still, agitating). Figure 17 shows a picture of an example of a computer screen displaying Section E – Processing Method.

Figure 17 - Step 5 (Section E) Processing Method: Thermally Processed Non-Aseptic System

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SECTION E PROCESSING METHOD: THERMALLY PROCESSED NON-ASEPTIC SYSTEMS

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf.

Clear

1. What is the finished equilibrium pH of the product after processing? 4 . 3

2. Heating Medium Steam-air

Attach a heat distribution study:

	File Name	File Size (MB)	
1	source_20140731131021088.doc	0.0215	Remove
Total Size:		0.0215	

<< Back >> Save & Exit >> Continue << Cancel & Start Again

**1. What is the finished equilibrium pH of the product after processing?**

Enter the representative pH of the product after processing using a maximum of two digits before the decimal point and two digits after the decimal point. We consider this pH value to be an average of a range between the low and high pH of the standard product. In instances where there is no decimal value, the decimal portion will be two zeros.

**2. Heating medium**

Heating medium is the method used to convey heat to a product during a thermal process (e.g., water immersion, steam, water cascade, water spray, steam-air, high pressure assisted). Select the one heating medium that comes in contact with the container.

*a) Steam Air - A Steam-air medium is a carefully proportioned mixture of steam and air. It does not use water during the heating process.*

If you select “steam-air” as the heating medium, you must attach a heat distribution study. See section II.C of this document for instructions on how to attach a document.

*The other available heating mediums are: High pressure assisted, Microwave, Ohmic, Steam, Water cascade, Water immersion, Water spray, or Other. If you select “Other,” enter a description of the heating medium next to “Other.”*

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 6 (Section F).

## L. Step 6 – Section F. Process Mode

### 1. Mode

There are two overall process modes: agitating (where there is container movement and orientation) and still (where there is no container movement). Figure 18 shows a picture of an example of a computer screen for Step 6 (Section F) (process mode).

Figure 18 - Step 6 (Section F) Process Mode

The screenshot displays the AF/LACF software interface for Step 6 (Section F) Process Mode. The interface includes a progress bar at the top with steps 01 through 10, where Step 06 is highlighted. The main content area is titled "SECTION F PROCESS MODE" and contains a note about file size and types, a "Clear" button, and two sections for user input: "1. Mode:" with a dropdown menu set to "Still" and a "Select one" dropdown set to "Horizontal"; and "2. Cooker:" with a question "What type of cooker do you use?" and a dropdown menu set to "Automatic". At the bottom, there are four buttons: "<< Back", ">> Save & Exit", ">> Continue", and "<< Cancel & Start Again".

Select one process mode and then select from the available choices applicable to that mode. Then continue to question F.2.

#### *a) Agitating*

- i. Axial (can apply to either batch or continuous)

In an axial rotating system, containers travel on their side and rotate on a longitudinal axis around the inner circumference of the processing vessel shell in a continuous or batch process. Select either “Batch” or “Continuous.”

- ii. End over end (only applies to batch).

In an end-over-end system, the containers are loaded vertically into a crate and the crate spins vertically 360 degrees from top to bottom.

- iii. Oscillation (only applies to batch). Select either high frequency or low frequency

In an Oscillation system, containers vibrate laterally at either a low or high frequency.

*b) Still*

i. Horizontal

In a horizontal still retort, the processing shell is horizontal and containers may be loaded horizontally, vertically, or randomly (jumble) from one end of the retort. If the retort has two doors, the product enters through one door and exits through the other door for processing “traffic” control.

ii. Vertical

In a vertical still retort, the processing shell is oriented vertically and containers are loaded from the top. Containers may be positioned, horizontally, vertically, or randomly (jumble). Some of these systems are crateless systems where containers are randomly loaded through the top and removed through the bottom.

**2. Cooker: What type of cooker do you use?**

Select one cooker type. If you select “Other,” enter the cooker type next to “Other” and attach supporting documentation. See section II.C of this document for instructions on how to attach a document.

Select “Continue”. The system will display Step 7 (Section G).

**M. Step 7 – Section G. Process System Critical Factors**

In Step 7 (Section G) of the form, you provide information about critical factors associated with the process system. (Note that this is distinct from in Step 8 (Section H) of the form, where you provide information about critical factors for the product.) Under 21 CFR 113.3(f), critical factor means “any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.” Figure 19 shows a picture of a computer screen for Step 7 (Section G).

Figure 19 - Step 7 (Section G) Process System Critical Factors

**SECTION G PROCESS SYSTEM CRITICAL FACTORS**

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls,xlsx, pdf, gif and rtf.

>> Clear

1) What is the filling method(s) used to fill the product into the container?

Hand filling  Piston filling  Pocket filler  Vibrating/Tumble filling  Volumetric filling

2) How many phases are used to fill the container with the product? Two Phase

a) Enter the number of ounces added in each Phase.

Phase 1: 3 - 5 Phase 2: 10 - 5 Phase 3: -

3) Is the product vacuum packed?  Yes  No

4) What is the container position in refer? Brick Stacked

5) Minimum Come-Up-Time: 4 - 5 (enter in minutes)

Attach a temperature distribution study:

	File Name	File Size (MB)	
1	Asamalia 20130413_2014071413130019.doc	0.5005	Remove
Total Size:		0.5005	

<< Back >> Save & Exit >> Continue  
<< Cancel & Start Again

### 1. What is the filling method(s) used to fill the product into the container?

We list several available filling methods. Select as many as apply. Below, we describe the listed filling methods:

- Hand filling - the primary ingredient(s) are placed in the food container manually. Select this method even if the brine/sauce/oil is topped off mechanically, after the primary ingredient is placed in the container by hand.
- Piston filling - liquid/paste/semi-solid is measured and filled by the positive displacement of a piston evacuating a fixed volume cylinder.
- Pocket filler - for solids/particulates that are gravity fed into a fixed volume pocket, which is then used to put the measured ingredient into the food container.
- Vibrating/Tumble filling - the solids are mechanically dropped into the can with or without the assistance of vibration.
- Volumetric filling – the liquid/sauce food product is mechanically filled.

### 2. How many phases are used to fill the container with the product?

A phase is a stage of filling the product into the container. Many formulated products contain several stages of filling where each ingredient (e.g., soup that contains vegetable, broth, meat) is filled separately to assure a fixed ratio between them and minimum/maximum quantities of each ingredient. Select the number of phases appropriate to your filling method and continue to question G.2.a.

a) Enter the number of ounces added in each Phase. Phase 1; \_\_\_\_ Phase 2; \_\_\_\_ Phase 3; \_\_\_\_

Enter the fill weight in ounces using a maximum of three digits before the decimal point and two digits after the decimal point for each Phase. For example, if Two Phase is selected in question G.2, enter the number of ounces for Phase 1 and Phase 2 in the appropriate spaces provided.

### **3. Is the product vacuum packed?**

Vacuum packed products are solid/dry packed without any fluid, and the majority of the air is removed from the container by mechanical vacuum. If the product is vacuum packed, select “Yes.” Otherwise, select “No.”

### **4. What is the container position in the retort?**

By “container position in the retort,” we mean how the containers are arranged in the retort (e.g., horizontal, random). If you selected “Agitating” in Step 6 (Section F) of the form, this question will be “greyed out” (i.e., unavailable for data entry) and you can skip this question and continue to the next question. Otherwise, select one of the available container positions. Below, we describe the listed container positions.

- Brick stacked - the containers on each layer are overlapping/offset from the containers on the layers below/above.
- Horizontal - the containers are on their sides.
- Jumbled/Random - there are no layers and there is no order to the crate/retort loading. Containers with a jumble load are at a variety of angles and positions with relation to other containers.
- Lid down - the containers are loaded with a specific orientation of the container lid facing the bottom of the retort.
- Lid up - the containers are loaded with a specific orientation of the container lid facing the top of the retort.
- Vertical - the containers are upright and layered, but there is no specific coordination between the layers (unlike brick staking).

### **5. Minimum Come-Up-Time**

If the heating medium you selected in Step 5 (Section E) of the form was “Steam-air”, “Water cascade”, “Water immersion”, “Water spray”, or “Other”, provide this information as described below. Otherwise, continue to Step 8 (Section H).

Minimum come-up-time is the amount of time between the time the steam is turned on and the time the retort achieves processing temperature at all locations within the retort. Enter the minimum amount of time in minutes using a maximum of two digits before the



decimal point and one digit after the decimal point and attach a temperature distribution study.

## **6. Minimum Water Flow Rate**

If the heating medium you selected in Step 5 (Section E) of the form was “Steam air,” this question will be greyed out (i.e., unavailable) and you can either select “Save and Exit” or select “Continue” to go on to Step 8 (Section H). Otherwise, provide the information as described below.

The minimum water flow rate refers to the minimum volume of water per unit time, flowing through a retort system that requires water circulation (i.e., water spray, water cascade) in the retort. If you use a water immersion system and the system does not use a pump for circulation, select “Not Applicable” and attach an explanation. See section II.C of this document for instructions on how to attach a document. Otherwise, enter the flow rate in gallons per minute (gpm) using a maximum of three digits before the decimal point and one digit after the decimal point.

At this stage in the data entry process, you can select “Save and Exit” or select “Continue” to go on to Step 8 (Section H).

## **N. Step 8 – Section H. Product Critical Factors**

In Step 8 (Section H), you provide information about critical factors for the product. (This is in contrast to Step 7 (Section G) which seeks information about critical factors associated with the process system.) As discussed above, critical factor means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility. Figure 20 displays an example of a computer screen for Step 8 (Section H).

Figure 20 - Step 8 (Section H) Product Critical Factors

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**SECTION H PRODUCT CRITICAL FACTORS**

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls,xlsx, pdf, gif and rtf.

Complete all product critical factor questions as delineated by process authority to ensure commercial sterility.

Clear

1. Does the product contain particulates?  Yes  No
2. Does the product contain any dry ingredients?  Yes  No
3. How are pieces arranged in the container?
4. Does the % total solids affect the heating of the product during processing?  Yes  No
5. Is the finalised equilibrium pH of the product after processing (identified in Section E) critical to the process?  Yes  No
6. Does consistency/viscosity affect the heating of the product?  Yes  No
7. Is starch added to maintain consistency/viscosity of the product?  Yes  No
8. Are other binders added?  Yes  No
9. Does syrup strength affect the heat penetration during processing of the product?  Yes  No

Back Save & Exit Continue Cancel & Start Again

## 1. Does the product contain particulates?

Particulates are any solid or semi-solid pieces that may erode or diminish during processing, but are still discernable in the finished product. If you select “Yes,” continue to question H.1.a. Otherwise, select “No” and continue to question H.2.

### *a) Is controlling particulate size a critical factor?*

Some particulates are naturally limited in size (e.g., rice, beans, peas, corn kernels) or mechanically modified in size (e.g., cut, diced). If failing to control the size could impact heat penetration into the particulate or impact convective heating, select “Yes” and continue to questions H.1.b-H.1.d. Otherwise, select “No” and continue to question H.2.

*b) What is the shape and dimension of the particulate size to be controlled? If more than one, list all that apply.*

Enter the dimensions (maximum and/or minimum, as applicable) of the particle size to be controlled, its unit of measure, and the food component to which the limitation applies (e.g., “cuts  $\geq 1/4$  inch”; shrimp sizes such as “small”; “minimum slice thickness  $\geq 3/16$  inch”; fish balls “maximum diameter  $3/4$  inch”; stuffed pasta tube “maximum 2 inch length by  $1/2$  inch diameter” etc.)

### *c) Does your product contain fines?*

Some of the processes result in the creation of fines (small pieces with increased surface area), which could increase the tendency for the product to mat during processing. If the distribution of the fine pieces throughout the production is not controlled, they can aggregate in a small group of containers or a single container, impacting heat penetration. If your product contains fines, select “Yes” and continue to question H.1.c.i. Otherwise, select “No” and continue to question H.1.d.

Question c.i: What is the maximum percent?

Enter the maximum percent of the fines using a maximum of three digits before the decimal point and one digit after the decimal point.

*d) Is full rehydration of the particulate a critical factor?*

If full hydration is necessary before filling, select “Yes.” Otherwise, select “No.”

## **2. Does the product contain any dry ingredients?**

Some processors hydrate dry ingredients before filling the containers and other processors control the liquid-dry ingredient ratio when filling, allowing for hydration in the containers during the thermal process. If your product contains dry ingredients, select “Yes” and continue to question H.2.a. If dry ingredients are hydrated before filling the container, select “No” and continue to question H.3.

*a) What is the minimum % moisture of dry ingredients before processing?*

Enter the percent moisture using a maximum of two digits before the decimal point and two digits after the decimal point. If the minimum % moisture is not a critical factor, select “Not Applicable.”

## **3. How are pieces arranged in the container?**

In some processes, arrangement of the solid pieces in the container can impact heat penetration (e.g. with asparagus products, the direction of the asparagus spears can affect heat penetration).

Select one of the available choices for how pieces are arranged. If you select “Other,” identify how the pieces are arranged next to “Other” and attach an explanation. If the arrangement of pieces in the container is not a critical factor, select “Not Applicable.”

## **4. Does the % total solids affect the heating of the product during processing?**

In some processes, the amount of total solids in the container can impact heat penetration. If the percent total solids affect the heating, select “Yes” and continue to question H.4.a. Otherwise, select “No” and continue to question H.5.

*a) What is the % total solids?*

Enter to the nearest tenth the maximum percent total solids in the product that is critical to the process using a maximum of two digits before the decimal point and two digits after the decimal point.

**5. Is the finished equilibrium pH of the product after processing (identified in Section E) critical to the process?**

In some instances, the thermal process delivered to a low-acid food product is calculated based upon the pH of the finished product. If pH is critical to the thermal process of the product, select “Yes.” Otherwise, select “No.”

**6. Does consistency/viscosity affect the heating of the product?**

Product heating is typically based upon convection and/or conduction. For products heated by convection and/or conduction, the consistency / viscosity of the liquids in the container can impact heat penetration during thermal processing. If the heating of the product is based upon control of the consistency/viscosity, select “Yes” and continue to questions H.6.a-H.6.c. Otherwise, select “No” and continue to question H.7.

*a) What instrument is used to measure the consistency/viscosity?*

Enter the instrument used (e.g., Brookfield, Brabender)

*b) What is the temperature when you measure the consistency/viscosity?*

Enter the product temperature in degrees Fahrenheit that the reading is to be taken at using a maximum of three digits before the decimal point and one digit after the decimal point.

*c) What is the consistency/viscosity? What is the unit of measure?*

Enter the measured value using a maximum of three digits before the decimal point and two digits after the decimal point. Specify the unit of measure either by selecting “Centipoise,” or by selecting “Other.” If you select “Other,” enter the units of measure next to “Other.”

Examples of other units of measure:

- Pascal-second (Pa.s)
- Saybolt Seconds Universal (SSU)
- Stokes (St)

**7. Is starch added to maintain consistency/viscosity of the product?**

If starch is added to achieve a desired consistency/viscosity, select “Yes” and continue to questions H.7.a-H.7.b. Otherwise, select “No” and continue to question H.8.

*a) What is the maximum % starch added?*

Enter the maximum percent starch of the total product formula weight using a maximum of two digits before the decimal point and two digits after the decimal point.

*b) What type of starch is added?*

Enter the type of starch added to the product.

Examples of starch types:

- Modified Corn starch
- Potato starch

### **8. Are other binders added?**

If binders other than starch are added to achieve a desired consistency/viscosity, select “Yes” and continue to questions H.8.a-H.8.b. Otherwise, continue to question H.9.

*a) What is the maximum % binder added?*

Enter maximum percent binder of the total product formula weight using a maximum of two digits before the decimal point and two digits after the decimal point.

*b) What type of binder is added?*

Enter the type of binder added to the product.

Examples of binder types:

- Gelatin
- Xanthan Gum

### **9. Does syrup strength affect the heat penetration during processing of the product?**

Syrups are included as ingredients in many products to achieve a desired taste and sensory quality. If adding syrups is critical to how the product heats, select “Yes” and continue to question H.9.a. Otherwise, you can either select “Save and Exit” or select “Continue” to go on to Step 9 (Section I).

*a) What is the brix measurement?*

Degree Brix is the % sugar, by weight, of an aqueous solution. Enter the maximum degrees (Brix) to the nearest one decimal place of a degree (e.g., 30.0) using a maximum of two digits before the decimal point and one digit after the decimal point.

You can either select “Save and Exit” or select “Continue” to go on to Step 9 (Section I).

## O. Step 9 – Section I. Process Source

### 1. Process Source:

a) *What is the Process Source?*

The process source is the individual or entity (e.g., organization, company, individual, university, or other entity) that establishes the scheduled process. Scheduled processes for low-acid foods must be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. Figure 21 shows a picture of a computer screen for Step 9 (Section I).

Figure 21 - Step 9 (Section I) Process Source

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**SECTION I - PROCESS SOURCE**

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf.

\*Note: If you selected "Still" as the mode in Section F.1, and "Steam" as the heating medium in Section E.1, you may select "Unknown" or "Locally Made" for sterilizer if applicable.

» Clear

1. Process Source :

a) What is the Process Source?

ABC Company

Attach support documentation:

File Name	File Size (MB)	
1 Examples 20130523_20140714131453004.doc	0.5505	Remove
<b>Total Size:</b>	<b>0.5505</b>	

b) What is the date of the Process Source Document (mm/dd/yyyy)? 07/08/2013

2. What is the Manufacturer's Name and the Sterilizer Model :

XYZ Corporation Model 4

« Back » Save & Exit » Continue  
« Cancel & Start Again

Enter the name of the process source who scientifically established the scheduled process(es) and attach the support documentation containing the process recommendations (e.g., letter, bulletin, scientific paper). See section II.C of this document for instructions on how to attach a document. You may refer to 21 CFR 113.83 for more detailed requirements concerning establishing scheduled processes. Below, we provide some examples of how to name the process source.

- If the process was established by your facility, enter the facility's name.

- If the process was established by an organization, individual, university or other entity, enter the name of that entity (followed by the name of an individual, as appropriate).
- If the process was established by a reference source document or publication, enter the reference source document.

*b) What is the date of the Process Source Document?*

Enter the date of the process source document that is attached in month/day/year format.

## **2. What is the Manufacturer’s Name and the Sterilizer Model?**

If you selected the process mode “Still” in Step 6 (Section F) of the form and you selected the heating medium “Steam” in Step 5 (Section E) of the form, you may, if applicable, select “Unknown/Locally Made” check box and attach pictures and supporting documentation. See section II.C of this document for instructions on how to attach a document.

Otherwise, enter the manufacturer’s name and the model of the sterilizer. Do not include in the name “still,” “agitating,” “hydrostatic,” “vertical,” or “horizontal.”

At this stage in the process, you can either select “Save and Exit” or select “Continue” to go on to Step 10 (Section J).

## **P. Step 10 – Section J. Scheduled Process**

Under 21 CFR 113.3(r), scheduled process means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. The scheduled process, which is the process established by a qualified process source as described in section II.O.1 of this document, may be in excess of what is necessary to ensure destruction of microorganisms of public health significance.

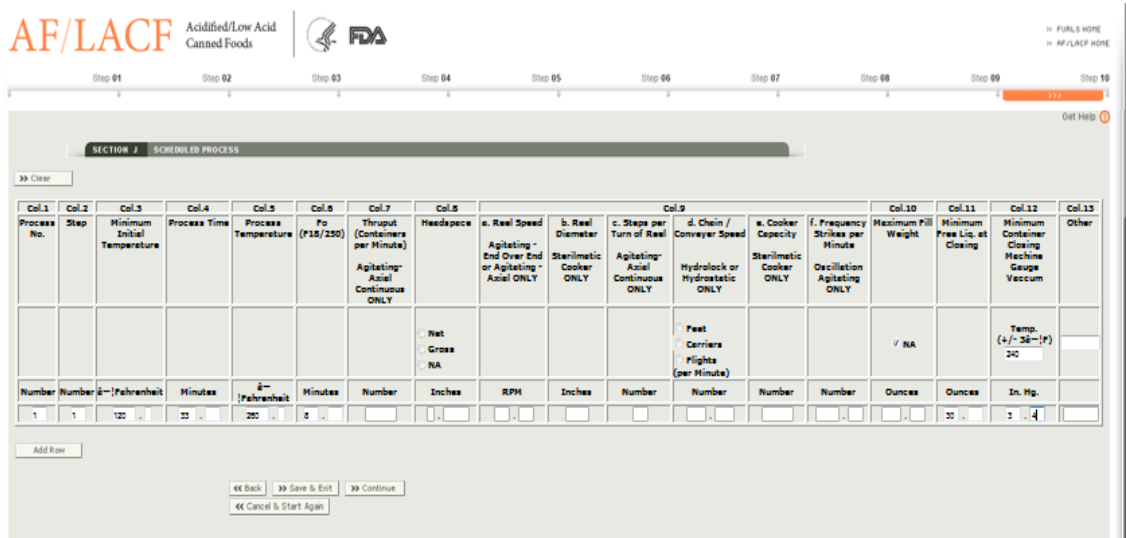
List each process on a single line, except for a multiple-step process. In a multiple-step process, only list the minimum initial temperature for the first step. In addition, only list the cumulative lethality value (i.e. total F value for all steps) for the last step.

For each listed process, you must provide information in columns 1-6. Whether you must provide information in columns 7 through 13 depends on your processing system. The system will identify columns that do not apply to your processing system and “grey them out” (i.e., make them unavailable for data entry). In the instructions for columns 7 through 13, we identify the processing systems that require data entry in those columns. Since all columns will not be visible on the screen, you will use the scroll bar at the bottom of the screen to view these columns.

To add additional rows for the columns available, select “Add Row” at the top of the screen. The screen will display a new row for the user to enter another process or

continue for a multiple step process. After all entries have been added, you can either select “Save and Exit” or select “Continue” to navigate to the Confirmation screen. Figure 22 shows a picture of an example of computer screen for Step 10 (Section J).

**Figure 22 - Step 10 (Section J) Scheduled Process**



**1. Column 1. Process No.**

Each process has its own process number. Enter the number 1 in the first row, the number 2 in the second row, and continue entering numbers in increments of 1 for each scheduled process that you list. The process number increases by increments of 1 regardless of the number of steps in each scheduled process.

**2. Column 2. Step**

A process may have one or more steps. For a single-step process, enter the number 1 in column 2. When the process has multiple steps, enter the number 1 for the first step, the number 2 for the second step, and continue entering numbers in increments of 1 for each subsequent step.

**3. Column 3. Minimum Initial Temperature**

Minimum Initial temperature (IT) is the lowest initial temperature permitted in the scheduled process. IT is the average temperature of the contents of the coldest container to be processed at the time the thermal process cycle begins. This may be calculated by agitating/shaking the filled, sealed container to mix the contents before obtaining this value.

Enter the minimum initial temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.



#### **4. Column 4. Process Time**

Enter the duration of the process time using a maximum of three digits before the decimal point and two digits after the decimal point. If the duration is a whole minute, enter the number of minutes and two zeros for the decimal portion.

Examples of how to enter process time:

- If the process time is 15 minutes and 30 seconds, enter 15.50
- If the process time is 150 minutes and 0 seconds, enter 150.00

#### **5. Column 5. Process Temperature**

Enter the temperature of the step in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

#### **6. Column 6. Fo (F18/250)**

Enter the number of minutes that the process requires to achieve commercial sterility using a z value of 18 degrees and a reference temperature of 250 degrees Fahrenheit. Enter the number of minutes using a maximum of two digits before the decimal point and two digits after the decimal point.

Examples of how to enter the Fo:

- 6.00
- 6.35

#### **7. Column 7. Thruput (Containers per Minute)**

Answer this question only if you selected “Agitating – Axial Continuous” in Step 6 (Section F) of the form. Enter the number of food containers going through the processing system per minute using a whole number with a maximum of four digits and no decimal point. The value entered should be the maximum number of containers per minute that provides the basis for the filed process time.

#### **8. Column 8. Headspace**

Answer this question only if you selected “Agitating” in Step 6 (Section F) of the form. Select either 1) Net, 2) Gross, or 3) NA.

Net headspace is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the lowest inside surface of the lid. Gross headspace is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

If you select net or gross headspace, enter in this column the value in inches using one digit before the decimal point and four digits after the decimal point. If you enter a zero

as the digit before the decimal point, you must follow the zero with a decimal value (e.g., 0.125). If you select “NA,” do not enter any numerical values in this column.

**9. Column 9a. Reel Speed**

Answer this question only if you selected “Agitating - End Over End” or “Agitating - Axial” in Step 6 (Section F) of the form. Enter the reel speed in rotations per minute (rpm) of the agitation that provides the basis for the filed process time and report the value using a maximum of two digits before the decimal point and two digits after the decimal point.

**10. Column 9b. Reel Diameter**

Answer this question only if you selected “Sterlimatic” in Step 6 (Section F) of the form. Enter the diameter of the reel in inches using a whole number with a maximum of three digits and no decimal point.

**11. Column 9c. Steps per Turn of the Reel**

Answer this question only if you selected “Agitating - Axial Continuous” in Step 6 (Section F) of the form. Enter the number of containers held in a 360 degree rotation of the reel that provides the basis for the filed process time, using a whole number with a maximum of two digits and no decimal point.

**12. Column 9d. Chain / Conveyor Speed**

Answer this question only if you selected “Hydrolock” or “Hydrostatic” cooker type in Step 6 (Section F) of the form. Select either 1) Feet, 2) Carriers, or 3) Flights. In this column, enter the value for the speed per minute using a maximum of three digits before the decimal point and three digits after the decimal point.

**13. Column 9e. Cooker Capacity**

Answer this question only if you selected “Sterilmatic” in Step 6 (Section F) of the form.

Enter the maximum number of containers that each cooker shell holds that provides the basis for the filed process time, using a whole number with a maximum of four digits and no decimal point. Do not include infeed or discharge valves. For processes with multiple shells in a multiple step process, enter the cooker capacity for each step on the appropriate step.

**14. Column 9f. Frequency Strokes per Minute (Oscillation Agitating ONLY)**

A stroke is the single movement in any direction up or down or side to side. The frequency is the number of strokes per period of time. Oscillating Agitating includes rocking or planar agitation. Answer this question only if you selected “Agitating - Oscillation” in Step 6 (Section F) of the form. Enter the strokes per minute using a maximum of three digits before the decimal point and two digits after the decimal point.

**15. Column 10. Maximum Fill Weight**

The maximum fill weight includes the weight of the entire product in the container, including brine or sauce, but does not include the weight of the container. The maximum fill weight is recorded before processing.

Enter the maximum fill weight in ounces using a maximum of three digits before the decimal point and two digits after the decimal point. If the process authority determines this is not critical to the process, select “NA” under the column header and do not enter any numerical values.

**16. Column 11. Minimum Free Liquid at Closing**

Answer this question only if you selected “Yes” to question G.3 (product vacuum packed) under Step 7 (Section G) of the form. Enter the amount of free liquid (e.g., water and/or brine) using a maximum of two digits before the decimal point and two digits after the decimal point.

**17. Column 12. Minimum Container Closing Machine Gauge Vacuum**

Answer this question only if you selected “Yes” to question G.3 (product vacuum packed) under Step 7 (Section G) of the form. Enter minimum container closing machine gauge vacuum in inches of mercury (Hg) using a maximum of two digits before the decimal point and two digits after the decimal point. Also enter the temperature in degrees Fahrenheit plus or minus 3 degrees as specified by the process source using a maximum of three digits before the decimal point and two digits after the decimal point.

**18. Column 13. Other**

If there are any other critical factors whose values have been specified by the process source as critical to the delivery of the scheduled process, enter them in the column heading and provide the applicable values for each scheduled process. If no additional critical factors have been identified by the process source, leave this column blank.

Example for Other:

- Cooling Water Temperature – 100 degrees F

**19. Add more entries:**

To add additional rows to Step 10 (Section J), select the “Add Row” button located at the top left hand side of the screen and continue adding information under the appropriate columns. After you complete all the column entries, select “Continue” to navigate to the Review screen for comments and additional attachments.

## **20. Full Name, Signature, Establishment Name and Date**

The system will automatically enter this information based on your FIS Account (i.e., person authorized to represent the facility, the date of the form submission, authorized person's telephone number) and the FCE facility information (i.e., facility name, state (for US) or province (for foreign countries), country). Because the electronic system automatically enters this information in the form, the system will skip Step 20 and displays the Comment and additional attachment section on the Review screen. Figure 25 shows an example of a computer screen displaying Step 20 (i.e., name and date) above the comment box.

## **Q. Review Step**

The review step provides an opportunity for you to review all the information supplied for the process filing and to add additional attachments (such as schematics of irregular shaped containers) that were not attached in Steps 1 through 9 (Section A through I). See section II.C of this document for instructions on how to attach a document. Since all the information covers more than a single screen, use the Page Down, Page Up, or scroll bar to the right and bottom of the browser screen to view the information on multiple screens. The review step also provides an opportunity for you to provide any other information you consider pertinent to the product and/or the scheduled process critical factor(s) in a comment box.

## **R. Section K. Additional Information (Optional)**

Under this section of the form, you may enter additional information and/or attachments. If you attached a required heat penetration study under Section C of the form or an optional heat penetration study under this section of the form, you may enter the heat penetration data from that study by selecting the checkbox and entering the information as identified below.

Heat Penetration Data (Optional) Enter applicable values:

- j value - Identify the j value reported in the heat penetration study in minutes using a maximum of two digits before the decimal point and two digits after the decimal point.
- fh value - Identify the fh value reported in the heat penetration study in minutes using a maximum of three digits before the decimal point and two digits after the decimal point.
- f2 value - Identify the f2 value reported in the heat penetration study in minutes using a maximum of three digits before the decimal point and two digits after the decimal point.

- jc value - Identify the jc value reported in the heat penetration study in minutes using a maximum of two digits before the decimal point and two digits after the decimal point.
- fc value - Identify the fc value reported in the heat penetration study in minutes using a maximum of three digits before the decimal point and two digits after the decimal point.
- x ( $x_{bh}$ ) value - Identify the x ( $x_{bh}$ ) value reported in the heat penetration study in minutes using a maximum of three digits before the decimal point and two digits after the decimal point.

For optional attachments, there are three choices listed. You may select one or more choices and identify the document name adjacent to the appropriate choice(s).

### **1. Comments and Additional Attachments:**

Enter any additional information you consider pertinent to the product and/or the scheduled process critical factor(s). Comments are optional unless you report multiple forms of the product, multiple packing mediums, or multiple product variations, in which case comments may be required in some circumstances as discussed under section II.A (General Information) in this document. The Comment text box allows up to 4,000 characters.

If you report multiple forms of a product (e.g., diced, chunks, cut, fillet), multiple packing mediums, or multiple products with minor formulation changes on a single form, the heat transfer rates may differ for each product variation. In such cases, the process for the slowest heating formulation of the product or its packing medium must be filed and you should use the comment box section to specify which formulation packing medium heats the slowest.

If you consider any additional information pertinent to the product and/or the scheduled process critical factor(s), enter that information in the comment box and/or attach one or more documents containing the additional information (see section II.C of this document for instructions on how to attach a document).

Figure 23, Figure 24, Figure 25, Figure 26, and Figure 27 show a complete example of the confirmation screen.

You can return to any previous step to edit information in that step by selecting the applicable “Edit” button adjacent to the Step (Section) on the review screen.

After reviewing the information and adding any applicable attachments and/or comments, you can select (1) Cancel the process filing; (2) Save and Exit to Draft Folder; or (3) Submit the process filing to FDA.

Figure 23 - Review Screen (Section A)

= FUP  
= RP/

PROCCESS FILING FOR RETORTED LOW-ACID FOODS PROCESSED TO COMMERCIAL STERILITY (FDA 2541a)

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Food and Drug Administration

**Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d)**

*Note: There are separate process filing forms for each of the following: Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d); Food Process Filing for Acidified Method (Form FDA 2541a); Food Process Filing for Water Activity/Formulation Control Method (Form FDA 2541f); and Food Process Filing for Low-Acid Aseptic Systems (Form FDA 2541g).*

**USE FDA INSTRUCTIONS ENTITLED "Instructions for Electronic Submission of Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)"**

Food Canning Establishment (FCE) Number:   
Submission Identifier (SID):  (YYYYMMDD###)

---

**SECTION A**    **PRODUCT INFORMATION**    **EDIT**

*Note: Section A.1 (Food Product Group) requests optional information.*

**1. (Optional) Select one Food Product Group. If there is no single best Food Product Group that applies, select Other.**

Select one:

**2. Enter Product Name (e.g., beans, green; mushrooms (button); tuna (light); sardines (oil)).**

**3. What is the form of the product?**

<input type="checkbox"/> Chunk (e.g., chunks, nuggets, etc.)	<input type="checkbox"/> Piece
<input checked="" type="checkbox"/> Cut	<input type="checkbox"/> Round/Sphere
<input type="checkbox"/> Diced	<input type="checkbox"/> Shredded/Zulienne
<input type="checkbox"/> Milled	<input type="checkbox"/> Sliced (e.g., slices, quarters, strips, etc.)
<input type="checkbox"/> French Cut	<input type="checkbox"/> Spices/Stalks
<input type="checkbox"/> Liquid (i.e., all liquid no solids)	<input type="checkbox"/> Whole
<input type="checkbox"/> On the Cob	<input type="checkbox"/> Other
<input type="checkbox"/> Paste/Purée	

**4. What is the packing medium?**

<input checked="" type="checkbox"/> Brine	<input type="checkbox"/> Syrup
<input type="checkbox"/> Cream/Sauce/Gravy	<input type="checkbox"/> Water
<input type="checkbox"/> Oil	<input type="checkbox"/> Other
<input type="checkbox"/> Solid (no packing medium)	

Figure 24 - Review Screen (Sections B - E)

**SECTION B**    **GOVERNING REGULATION**

Low-acid (21 CFR 105.35 and 21 CFR Part 113)

---

**SECTION C**    **CONTAINER TYPE**    **EDIT**

*Note: If the product is not packaged in one of the container types identified below, select Other.*

Select one:

**1.  Aluminium/Tinplate/Steel Can**

a) What is the shape of the container?

b) How many pieces are used to construct the container?

i.  2 pieces. Do you use perforated divider plates?  Yes  No

ii.  3 pieces

c) Is the container a low-profile container?  Yes  No

**2.  Ceramic/Glass**

**3.  Flexible Pouch**

**4.  Retortable Paperboard Carton**

**5.  Semi-Rigid**

**6.  Other**

---

**SECTION D**    **CONTAINER SIZE**    **EDIT**

*Note: Section D.1 (dimensions) is required information; However, Section D.2 (net weight) is optional information.*

**1. Dimensions:**

a)  Diameter     Height

**2. Net Weight (Optional):**  -  (enter in ounces)

---

**SECTION E**    **PROCESSING METHOD: THERMALLY PROCESSED NON-ASEPTIC SYSTEM**    **EDIT**

**1. What is the finished equilibrium pH of the product after processing?**  -

**2. Heating Medium:**

Figure 25 - Review Screen (Sections F – H)

**SECTION F**      **PROCESS MODE**      **EDIT**

1. Mode :

Select one:

2. Cooker :  
What type of cooker do you use?

---

**SECTION G**      **PROCESSING PARAMETERS**      **EDIT**

1) What is the filling method(s) used to fill the product into the container?  
 Hand filling     Piston filling     Pocket filler     Vibrating/Tumble filling     Volumetric filling

2) How many phases are used to fill the container with the product?

a) Enter the number of ounces added in each Phase.  
Phase 1:  -     Phase 2:  -     Phase 3:  -

3) Is the product vacuum packed?     Yes     No

4) What is the container position in ream?

5) Minimum Come-Up-Time:  -  (enter in minutes)

Attach a temperature distribution study:

	File Name	File Size (MB)
1	Temperature Distribution_2016071416513330.doc	4.874
Total Size:		4.874

---

**SECTION H**      **PRODUCT CRITICAL FACTORS**      **EDIT**

Complete all product critical factor questions as delineated by process authority to assure commercial sterility.

1. Does the product contain particulates?     Yes     No

2. Does the product contain any dry ingredients?     Yes     No

3. How are pieces arranged in the container?

4. Does the % total solids affect the heating of the product during processing?     Yes     No

5. Is the finished equilibrium pH of the product after processing (identified in Section E) critical to the process?     Yes     No

6. Does consistency/viscosity affect the heating of the product?     Yes     No

7. Is starch added to maintain consistency/viscosity of the product?     Yes     No

8. Are other binders added?     Yes     No

9. Does syrup strength affect the heat penetration during processing of the product?     Yes     No

Figure 26 - Review Screen (Sections I – J)

**SECTION I**      **PROCESS SOURCE**      **EDIT**

\*Note: If you selected "GEL" as the mode in Section F.1, and "Steam" as the heating medium in Section E.1, you may select "Unknown" or "Locally Made" for sterilizer if applicable.

1. Process Source :

Attach support documentation:

	File Name	File Size (MB)
1	ADD Technical Note/Process Source_2016071416513335.doc	4.874
Total Size:		4.874

a) What is the date of the Process Source Document (mm/dd/yyyy)?

2. What is the Manufacturer's Name and the Sterilizer Model :

---

**SECTION J**      **SCHEMATIC PROCESS**      **EDIT**

Col.1	Col.2	Col.3	Col.4	Col.5	Col.6	Col.7	Col.8	Col.9				Col.10	Col.11	Col.12	Col.13	
Process No.	Step	Minimum Initial Temperature	Process Time	Process Temperature	PS (F/R/SS)	Throughput (Containers per Minute)	Headspace	a. Reel Speed	b. Reel Diameter	c. Steps per Turn of Reel	d. Chain Conveyor Speed	e. Cooler Capacity	f. Frequency	g. Minimum Fine Liq. at Clooting	h. Minimum Machine Cycle Vacuum	Other
Number	Number	°F	Minutes	°F	Minutes	Number	Inches	OPM	Inches	Number	Number	Number	Number	ounces	In. Hg	
<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="250"/>	<input type="text" value="3"/>	<input type="text" value="250"/>	<input type="text" value="R"/>	<input type="text" value=""/>	<input type="checkbox"/> Net <input type="checkbox"/> Gross <input checked="" type="checkbox"/> NA	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Feet <input type="checkbox"/> Centimeters <input type="checkbox"/> Meters <input type="checkbox"/> Mils <input type="checkbox"/> Microns	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
<input type="text" value="2"/>	<input type="text" value="1"/>	<input type="text" value="250"/>	<input type="text" value="3"/>	<input type="text" value="250"/>	<input type="text" value="R"/>	<input type="text" value=""/>	<input type="checkbox"/> Net <input type="checkbox"/> Gross <input checked="" type="checkbox"/> NA	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Feet <input type="checkbox"/> Centimeters <input type="checkbox"/> Meters <input type="checkbox"/> Mils <input type="checkbox"/> Microns	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

**Figure 27 - Review Screen (Section K)**

The screenshot displays a web-based review screen with the following sections:

- Meet Penetration Data (optional):** Other applicable values: 1. p value, 2. fr value, 3. fd value, 4. pr value, 5. fr value, 6. x (DBP) value.
- Attachment Type:** Please Select.
- Attach document:** Includes a file selection button and a 'Comment Line' field.
- Attachment Table:**

Attachment Type	File Name	File Size (KB)	Remove
Other	Description of comment-20140714162117477.doc	4.274	Remove
	Total Size:	4.274	
- Comments:** A text area with a character limit of 4000. A note states: "Note: You may enter up to 4000 characters in the comment field. If your comment exceeds 4000 characters, you can upload a file with your comment." The current comment is: "Attached a picture of the type of seal/liner used."
- User Information:**
  - Full Name: [Redacted]
  - Establishment Name: Test Company
  - State or Province: Maryland
  - Country (other than U.S.): UNITED STATES
  - Date: 07/15/2014
  - Telephone No: 2011212121
- Navigation:** Buttons for '<< Cancel & Start Again', '>> Save & Exit', and '>> Submit'.

After reviewing the information on the review screen, editing information, if appropriate, and adding any applicable attachments or comments, you can either:

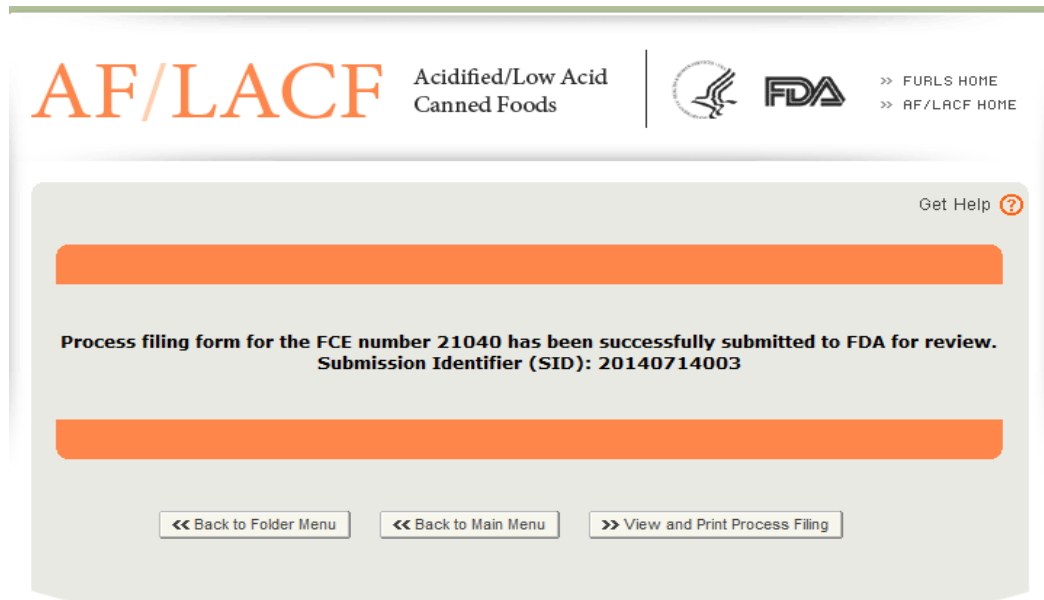
- Select “Cancel and Start Again” to start over without saving any information;
- Select “Save and Exit” to save the process filing form to the Draft Folder without sending it to FDA. Process filings in the Draft Folder remain available to the user who creates them and to users authorized as the ECP or a Super AR (see the Appendix section of Ref. 2 for information about user roles). Process filings in the Draft Folder cannot be viewed by FDA or by users other than the ECP and Super AR for an FCE; or
- Submit the completed process filing form to FDA.

## **R. Filing Message**

After you select Submit, the system will provide a message that your form has been successfully filed. Figure 28 shows a picture of an example of the message screen informing a user that a process filing has been submitted for a particular FCE. This message screen specifies the SID assigned to the submitted process filing form.



**Figure 28 - System Display of Successful Message of a Filed Process Filing Form**



You can select either:

- Return to Folder Menu to return to the FCE Process Filing Folder Main Menu;
- Return to Main Menu to return to the AF/LACF Main Menu; or
- View Process Filing to view the submitted process filing. When you view the submitted process filing, you can print it.

### **III. How to Contact FDA or Obtain Help**

You may contact us:

- By email at [LACF@fda.hhs.gov](mailto: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

## IV. 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. How to Use AF/LACF Electronic System. Accessible at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM417291.pdf>
3. LACF/AF Precursor Questions. Accessible at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM417292.pdf>

## V. Appendix

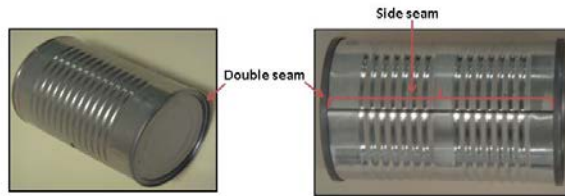
### A. Container Types and Shapes



**Figure 29 – Cylindrical Shape 2-Piece Aluminum Containers Depicting Double Seams**



**Figure 30 – Low-Profile Rectangular Shape 2-Piece Aluminum Containers**



**Figure 31 – Cylindrical Shape 3-Piece Steel Containers with a Double Seam and Side Seam**



**Figure 32 – Cylindrical Shape 2-Piece Steel Containers with a Double Seam**



**Figure 33 – Flexible Pouch**



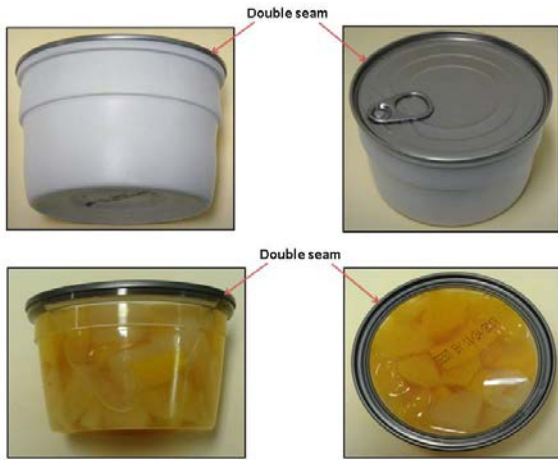
**Figure 34 – Glass Containers**



**Figure 35 – Semi Rigid Body, Oval Shape Containers with Heat Seal**



**Figure 36 – Semi Rigid Body, Rectangle Shape Containers**



**Figure 37 – Semi Rigid Body with an Aluminum Double Seam**



**Figure 38 – Semi Rigid Body, Cylinder Shape Containers with Induction Weld Seal**



**Figure 39 – Semi Rigid Body with Heat Seal**

## **B. Container Dimension Measurements**

Container dimension measurements should always be measured from the outside edge of the container. Below, we list different types of materials and descriptions of how to properly measure the dimensions of the container.

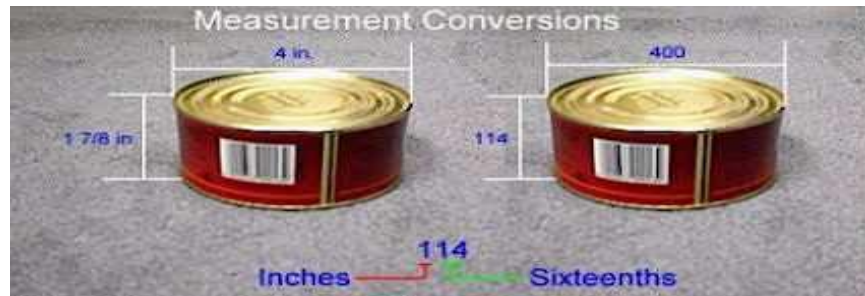
### **1. Cylindrical Measurement**

Measure the diameter from the outside of the double seam on the container. Measure the height from the top of the double seam to the opposing double seam top. If the can is a two piece can, measure from the top of the double seam to the furthest point on the other end. For glass bottles or unusually shaped cylindrical containers, always measure the widest part of the container.

For heat-sealed, semi-rigid containers, do not measure the sealing flange as part of the container dimensions. Only measure from the inner edge of the flange where the seal edge meets the chamber holding the food.

When measuring cylindrical shaped containers, list diameter x height (e.g., 0211 x 0400 for a 2 11/16 inch x 4 inch container).





**Figure 40 – Measurement of a Cylindrical Shape Container.**

When measuring unusually shaped cylindrical containers, always measure the widest part of the container.



**Figure 41 – Measurement of an Unusual Shape Cylindrical Container.**

## 2. Oval Shape Measurement

When measuring unusually shaped oval containers, always measure the widest part of the container.



**Figure 42 – Measurement of an Oval Shape Container**



**Figure 43 – Measurement of Outer Edges of Container**

### **3. Rectangular Shape, Rectangular Tray and Low-Profile Measurement**

For all rectangular containers (including trays), list length (longest dimension) x width (second longest dimension) x height; for example, list 0405 x 0301 x 0014 for a container that is 4 5/16 inches long, 3 1/16 inches wide, and 14/16 of an inch.

For a rectangular can, measure the length and width from outside of the double seam. When measuring the height of the container, measure from the top of the double seam to the furthest point on the bottom.

For a rectangular pouch, measure from the inner edge of the seams for the length and width. For the height, measure the thickness at the thickest point.

For paper board rectangular containers, measure the length, width, and height from the outside edge of the container.

### **4. Rectangular Shape Measurement**

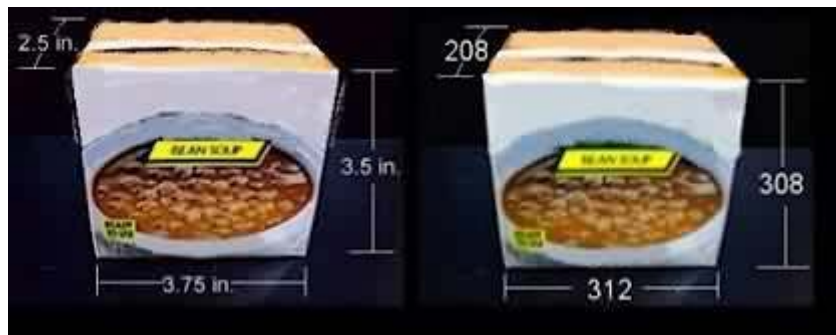


Figure 44 – Measurement of a Rectangular Shape Container

5. Rectangular Tray Measurement

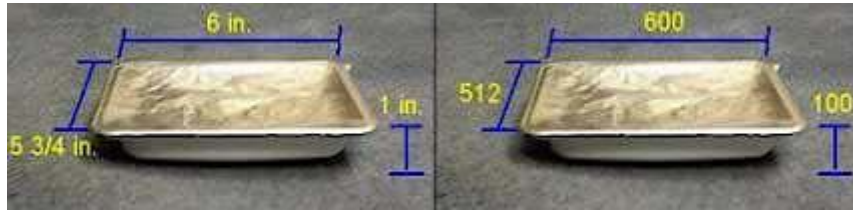


Figure 45 – Measurement of a Rectangular Tray Shape Container

6. Low-Profile Measurement



Figure 46 – Measurement of a Low-Profile Container