

FDA 2541d

Step 1 – Section A

The screenshot shows the AF/LACF web application interface for Step 1, Section A: PRODUCT INFORMATION. The header includes the AF/LACF logo, 'Acidified/Low Acid Canned Foods', and the FDA logo. A progress bar at the top indicates steps 01 through 10, with Step 01 highlighted. A 'Get Help' link is visible in the top right corner.

SECTION A PRODUCT INFORMATION

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

>> Clear

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

Leafy/Stem Vegetables

Select one: Leafy/Stem Vegetable

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

spinach in brine

3. What is the form of the product?

<input type="checkbox"/> Chunk (e.g., chunks, nuggets, etc.)	<input type="checkbox"/> Pico
<input checked="" type="checkbox"/> Cut	<input type="checkbox"/> Round/Sphere
<input type="checkbox"/> Diced	<input type="checkbox"/> Shredded/Julienne
<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/Puree	

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)	

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

Step 2 – Section B

The screenshot shows the AF/LACF web application interface for Step 2, Section B: GOVERNING REGULATION. The header is consistent with Step 1, but the progress bar highlights Step 02. A 'Get Help' link is visible in the top right corner.


SECTION B GOVERNING REGULATION

Click [here](#) to refer to the precursor questions in the instructions.

Low-acid (21 CFR 108.35/113)

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<< Cancel & Start Again

Step 3 – Section C

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

Get Help ?

SECTION C CONTAINER TYPE

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


>> Clear

Select one:

- Aluminium/Tinplate/Steel Can
 - What is the shape of the container? Cylindrical
 - How many pieces are used to construct the container?
 - 2 pieces Do you use perforated divider plates? Yes No
 - 3 pieces Do you use perforated divider plates? Yes No
 How is the side seam sealed? Welded
 - Is the container a low-profile container? Yes No
- Ceramic/Glass
- Flexible Pouch
- Retortable Paperboard Carton
- Semi-Rigid
- Other

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<< Cancel & Start Again

Step 4 – Section D

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

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SECTION D CONTAINER SIZE

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

>> Clear

1. Dimensions:

a) 303 Diameter 404 Height

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

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<< Cancel & Start Again

Step 5 – Section E

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

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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? .

2. Heating Medium

Attach a heat distribution study:

	File Name	File Size (MB)	
1	source_201407141310211055.doc	0.0215	Remove
Total Size:		0.0215	

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

Step 6 – Section F

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

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SECTION F PROCESS MODE

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. Mode :

Selection:

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

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

Step 7 – Section G

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

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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 Platen 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 retort?

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

Attach a temperature distribution study:

File Name	File Size (MB)	
1 Bismolice 20120212_20140714121322012.doc	0.5505	Remove
Total Size:	0.5505	

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

Step 8 – Section H

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

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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 final 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

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Step 9 – Section I

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Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09 **Step 10** Get Help

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	Example 10130823_20140714131483004.doc	0.5808	Remove
Total Size:		0.5808	

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 :

KYZ Corporation Model 4

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« Cancel & Start Again

Step 10 – Section J

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Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09 **Step 10** Get Help

SECTION J SCHEDULED PROCESS

» Clear

Col.1 Process No.	Col.2 Step	Col.3 Minimum Initial Temperature	Col.4 Process Time	Col.5 Process Temperature	Col.6 F ₀ (F18/250)	Col.7 Thruput (Containers per Minute) Agitating - Azial Continuous ONLY	Col.8 Headspace	Col.9 a. Reel Speed Agitating - End Over End or Agitating - Azial ONLY	b. Reel Diameter Sterilmetic Cooker ONLY	c. Steps per Turn of Reel Agitating - Azial Continuous ONLY	d. Chain / Conveyor Speed Hydrolock or Hydrostatic ONLY	e. Cooker Capacity Sterilmetic Cooker ONLY	f. Frequency Strikes per Minute Oscillation Agitating ONLY	Col.10 Maximum Fill Weight	Col.11 Minimum Free Lq. at Closing	Col.12 Minimum Container Closing Machine Gauge Vacuum	Col.13 Other
							Net Gross NA				Feet Carriers Flights (per Minute)			✓ NA		Temp. (+/- 30-1P) 20	
Number	Number	° Fahrenheit	Minutes	° Fahrenheit	Minutes	Number	Inches	RPH	Inches	Number	Number	Number	Number	Ounces	Ounces	In. Hg.	
1	1	120	33	280	8										30	1	4

Add Row

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

Additional Attachments (optional) – Section K

Heat Penetration Data (optional): Enter applicable values:

1. D value 1 2. F0 value 1 3. F2 value 1
 4. Dc value 1 5. Fc value 1 6. W (QBR) value 1

If the vendor has additional information pertinent to the product or the product label, enter that information in the comment field or attach any relevant documents to the additional information. Please limit the file size to 4 MB. Allowed file types are .jpg, .gif, .png, .doc, .xls, and .pdf only.

Attachment Type:

Attach document:

	Attachment Type	File Name	File Size (MB)	
1	Other	Description of container-031ACD14165717477.doc	4.874	Remove
Total Size:			4.874	

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)
 No. of 2552 characters left.

Full Name :
 Establishment Name : Test Company
 State or Province : Maryland
 Country (other than U.S.) : UNITED STATES
 Date : 07/15/2014
 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.